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#### New hypertension guidelines to be released Monday

The American Heart Association, American College of Cardiology and nine other health organizations will release new prevention, diagnosis and treatment guidelines that redefine hypertension on Monday. The announcement will take place at 2 p.m. PST in Main Event I, Hall D. See complete coverage in Professional Heart Daily on professional.heart.org and in the Tuesday Scientific Sessions Daily News.

## Warner to discuss focus on patients, opportunities to combat CVD

#### John J. Warner, MD, FAHA,

brings a unique perspective to the presidency of the American Heart Association.

The CEO of UT Southwestern

University Hospitals in Dallas, who also cares for patients, will discuss critical issues facing clinicians and scientists Sunday



during his Presidential Address.

Warner said his physicianexecutive vantage point, and his many years volunteering for the AHA, allow him to view the fight against cardiovascular diseases through many lenses - but with one clear vision.

"Having the patient at the center of our work is the reason we all do what we do," said Warner, whose address is titled "Amplifying the Voices of Patients."

The Presidential Address kicks off Sunday's Opening Session, which officially launches the AHA's 2017 Scientific Sessions. The Opening Session will be held from 1-3 p.m. in Main Event I, Hall D, Main Building.

PRESIDENT continued on page 17

## Study: Traumatic OHCA outcomes better when ALS provided by physicians

raumatic out-of-hospital cardiac arrest (OHCA) patients who received advanced life support (ALS) from physicians in a pre-hospital setting achieved better outcomes than patients who received ALS by emergency medical service personnel or basic life support (BLS), according to a cohort study from the Japanese National Registry presented Saturday during the Resuscitation Science Symposium.

Tatsuma Fukuda, MD, PhD, from the University of Ryukyus in Okinawa, Japan, presented the population-based study that included 4.382 patients who experienced OHCA following a traffic accident in Japan from 2013 to 2014. The primary outcome was one-month survival.

If a patient received at least one ALS procedure — for example, intravenous line insertion, epinephrine administration or advanced airway management the patient was assigned to the ALS group. Patients in the BLS group did not receive any ALS procedures.

In the study cohort, 828 patients received physician-performed ALS;



1,591 received pre-hospital ALS by EMS personnel; and 1,963 patients received BLS only. Of all patients in the study, 2.2 percent survived one month after OHCA, including 3.1 percent treated with ALS by a physician, 1.6 percent with ALS from EMS and 2.3 percent who received BLS.

Multivariable analysis showed that physician-administered ALS resulted in about twice the chance for onemonth survival compared with both ALS by EMS and BLS (adjusted odds ratio=2.13; 95 percent CI, 1.20-3.78; and adjusted OR=1.94; 95 percent CI, 1.14-3.25). There was no significant difference in one-month survival between the ALS by EMS and BLS groups.

ADVANCED LIFE SUPPORT continued on page 17

## AHA announces two new research awards

#### The American Heart Association

has unveiled two new awards to support innovative and transformational research that will help reimagine its

research-funding portfolio.

The Innovative Project Award will support ideas that introduce new paradigms, challenge current paradigms or look at existing problems from new perspectives. Preliminary data is not accepted with proposals for this award. The

application deadline is Jan. 11, 2018. The Transformational Project Award will fund the second phase of a new idea. Winning proposals will represent

the next logical step of previous work and demonstrate high probability of revealing new avenues of investigation.

Proposals for this award should include preliminary data. The application deadline is Jan. 23, 2018.

The awards are open to all U.S.-based, nonprofit institutions conducting all types of research.

"With the Innovative Project Award, we're trying to attract new and innovative ideas," said Steven R. Houser, PhD,

FAHA, immediate past-president of the AHA and chair of the Research Funding Subcommittee.

"This award gives researchers an

opportunity to suggest new directions they'd like to explore. This is rare in research, where you usually must support ideas with preliminary data. In this case, if we think it's a really great idea, we'll support it and give the awardee an opportunity to get the data needed to continue their research."

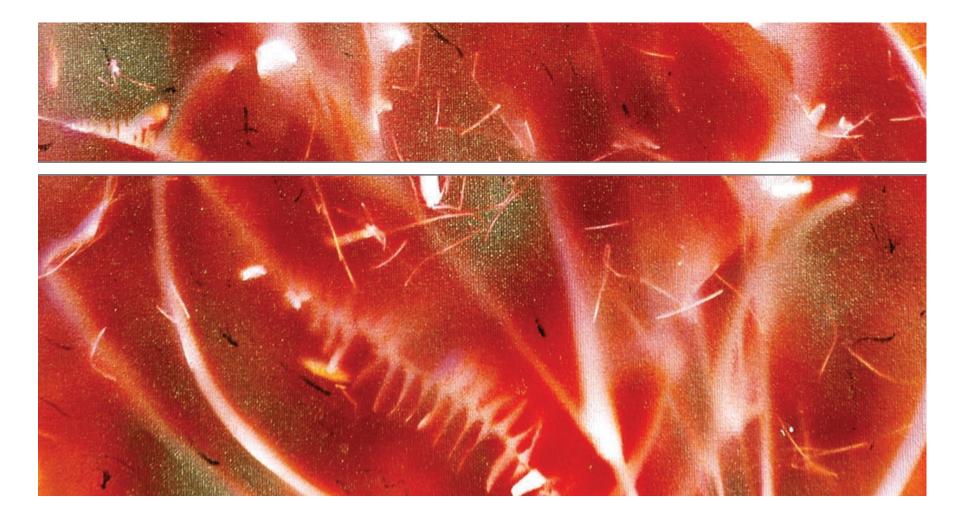
The Transformational Project Award will focus on slightly more developed theories, said Houser, senior associate dean of research and director of the Cardiovascular Research Center at Temple University in Philadelphia, Pennsylvania.

"For this award, we're looking for some preliminary data that shows the idea is likely to be correct," he said. "Then we

RESEARCH AWARDS continued on page 15

Steven R. Houser, PhD, FAHA

**Go Red For Women** Remember to wear red Monday in honor of the movement raising awareness that heart disease is the No. 1 killer of women.





## Committed to Coronary Artery Disease (CAD) & Peripheral Artery Disease (PAD)

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#### HIGHLIGHTS FROM THE PROGRAM CHAIR By Eric D. Peterson, MD, MPH, FAHA, Committee on Scientific Sessions Program Chair

The second day of Scientific

Sessions features more comprehensive programming on the most up-to-date basic, clinical and population science.

Today's highlights include the Opening Session at 1 p.m. in Main Event I, Hall D. It will feature the AHA presidential address by John J. Warner, MD, and the annual Lewis A. Conner Memorial Lecture by Eric Dishman, director of the National Institutes of Health's *All of Us* Research Program.

Today's events also include the first of seven Late-Breaking Science Sessions over the next four days that cover some of the most important clinical trials in cardiac science. Today's session, "CABG and EP Peri-procedural Dilemmas," begins at 3:45 p.m. in Main Event 1, Hall D, featuring results from the TRICS III, DACAB, PRESERVE, BRUISE CONTROL-2 and ABRIDGE-J trials.

A Sunday afternoon Main Event session, "Curing Atrial Fibrillation: Where to Next?," will include presentations on screening, interventional therapies and stroke prevention, as well as a unique presentation by a patient living with AF. The session begins at 3:45 p.m. in Ballroom CD, 3rd Level, Main Building. The AHA's joint sessions with other domestic and international cardiology societies are always popular. These sessions offer an invaluable opportunity to collaborate and network with multidisciplinary colleagues from the United States and abroad.

Among the 16 joint sessions scheduled Sunday are collaborations with specialty societies such as the Society of Thoracic Surgeons, Heart Rhythm Society, Society for Cardiovascular Pathology and National Lipid Association. Joint programming with our international colleagues includes the Mexican Society of Cardiology, Brazilian Society of Cardiology, Japanese Circulation Society, Iranian Heart Association and the World Heart Federation.

Abstract poster presentations begin today in the Science and Technology Hall, which opens at 11 a.m. in Hall ABC. Poster sessions offer a terrific opportunity to interact with poster presenters, ask questions and learn about some of the most cutting-edge clinical and basic research in cardiac science. Abstract oral presentations begin this afternoon, including 10 Rapid Fire Oral sessions featuring fiveminute abstract presentations. An



audience Q&A session will follow each presentation.

Also located in the Science and Technology Hall is the AHA Simulation Zone (booth 2149), which features hands-on demonstrations and case-based learning opportunities to test your cardiac knowledge, skills and critical thinking. The Science and Technology Hall also includes more than 200 exhibitor booths, where you can get information on current drugs and devices related to cardiovascular care.

Check the Final Program and the Mobile Meeting Guide for the complete schedule, including the times and locations of today's sessions, events and activities. And be sure to check the *Daily News* each day for program highlights and coverage of the hottest science presented this week. ▼

## TODAY AT SESSIONS

Don't miss today's highlighted presentations and events. For a complete schedule, download the Mobile Meeting Guide, see the Final Program or view the online program at **scientificsessions.org.** 

8-9:30 a.m. ReSS Poster Session, Day 2 155-159, ACC North

8-11 a.m. Groundbreaking Studies in the Practice of Cardiovascular Medicine Ballroom A, 3rd Level, Main Building

8-11 a.m. The Best of Circulation Research Symposium Ballroom B, 3rd Level, Main Building

8-11 a.m. Best of 2017 210AB, Main Building

9-11 a.m. ABIM Learning Session: Clinical Cardiac Electrophysiology, 2017 Update 201CD, Main Building

**9:30-10:30 a.m. ReSS Year in Review** 154-158, ACC North

11:30 a.m.- 12:45 p.m. Abstract Poster Sessions Science and Technology Hall

Noon-1:15 p.m. ReSS Main Event: The Role of Genetics in Cardiac Arrest and Trauma

154-158, ACC North 1-3 p.m.

Opening Session Main Event I, Hall D, Main Building

3:15-4:30 p.m. Abstract Poster Sessions Science and Technology Hall

3:30-5:30 p.m. ABIM Learning Session: Cardiovascular Disease, 2017 Update 201CD, Main Building

3:45-4:45 p.m. ATVB Early Career Investigator Award Competition 252ABC, ACC North

3:45-5 p.m. Cournand and Comroe Young Investigator Award 209AB, Main Building

4:30-5:45 p.m. ReSS Main Event: New Directions in Dispatch-Assisted CPR 154-158, ACC North

5:30-6:45 p.m.

Melvin L. Marcus Young Investigator Award in Cardiovascular Sciences Competition 251AB, ACC North



#### Late-Breaking Science: CABG and EP Peri-procedural Dilemmas LBS.01 | 3:45-5 p.m. Sunday | Main Event I, Hall D, Main Building

Trial	Description	
TRICS III — An International Multicenter Randomized Trial of Transfusion Requirements in Cardiac Surgery	TRiCS III evaluated liberal versus restrictive transfusion strategies in cardiac surgery.	
DACAB — Efficacy and Safety of Dual Acetylsalicylic Acid Plus Ticagrelor or Ticagrelor Alone Antiplatelet Strategy After Coronary Artery Bypass Surgery at 12 Months: Randomized Multicentre Trial	DACAB evaluated the efficacy and safety of dual ASA plus ticagrelor or ticagrelor alone antiplatelet strategy after CABG at 12 months.	
PRESERVE — Sodium Bicarbonate and N-Acetylcysteine for the Prevention of Serious Adverse Outcomes Following Angiography	The PRESERVE trial evaluated the efficacy of IV sodium bicarbonate and oral N-acetylcysteine, which are used to prevent contrast-associated acute kidney injury.	
BRUISE CONTROL-2 — A Randomized Controlled Trial of Continued versus Interrupted Novel Oral Anti-Coagulant at the Time of Device Surgery	Bruise Control-2 compared continued versus interrupted novel oral anti-coagulant therapy at the time of device surgery with respect to clinically significant pocket hematoma, bleeding and thromboembolic events.	
ABRIDGE-J — Clinical Benefit of Minimally-Interrupted Dabigatran versus Uninterrupted Warfarin for Catheter Ablation of Atrial Fibrillation: A Prospective Randomized Multicenter Trial	ABRIDGE-J compared the efficacy and safety of minimally interrupted dabigatran as an anticoagulant therapy with that of uninterrupted warfarin for catheter ablation for nonvalvular atrial fibrillation.	



## Former AHA intern puts knowledge to use in the community

As a graduate student working

as an AHA intern, Christy Taylor, MPH, CPH, participated in community outreach initiatives where she applied the skills she learned in school to help people live healthier.

Pairing her professional experience with her personal experience growing up in a family with a significant heart disease history has shaped her path, said Taylor, a student at the University of Pittsburgh School of Medicine, where she's a member of the MD candidate class of 2020.

"As an AHA intern, I learned so much about the importance of community outreach and the public health principles the AHA uses to help communities," Taylor said. "Now, as a medical student, I have been able to continue volunteering and using the skills I learned to further help patients."

Growing up seeing the consequences of cardiovascular disease sparked Taylor's passion for healthcare. Eventually, a mentor introduced Taylor to the opportunities the AHA offers students.

"Membership has allowed me to join a growing community of people who work selflessly to improve the lives of those afflicted by cardiovascular disease through research, outreach and scholarship," Taylor said. "I feel privileged to have the opportunity to meet and work alongside such courageous people and to hopefully contribute something that will improve the lives of patients."

On a national level, Taylor serves on the Council on Epidemiology and Prevention. She also works with the Pittsburgh AHA chapter, where she volunteers at health fairs and works on multicultural initiatives. She hopes her next stop is the 2018 EPI | Lifestyle Scientific Sessions, as she recently submitted an abstract for consideration. She's also looking forward to connecting with fellow members.

The 2018 EPI | Lifestyle Scientific Sessions will take place March 20-23 in New Orleans. ▼

## Top-performing IHCA hospitals focus on teams, roles and communication

op-performing hospitals for inhospital cardiac arrest (IHCA) not only have improved outcomes, but fundamentally different organization,

composition and function, according to the results of a National Heart, Lung, and Blood Institute-funded study presented Saturday during the Resuscitation Science Symposium.

The study was presented by Brahmajee K. Nallamothu, MD, professor in the division of cardiovascular diseases and the department of internal medicine at the University of Michigan, Ann Arbor. Nallamothu and colleagues identified several themes to summarize the differences in resuscitation approaches at top-performing hospitals compared with middle- and bottom-performing hospitals.

Nallamothu and colleagues used riskstandardized IHCA survival discharge rates to identify nine geographically and academically diverse hospitals in the AHA Get With The Guidelines®-Resuscitation registry from 2012 and 2014. They included five hospitals in the top quartile of IHCA survival, one in the middle quartile and three in the bottom quartile.

The researchers conducted oneto two-day site visits with in-depth interviews of clinical and administrative staff. Of the 158 interviews conducted, 20.9 percent were with physicians, 49.4 percent with nurses, 7 percent with respiratory therapists and 22.7 percent with quality improvement staff, administration and other staff. Based on these interviews, the researchers identified five large themes related to improved IHCA outcomes. "The first theme we identified was that resuscitation team design makes a difference," Nallamothu said. "We found that if you looked at top-performing hospitals, they consistently described having either dedicated or designated resuscitation teams." Dedicated teams

included nurses and other clinical providers whose primary responsibility was resuscitation and responding to emergency situations. Top-performing hospitals that didn't have dedicated teams instead had designated teams with members who were able to respond to an arrest right away, even if they had primary patient care duties, thanks to established procedures that relieved them from their current task. Middleand bottom-performing hospitals had resuscitation teams formed on more of an ad hoc basis, Nallamothu said. The second theme was team

composition, or the size and types of team members. The third theme was roles and responsibilities of team members.

"Top-performing hospitals seem to be very specific about how they thought about individual roles," Nallamothu said. "People knew beforehand what they were supposed to do. For example, an ICU nurse might know that it was his or her job to immediately go and ensure IV access." In contrast, one interviewee at a

bottom-performing hospital mentioned



walking into a room during an arrest and seeing two people working on IV access while nobody was focused on chest compressions.

The fourth theme was that top-performing hospitals thought about their resuscitation team in terms of communication and leadership much

differently than middle- and bottomperforming hospitals.

"They still struggled with this area but seemed to think about them in a more sophisticated way and had mechanisms in place if there was a failure in communication or leadership," Nallamothu said.

Finally, top-performing hospitals considered quality improvements and education events for their resuscitation teams differently. For example, in top-performing hospitals, mock codes were taken very seriously and were followed with in-depth debriefings. In contrast, other hospitals did mock codes but struggled to get personnel to participate.

"Resuscitation teams are a big part of every hospital in the United States, yet we understand very little about how we got the current system we have," Nallamothu said. "Even though we have had this system for five decades, until now, no one really has thought very systemically about how they could be designed for the output that we all want with improved performance and outcomes." **•** 



## **ILCOR celebrates 25th anniversary**

The International Liaison Committee on Resuscitation celebrated its 25th anniversary at its 2017 annual meeting this week in Anaheim, which immediately preceded the AHA Resuscitation Science Symposium.

Established in 1992, ILCOR created a forum for collaboration among

principal resuscitation councils worldwide, including the American Heart Association. Since then, ILCOR has established and distinguished itself for its pioneering vision and leadership in resuscitation science.

ILCOR reached consensus on international resuscitation guidelines in 2000, and on international science and treatment recommendations in 2005, 2010 and 2015. ILCOR's efforts have enhanced international cooperation, and progressively more transparent and systematic collection and analysis of pertinent scientific evidence. Going forward, this sets the stage for ILCOR to pursue its vision to save more lives globally through resuscitation. ▼

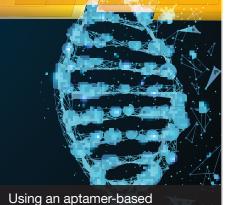
## Conner Lecture: All of Us have a role to play in future of precision health

recision medicine helped save Eric Dishman's life. And today, he'll discuss how it could save many others in, "Accelerating Precision Health for All: The All of Us Research Program," during the Lewis A. Conner Memorial Lecture.

The prestigious annual lecture is part of the Opening Session, which will be held 1-3 p.m. in Main Event I, Hall D, Main Building.

Dishman, director of the All of Us Research Program at the National

## **BUILDING THE GENETIC ARCHITECTURE FOR THE CVD RISK PROTEOME**



proteomics platform, researchers in Boston recently identified 156 plasma proteins associated with the Framingham Risk Score in Framingham Heart Study Offspring participants. They hypothesized that integrating genetic and proteomic data would highlight novel determinants of circulating levels of the FRS-associated CVD risk proteome, and pathways that may contribute to disease biology.



The study results will be presented during the Functional Genomics & Translational Biology Young **Investigator Award Competition at** 3:45 p.m. Sunday in room 304CD, Main Building.



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an approved paper recycling bin. Thank you.

Institutes of Health, said the unprecedented research initiative will include at least 1 million people across the United States who volunteer to share information about their health, lifestyle and environment. The program aims to create one of the largest, richest biomedical datasets for future studies, thus accelerating scientific and medical breakthroughs to improve and save lives.

Advances in science, technology

and computing make precision medicine possible, Dishman said.

"With everything from smartphones to sequencers, we can now collect data about our genetics, environments and behaviors in ways that just weren't possible even a few years ago," he said. "With this wealth of data, we can do new science and make new discoveries to help deliver the right treatment for the right person at the right time." **V** 



**LECTURE PREVIEW** Lewis A. Conner Memorial Lecture: Accelerating Precision Health for All: The All of Us Research Program 1-3 p.m. Sundav Main Event I, Hall D, Main Building



# **TO IMPROVE OUTCOMES** IMPLEMENTING THE NEW GUIDELINE

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FOR MANAGING HEART FAILURE WITH REDUCED EJECTION FRACTION

MONDAY, NOVEMBER 13, 2017 1:15 PM - 2:00 PM**Booth 2467** 

**Anaheim Convention Center** Anaheim. CA

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GREGG C FONAROW, MD, FAHA, FACC, FHFSA Professor, University of California Los Angeles Los Angeles, California



**ROBERTA BOGAEV, MD** Director, Advanced Heart Failure and Mechanical Circulatory Support Center Bon Secours Advanced Heart Failure Center Richmond, Virginia



BETH DAVIDSON, DNP, ACNP, CHFN, CCRN Director, HF Disease Management Program TriStar Centennial Medical Center Nashville, Tennessee

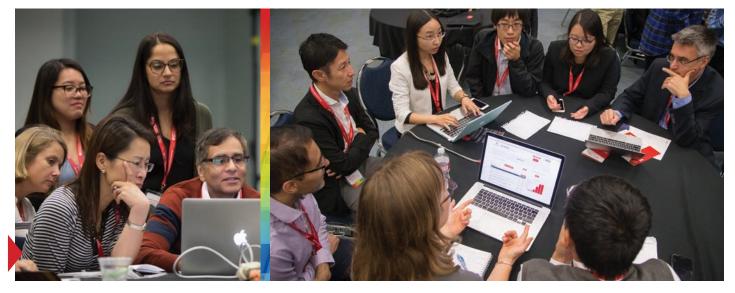
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## Workshop offers interactive demo of AHA Precision Medicine Platform

Saturday's Early Career workshop,

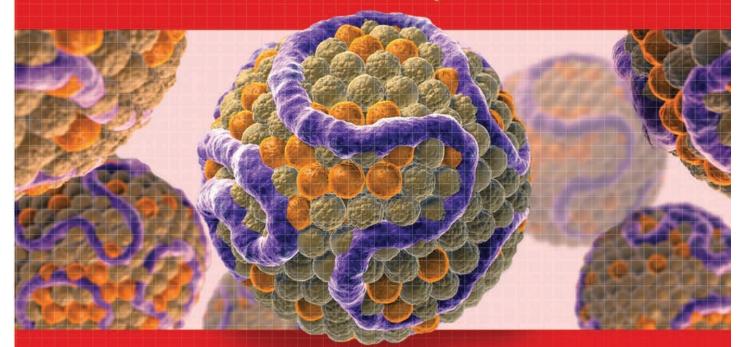
"Using AHA's Precision Medicine Platform and the Type 2 Diabetes Knowledge Portal to Search and Analyze Data," offered early career scientists an introduction to the platform and an opportunity to see how it can enhance and expand research capabilities. Laura Stevens, a PhD candidate in computational biology at the University of Colorado at Denver and a data scientist with the AHA Institute for Precision Cardiovascular Medicine, led attendees through a hands-on demonstration of the platform workspace, including how to search, filter, access and analyze available datasets. For more information on Stevens' role at the institute, see page 15.



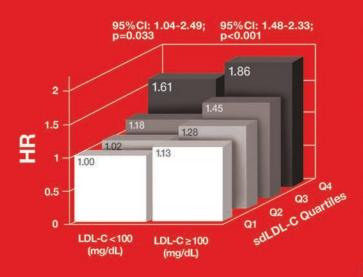
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## Cardiovascular Disease Prediction by Small Dense LDL Cholesterol

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Adjusted hazard ratios for incident coronary heart disease consisting of myocardial infarction, coronary heart disease death and revascularization by small dense LDL cholesterol (sdLDL-C) quartiles stratified by LDL-C risk categories. Adjusted for age, sex, and race, smoking, body mass index, hypertension, diabetes mellitus, diabetes mellitus medications, and log high-sensitivity C-reactive protein. Cl indicates confidence interval (adapted from Hoogeveen et al. Arterioscler Thromb Vasc Biol. 2014;34:1069-1077 with approval).



### Visit Recharge Institute Lounge to learn about AHA Precision Medicine Platform, My Research Legacy

#### Scientific Sessions attendees

can learn about the AHA's Institute for Precision Cardiovascular Medicine at the Recharge Institute Lounge in Hall D, Main Building.

The lounge, which opens 7 a.m.-5:30 p.m. Sunday and Monday and 7:30 a.m.-5:30 p.m. Tuesday, features daily demos of the AHA Precision Medicine Platform and My Research Legacy.

You can also have one-on-one discussions with precision medicine experts, recharge your devices at multiple stations and enjoy free coffee.

So drop by and be sure to use #AHAprecision on Twitter and Instagram.

#### DAILY DEMONSTRATIONS

#### Sunday

12:15-12:55 p.m. AHA Precision Medicine Platform

1-1:30 p.m. My Research Legacy + Meet a Heart Valve Survivor

2-2:30 p.m. Amazon Web Services

#### Monday

1-2 p.m.
AHA Precision Medicine Platform
2:05-2:30 p.m.
My Research Legacy + Meet a Heart
Valve Survivor
3:15-3:45 p.m.

Amazon Web Services

#### Tuesday

**10-10:30 a.m.** AHA Precision Medicine Platform

#### LOUNGE HOURS

7 a.m.-5:30 p.m. Sunday and Monday 7:30 a.m.-5:30 p.m. Tuesday

# Inaugural Health Tech Summit will explore new applications, benefits of health technology

he inaugural Health Tech Summit on Monday will highlight the best and most challenging healthcare technology transformations.

The summit — held 9 a.m.-6 p.m. in room 303CD, Main Building — starts with the Main Event session, "Technology and Healthcare: The Road Ahead."

"This is really a meeting within a meeting," said Mintu Turakhia, MD, MAS, who co-chaired the summit planning committee with Maulik D. Majmudar, MD, associate director of the Healthcare Transformation Lab at Massachusetts General Hospital in Boston. "It's not just about the broad topic of health technology. This is an in-depth examination of the application of a whole new set of tools in creative, new ways that can — and should — be highly impactful in cardiovascular health.

"The summit format brings together people who are interested in the problems, the solutions and the tools, and who want to apply them across multiple clinical areas and learnings. The things we are talking about — opening up electronic records; using sensor data; doing clinical trials better, faster, smarter; artificial intelligence — these can be applied to many different aspects of cardiology."

If the topics sound familiar, the approaches won't be. Artificial intelligence, for example, isn't about artificiality or robots. It's about efficiency. The role of AI is to be assistive, not artificial, said Turakhia, associate professor of cardiovascular medicine and executive director of the Center for Digital Health at Stanford University in Palo Alto, California. Al should make health care easier, faster, more effective and less expensive by automating routine tasks that are more about attention to detail than creativity and interpretation of data, he said.

One key application is to speed tasks such as reading EKGs and identifying the arrhythmia in the heart. Both tasks are tedious and prone to errors of human judgment, Turakhia said.

Another application is to speed tasks that are computationally intensive to make them more efficient. A common example is improving operating room scheduling to increase efficiency and lower the pain points for patients, clinicians and staff.

#### Where are they now?

A special session during Monday's Health Tech Summit will feature past winners of the annual Health Tech Competition at Scientific Sessions.

Representatives from Eko Devices, Twiage and Constant Therapy will update attendees on their awardwinning products during "Health Tech Competition: Where Are They Now?" The 25-minute session begins at 3:30 p.m. in room 303CD, Main Building. The fourth annual Health Tech

Competition will be held 1-2:30 p.m. Monday at EP Central, booth 2411, in the Science and Technology Hall. "The spectrum of AI use is not different from any other use case outside of health care," said Turakhia, who is also director of cardiac electrophysiology at the Palo Alto Veterans Affairs Health Care System. "That's why AI is so important. It's not about building robots that can care for patients."

Sensors and diagnostics are just as likely to transform health care in ways many cardiologists might not envision. The current generation of sensors is highly sensitive and robust, and every successive generation improves performance. But a mature understanding of how to deploy sensors to improve health and patients' and clinicians' experience is lacking. "It's not just about the data sci-

Mintu Turakhia, MD, MAS ence and the sensors," Turakhia said. "It is increasingly an issue of coupling data with clinically provh care in en behavioral science strategies. It's about keeping patients looped in and engaged. We aren't facing problems of technology; we are facing problems of behavioral science and behavioral psychology."

Another key issue is who will pay for health technology. Familiar devices such as implanted pacemakers are typically paid by a private or public insurer.

"There's very limited and ambiguous reimbursement for some of these digital devices and technologies," Turakhia said. "These are the sorts of issues we will address as we look at how these technologies will impact cardiology." ▼



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## Award recipients to be recognized Sunday

he AHA will honor several leaders in cardiovascular disease research and care during the Opening Session that begins at 1 p.m. Sunday in Main Event I, Hall D, Main Building.

The awards recognize contributions and achievements in research, mentorship and furthering the AHA's goals. The 2017 award recipients are:

#### **Chairman's Award**

#### Gregg Fonarow, MD, FAHA Fonarow is the Chairman's Award honoree for

his efforts to help the AHA achieve its goals. He has given his time in AHA leadership positions at the local and national levels.

He currently serves as chair of the AHA/ACC Task Force on Performance Measures, the Workplace

Health Steering



Committee and the Get With The Guidelines® Quality Improvement Subcommittee. He's also a member of several other AHA committees, including the Quality Oversight Committee, the AMA/AHA Blood Pressure Volunteer Advisory Group and the Hospital Accreditation Science Committee.

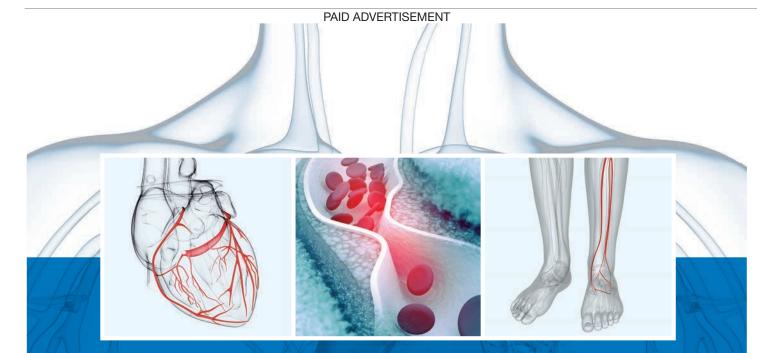
Fonarow is the Eliot Corday Professor of Cardiovascular Medicine and Science in the David Geffen School of Medicine at the University of California, Los Angeles.

#### **Basic Research Prize**

Walter Koch, PhD, FAHA Koch will receive the 2017 Basic Research Prize for his seminal contributions to cardiovascular science. Koch's research focuses

on cardiovascular gene transfer and molecular

signaling of cardiac injury and repair. He is a pioneer in the basic molecular biology



Please Join Us for a Cardiovascular Expert Theater at the American Heart Association Scientific Sessions 2017

## **The Underlying Thrombotic Risk** in Patients With Atherosclerotic Vascular Disease

#### Monday, November 13, 2017 • 12:00 РМ – 12:45 РМ

Anaheim Convention Center Cardiovascular Expert Theater Booth 1473 Anaheim, CA

Marc Bonaca, MD, MPH Cardiovascular Medicine Specialist Brigham and Women's Hospital (BWH) Assistant Professor Harvard Medical School Boston, MA

080178-170911

#### **PROGRAM DESCRIPTION**

Coronary artery disease (CAD) and peripheral artery disease (PAD) are clinical manifestations of vascular disease, sharing common pathophysiologic characteristics of atherosclerosis and atherothrombosis. Both are associated with a persistent underlying thrombotic risk of recurrent cardiovascular events (MACE), which can confer significant morbidity and mortality. This presentation will discuss the prevalence, epidemiology, risk factors, and the residual risk of CV events that exist in spite of current guidelines-based treatment recommendations in managing these patient populations.

November 2017

In adherence with PhRMA guidelines, spouses or other guests re not permitted to attend company

For all attendees, please be advised that information such as your name and the value and purpose of any educational item, meal, or other items of value you receive may be publicly disclosed. If you are licensed in any state or other jurisdiction, or are an employee or contractor of any organization or governmental entity that limits or prohibits meals from pharmaceutical companies, please identify yourself so that you (and we) are able to comply with such requirements

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This event is not part of the official Scientific Sessions as planned by the AHA Committee on Scientific Sessions Programming.



of the heart and his studies have identified novel molecular targets for treating heart failure. For the past 20 years, his research has examined the role that G proteincoupled receptor kinases (GRK) play in

alter Koch,

normal and failing heart function essentially creating a new field of study based on the significant role that GRKs play in the cardiovascular system.

Koch is the William Wikoff Smith Endowed Chair in Cardiovascular Medicine and chair of the Department of

Pharmacology at the Lewis Katz School of Medicine at Temple University in Philadelphia. He also directs the Center for Translational Medicine at Temple University.

#### **Clinical Research Prize**

Robert A. Harrington, MD, FAHA, FACC, FESC

Harrington is receiving the 2017 **Clinical Research** Prize for his novel approach to designing and conducting clinical trials focused on



improving the care of patients with coronary artery disease with bloodclotting complications. He is being honored for his leadership of landmark studies, including PURSUIT, REPLACE, TRACER, CHAMPION and APEX.

An interventional cardiologist, Harrington's studies have been key to the approval of multiple anti-thrombotic agents. He continues to innovate research methods by leveraging electronic health data, mobile health applications and novel analytic methods in large trials.

Harrington is chair of the Department of Medicine and the Arthur L. Bloomfield Professor of Medicine at Stanford University in California.

#### **Population Research Prize**

Donna R. Arnett, PhD, MSPH, BSN, FAHA Arnett, AHA past-president, is the recipient of the 2017 Population Research Prize for merging basic



molecular sciences with population studies to develop a novel understanding of cardiovascular disease. Her work

includes seminal research in

identifying genetic biomarkers and risk prediction. She was also instrumental in helping develop the AHA's population research portfolio by bridging the gap between population and molecular research investigators.

Arnett is dean of the College of Public Health at the University of Kentucky in Lexington.

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#### **Eugene Braunwald Academic Mentorship Award**

#### Gary D. Webb, MD, FRCP(C), FACC, FAHA

Webb will receive the 2017 Eugene Braunwald Academic Mentorship Award for his extensive mentoring of pediatric and



adult cardiologists.

In a mentorship career that began in the early 1970s, Webb has shared his knowledge widely with trainees, fellow physicians, other clinicians and patients. He's mentored 80 trainees since 1993.

Webb, a champion of educating professionals and patients about adult congenital heart disease, has seen many of his trainees establish congenital heart disease treatment programs worldwide. He was a founding member and the first president of the International Society for Adult Congenital Heart Disease.

Webb is director of the Cincinnati Adult Congenital Heart Disease Program and professor of clinical pediatrics and internal medicine at the University of Cincinnati in Ohio.

#### **Research Achievement Award**

Thomas G. Brott, MD Brott will receive the Research



developing lifesaving interventions that have revolutionized acute ischemic stroke treatment. In collaboration

with the National Institute of Neurological Diseases and Stroke, Brott and his research team identified and tested what became the first scientifically proven treatment for ischemic stroke - the intravenous administration of t-PA. Treatment with t-PA was shown to be efficacious for breaking up blood clots causing thrombotic strokes, and in 1996 the FDA approved t-PA for treatment of acute stroke. Before the treatment, clinicians

Brott is professor of neurology and director of research at the Mayo Clinic in Jacksonville, Florida.

#### Joseph A. Vita Award

Laura Mauri, MD, MSc, FAHA

could little do for stroke patients.

The AHA's newest honor recognizes Mauri for her transformative clinical investigations of treatment methodologies



for a variety of cardiovascular disorders. Her research clarified the balance of

risk and benefit for continued bloodclot prevention therapy with plateletinhibiting drugs in patients with coronary artery disease and stents. Her research group also has developed decision tools to individualize treatment choices by identifying patients most likely to benefit without significantly increasing

bleeding risk. These tools have been widely adopted and have been incorporated into the AHA's updated clinical practice guidelines.

Mauri is professor of medicine at Harvard Medical School and director of the Center for Clinical Biometrics at Brigham and Women's Hospital in Boston.

### **Merit Awards**

Joseph C. Wu, MD, PhD, and Garrett A. FitzGerald, MD, FRS, FAHA On Friday, the AHA presented its annual five-year, \$1 million Merit Awards to Wu and FitzGerald as promising investigators - rather than for specific research

of science with creative

and novel approaches.

director of the Stanford

of stem cells. He is

Wu's research focuses on

the biological mechanisms

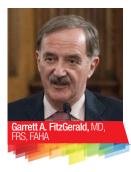


Cardiovascular Institute and the Simon H. Stertzer, MD, Professor of Cardiovascular Medicine & Radiology

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at Stanford University School of Medicine.

The FitzGerald Lab focuses on postanoid biology and the projects - who have the role of peripheral potential to advance a field molecular clocks in cardiovascular



biology, metabolism and aging. FitzGerald is the McNeil Professor in Translational Medicine and Therapeutics and director of the Institute for **Translational Medicine & Therapeutics** at the Perelman School of Medicine at the University of Pennsylvania in Philadelphia.

# Join Us Optimization of Care Heart Failure

IN THE HOSPITALIZED PATIENT

#### Wayne C. Levy, MD

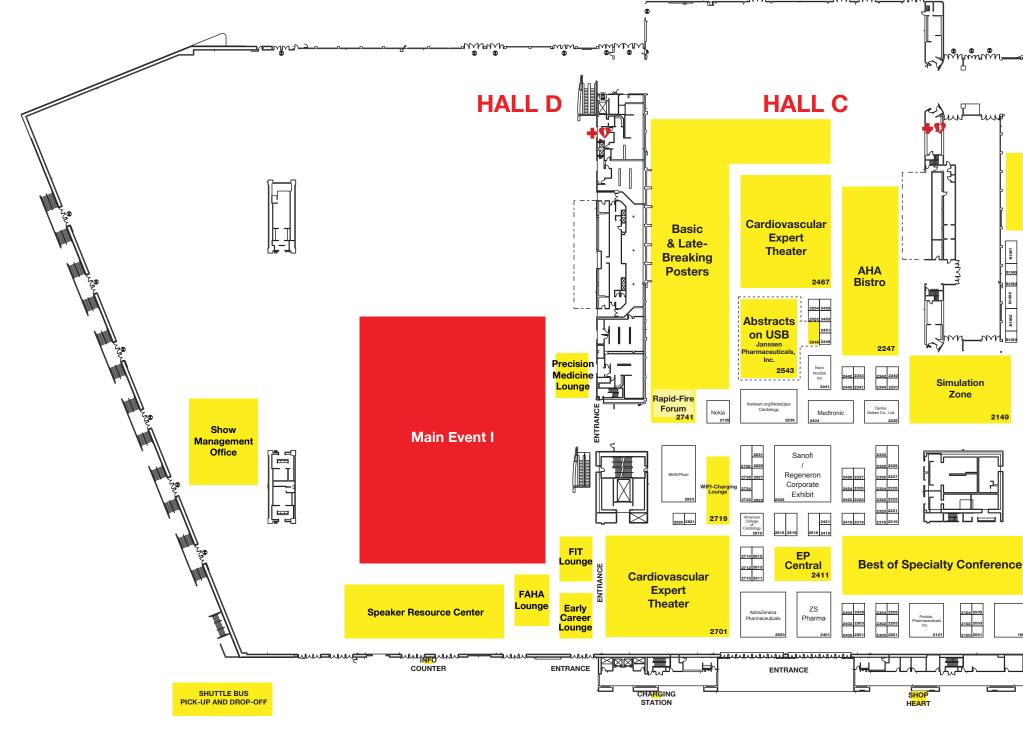
Professor of Medicine/Cardiology Fellowship Director, Advanced Heart Failure and Cardiac Transplantation University of Washington Seattle, Washington

Sunday, November 12, 2017 | 12:30–1:15 PM | Booth 2701 Anaheim Convention Center | Anaheim, California

This event is not part of the official Scientific Sessions 2017 as planned by the AHA Committee on Scientific Sessions Program. Sponsored by Novartis Pharmaceuticals Corporation

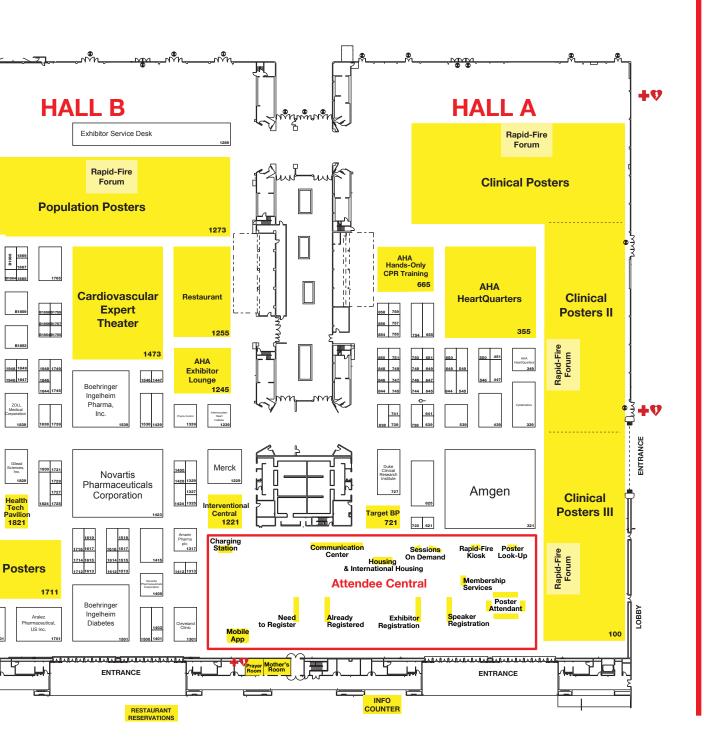
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2017 Scientific Sessions Exhi	Monday 10	a.m5 p.m. Sur ) a.m4:30 p.m. Mo	I Breaks           nday         11 a.m1 p.m. and 3:15-3:45 p.m.           nday         10:15-10:45 a.m., Noon-2 p.m. and 3:15-3:45 p.m.           sday         10:15-10:45 a.m. and Noon-2 p.m.
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SCIENTIFIC 20 SESSIONS 17

### SUNDAY'S THEATER PRESENTATIONS

#### CARDIOVASCULAR EXPERT THEATER BOOTH 1473

#### 11:15 a.m.-Noon

Clinical Inertia and LDL-C Levels in Atherosclerosis Supporter: Amgen, Inc. Presenter: James A. Underberg, MD

#### 12:30-1:15 p.m.

## JARDIANCE<sup>®</sup> (empagliflozin) Tablets: Evolving Clinical Development

Supporter: Boehringer Ingelheim Pharmaceuticals, Inc. Presenters: James R. Gavin III, MD, PhD, and Pam R. Taub, MD, FACC

#### CARDIOVASCULAR EXPERT THEATER BOOTH 2467

#### 11:15 a.m.-Noon

PRALUENT<sup>®</sup> (alirocumab) Injection: The Time to Treat the Appropriate Patient is Now Supporter: Sanofi/Regeneron Presenter: Paul Thompson, MD, FACC

#### 12:30-1:15 p.m.

Repatha (evolocumab): Take the Next Step Supporter: Amgen, Inc. Presenter: Seth J. Baum, MD, FACC, FACPM, FAHA, FNLA, FASPC

#### CARDIOVASCULAR EXPERT THEATER BOOTH 2701

#### 11:15 a.m.-Noon

Clinical Data and Real-World Evidence to Support NVAF & DVT/PE Treatment Decision Making Supporter: Janssen Pharmaceuticals, Inc. Presenter: Dharmesh Patel, MD

#### 12:30-1:15 p.m.

Optimization of Care for Chronic Heart Failure in the Hospitalized Patient Supporter: Novartis

Presenter: Wayne Levy, MD, FACC

#### 3-3:45 p.m.

Vascular Inflammation in Atherosclerosis: Clinical Implications Supporter: Novartis Presenters: George Abela, MD, MBA, MSc, and Roxana Mehran, MD, FACC, FACP, FAHA, FESC, FSCAI

#### HEARTQUARTERS THEATER

#### BOOTH 335

**11-11:45 a.m. ECC presentation** *Presenter: Kristy Rogers* 

#### Noon-12:45 p.m.

## Building a Strategic and Impactful Global Cardiovascular Response

Presenters: Marc Jaffe, MD, Vice President, RESOLVE; Jennifer Keltz, Centers for Disease Control and Prevention, Global Heart Initiative; John Meiners, Chief of Mission Aligned Businesses, American Heart Association

#### 1-1:45 p.m.

Hypertension Journal CPC: Hypertension and its Complications in a Young Man with Autoimmune Disease

Presenter: Eve Miller-Hodges, MD, PhD

#### 3:30-4 p.m.

#### Social Determinants of Health Presentation-Multicultural Markets

Presenters: Francesca Martinez, Bry Mabry, Arika Cason

#### 4:30-5 p.m.

**Research Funding Opportunities** Presenter: Steven B. Houser, PhD, FAH

Presenter: Steven R. Houser, PhD, FAHA, Temple University School of Medicine & AHA Immediate Past-President

# Seven Distinguished Scientists to be honored during Sunday afternoon Opening Session

he American Heart Association will honor seven researchers as 2017 Distinguished Scientists during the Opening Session, which begins at 1 p.m. Sunday in Main Event I, Hall D.

The annual awards recognize AHA/ASA members for significant, original and sustained scientific contributions that have advanced the AHA's mission to build healthier lives, free of cardiovascular diseases and stroke. This year's recipients join 100 past honorees. They are:

Bernard J. Gersh, MB, ChB, DPhil, FAHA Gersh's major contributions have been in understanding the natural history of atrial

fibrillation, the cardiomyopathies, revascularization in stable coronary disease and acute reperfusion therapy for STEMI.

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Gersh is professor of medicine at the Mayo Clinic College of Medicine. Past positions include the W. Proctor Harvey Teaching Professor of Cardiology and chief of the Division of Cardiology at Georgetown University in Washington, D.C. He received his MB and ChB from the University of Cape Town in South Africa, and his DPhil from Oxford University in England, where he was a Rhodes Scholar.

In 2004, Gersh received the AHA Council on Clinical Cardiology's

American American Heart Stroke Association **Association** . LET'S MAKE SURE YOUR PATIENTS HAVE A LEG TO STAND ON.

#### LEARN TO RECOGNIZE THE SIGNS OF PAD

Peripheral artery disease (PAD) is currently the leading cause of amputations in the U.S. and is a serious risk factor for coronary artery disease and cerebrovascular disease. Learn how to detect, diagnose and treat PAD, ultimately saving both lives and limbs.

Visit AHA Booth 335 to pick up your free copy of the PAD Toolkit, designed specifically for healthcare professionals.

ra

**GETTING TO THE HEART OF VASCULAR HEALTH** heart.org/PADtoolkit Distinguished Achievement Award. He was the recipient of the AHA's James B. Herrick Award in 2012, and in 2013 was designated Master of the American College of Cardiology. He was the 2015 recipient of the Mayo Clinic Distinguished Alumni Award and the Silver and Gold Medals of the ESC in 2016.

Gersh has authored 1,073 publications and was named in the Thomson Reuters list of people with the greatest number of cited scientific papers, 2002-2012. Gersh is the editor of 15 books and on the editorial board of 27 journals, including The European Heart Journal as deputy editor and UpToDate for Cardiovascular Medicine as editor-in-chief.

#### Stanley L. Hazen, MD, PhD, FAHA

Hazen has made several pioneering discoveries in atherosclerosis and inflammatory disease research that have

impacted clinical practice. He made the seminal discovery linking gut microbial pathways to cardiovascular disease

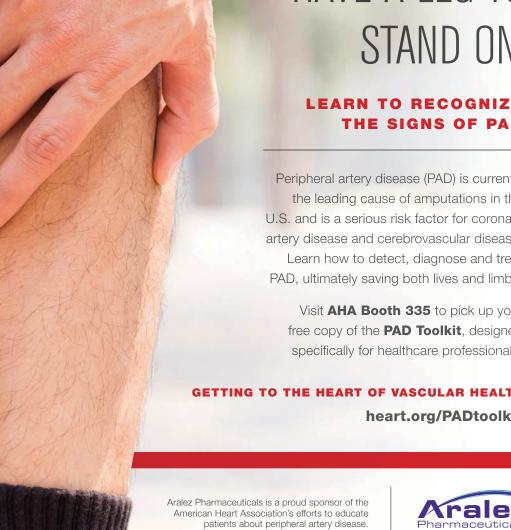
pathogenesis and



development of heart failure and chronic kidney disease. His comprehensive work established a paradigm for understanding diet-gut microbiome-host interactions in diseases, and has spawned development of new diagnostic tests and therapeutic approaches to treat and prevent CVD and metabolic disorders.

Hazen's numerous other discoveries include defining pathways leukocytes use to generate reactive oxidants, the functional importance of oxidation processes in CVD, macrophage recognition of senescent and apoptotic cells, modified lipoproteins, or in vivo regulation of platelet hyperresponsiveness. His studies laid the foundation for the development of diagnostic tests for CVD risk assessment that are in use worldwide, and have helped to spawn pharmaceutical development of myeloperoxidase inhibitors that are in clinical trials.

He received his training at Washington University School of Medicine in St. Louis. where he received his medical degree, a PhD in biophysical chemistry and molecular biology, and clinical training in internal medicine with subspecialty training in diabetes, endocrinology and metabolism. He has been at the Cleveland Clinic in Ohio his entire professional career, where he serves as chair of the Department of Cellular and Molecular Medicine at the Lerner Research Institute and section head of preventive cardiology and rehabilitation at the Heart and Vascular Institute.



#### Sekar Kathiresan, MD, FAHA

Kathiresan has pursued a systematic approach to understand the inherited

basis for myocardial infarction to discover root causes, inform new therapeutic approaches and identify at-risk individuals. He



has distinguished non-causal factors (HDL cholesterol) from causal factors (LDL cholesterol and triglyceride-rich lipoproteins). His research identified that individuals who carry loss-of-function coding mutations in either of two genes — APOC3 or ANGPTL3 — rapidly clear triglyceride-rich lipoproteins from the circulation and have substantially lower MI risk. These observations have inspired the development of medicines to mimic these protective mutations.

In the past year, Kathiresan has uncovered two non-lipid pathways underlying MI risk: genes that regulate the migration of inflammatory cells across the blood vessel lining into the artery wall; and acquired mutations in blood stem cells that increase with aging and provoke inflammation. He has developed a genetic test (*i.e.*, polygenic risk score) to predict risk for MI and show that statin therapy and/or a healthier lifestyle can modify inherited risk.

Kathiresan is the director of the Center for Genomic Medicine at Massachusetts General Hospital, director of the Cardiovascular Disease Initiative at the Broad Institute of MIT and Harvard, and an associate professor of medicine at Harvard Medical School.

Kathiresan immigrated to the United States from India in 1980 and attended public schools in Pittsburgh, Pennsylvania, before graduating summa cum laude with a BA in history from the University of Pennsylvania in 1992. He received his MD from Harvard Medical School in 1997 and completed clinical training in internal medicine and cardiology at Massachusetts General Hospital.

#### Leslie Leinwand, PhD, FAHA

Leinwand's laboratory is researching the genetics and molecular physiology of

inherited diseases of the heart and how gender and diet modify the heart. The study of these diseases has required multidisciplinary approaches



involving molecular biology, mouse genetics, mouse cardiac physiology and the analysis of human tissues. She received funding from the Howard Hughes Medical Institute's Professor Program for her teaching.

Leinwand is distinguished professor of molecular, cellular and developmental biology, and chief scientific officer of the BioFrontiers Institute at the University of Colorado in Boulder. She received her Bachelor's degree from Cornell University, her PhD from Yale University and did post-doctoral training at Rockefeller University. In 1981, she joined the faculty at Albert Einstein College of Medicine in New York and remained there until moving to Colorado in 1995.

Leinwand co-founded Myogen, Inc., which was sold to Gilead Pharmaceuticals. She was also a co-founder of Hiberna, Inc., and more recently of MyoKardia, Inc., a publicly traded company that develops therapeutics for inherited cardiomyopathies.

She is a fellow of the American Association for the Advancement of Science, a former MERIT Awardee of the NIH and an Established Investigator of the AHA. She was recently elected to the American Academy of Arts and Sciences and the National Academy of Inventors.

#### Mary M. McDermott, MD, FAHA

McDermott is a leading clinician investigator studying lower extremity peripheral artery disease. Using a prospective study design with systematic assessment of objectively measured walking performance over time, McDermott's investigative team demonstrated that people with PAD have greater functional impairment and faster functional decline than people without PAD. Her team also demonstrated that most people with PAD do not

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have classical symptoms of intermittent claudication and that even people with asymptomatic PAD have greater functional impairment and



faster functional decline than people without PAD. She was the first investigator to report that supervised treadmill exercise improves walking ability among PAD patients who are asymptomatic or who have atypical leg symptoms. Her work has established the presence and importance of ischemic calf muscle damage in PAD. DISTINGUISHED SCIENTISTS continued on page 14

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### DISTINGUISHED SCIENTISTS continued from page 13

More recently, McDermott has led randomized clinical trials to identify innovative therapies to improve functional performance and prevent mobility loss in PAD patients. Her investigative team is currently studying interventions that include Granulocyte-Macrophage Colony Stimulating Factor, telmisartan, home-based exercise, metformin and epicatechin-rich cocoa to improve functional performance and other outcomes in PAD patients.

McDermott is the Jeremiah Stamler Professor of Medicine and Preventive Medicine at Northwestern University Feinberg School of Medicine.

McDermott has received multiple national awards, including an Established Investigator Award from the AHA. In 2013, she was named master in the Society of Vascular Medicine for "outstanding contributions to vascular medicine." In 2011-13, she served as chair of the AHA's Council on Peripheral Vascular Disease.

#### Jeffrey A. Towbin, MD, FAHA

Towbin's research has focused on cardiomyopathies and heart failure, cardiac transplantation and cardiovascular genetics. His research has focused on the genetics and mechanisms of cardiomyopathy and advanced heart failure, arrhythmias and inflammatory heart disease and their etiologies. His research has been funded continuously since 1987 and he has trained

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more than 50 post-doctoral and 20 pre-doctoral students, many of whom have high level academic faculty positions. His laboratory re-

been a leader for many years in the field of gene discovery and mechanisms of these disorders, as well as viral causes of inflammatory heart disease, including transplant rejection and transplant coronary disease.

Towbin is co-director of the Heart Institute at Le Bonheur Children's Hospital, chief of cardiology at St. Jude's Children's



n MD FAHA

ASPC



lications in high-impact journals, served as a principal mentor for multiple K-Grant-funded

trainees and has been a member of multiple T32 training grants. He received the American College of Cardiology Distinguished Scientist (Basic Science) Award in 2007 and the AHA's Basic Research Prize in 2013.

Research Hospital and professor and chief

He has co-authored more than 500 pub-

of pediatric cardiology at the University of Tennessee Health Sciences Center.

#### Denisa D. Wagner, PhD, FAHA

Wagner's expertise is in the fields of vascular biology, inflammation and thrombosis. For many years, her laboratory's research has focused on



adhesion molecules - specifically, the regulation of their expression and function in normal physiology and in pathological situations. Her lab has engineered mice lacking platelet, endothelial or leukocyteadhesion molecules, such as von Willebrand factor and P-selectin, and has studied these mice in disease models.

One of the lab's main interests is the interplay of inflammation and thrombosis. Recently, they have begun to explore the impact of neutrophil extracellular traps, which are chromatin coated with enzymes actively released from stimulated neutrophils. Her group has found an important pro-thrombotic role of NETs and detrimental/toxic effects of NETs formed during injury and after MI. Most recently, they observed that NET formation is enhanced by cancer, diabetes and the aging process.

Wagner grew up in Prague, Czechoslovakia. She became interested in biology in middle school and started to do research in labs at Charles University. After the invasion by the Soviet block in 1968, Wagner fled the country with her parents. She finished high school in Austria and studied biochemistry at the University of Geneva in Switzerland. She then moved to the United States, where she obtained a PhD in biology at Massachusetts Institute of Technology under the guidance of Dr. Richard Hynes.

Wagner held early faculty positions at the University of Rochester and Tufts University until she was recruited to Harvard Medical School in 1994. Still there, she is currently the Edwin Cohn Professor of Pediatrics in the program in cellular and molecular medicine and the division of hematology/oncology at Boston Children's Hospital.

#### 0 Join us for our annual awardee group photo at Scientific Sessions If you have ever had an AHA research grant or fellowship, please join us for an Awardee Photo at 1:30 p.m. Tuesday immediately following the Distinguished Scientist Lecture in Main Event II, Ballroom CD. The ballroom is located on the third level of the Anaheim Convention Center. AHA officers are slated to join in the photo as well. Participants will receive a special AHA Awardee lapel pin!

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#### COMPLIMENTARY **NON-CME BREAKFAST EVENT**

Monday, November 13 6:30am - 8:30am Anaheim Marriott - Platinum Ballroom 1-4

#### **FEATURING:**

Seth J. Baum, MD Martha Gulati, MD Peter P. Toth, MD, PhD Michael Shapiro, DO





## AHA adds first data scientist focused on precision medicine

he American Heart Association has hired its first data scientist dedicated to precision medicine, bolstering efforts by researchers and physicians to mine biological data in search of more precise approaches to treat and prevent heart disease and stroke.

Laura Stevens recently joined the growing American Heart Association Institute for Precision Cardiovascular Medicine, which is the only entity of its kind focused exclusively on cardiovascular diseases and stroke.

Stevens, a PhD candidate in computational biology from the University of Colorado at Denver, brings experience in data science as well as chemical and biological engineering.

"I wanted the opportunity to change people's lives, to use data to better treat disease and to help propel medical research forward," she said.

"It is terrific to have the opportunity to build a team of data scientists here," said Jennifer L. Hall, PhD, who heads the institute. "Our goal is to do much of the heavy lifting for the researchers, thereby allowing them to focus on the science. Laura will play an important role in our reaching that goal."

Stevens first developed a passion for data science when she began writing computer programs to help her analyze data on heart cells. She heard about the

#### RESEARCH AWARDS continued from page 1

want to support those likely successful ideas to transform them into knowledge, novel therapeutics or new preventative measures.

"So we have two different flavors of grants — both open to all researchers in all walks of science. We hope people will send us their best ideas, and we'll bring our best resources to support novel science."

For more information, visit **professional.heart.org** and click "Application Information" under the "Research Programs" tab. ▼

#### Visit HeartQuarters Theater to learn more about the AHA's new funding opportunities

Steven R. Houser, PhD, FAHA, immediate past-president of the AHA and chair of the Research Funding Subcommittee, will present information on the AHA's new funding opportunities at 4:30-5 p.m. Sunday in the HeartQuarters Theater, Booth 355, in the Science and Technology Hall.

The session, which will include information about the new Innovative Project Award and the Transformational Project Award and other AHA research funding opportunities, will be repeated at 2:15-2:45 p.m. Monday. Institute's work while attending Scientific Sessions 2016. Soon after, she was involved in testing early versions of the AHA Precision Medicine Platform, which allows researchers and clinicians from around the globe to easily search, access and analyze millions of data sets online. She's committed to maintaining the security measures of the platform, which is powered by Amazon Web Services, because it's important to educate users and instill confidence in the platform.

Gabriel Musso has been exploring the platform since the beta version went online in March. "I've been using it to evaluate and process large research files, running analyses, summarizing the data sets and creating visuals," said Musso, vice president of life sciences for Torontobased data analytics firm BioSymetrics. "It's very useful for what I do, and I know Laura will be successful in making it an even more powerful resource."

The platform, which launched in 2016 and officially opened in July, houses more than 36 million records.

"I'd encourage researchers thinking about using the platform to get involved, to go online and check it out, see what's available and let us know what you need and how

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we can improve it," Stevens said. "It's just beginning and there is so much potential to create and build an environment that changes the way we collaborate and conduct research." To be part of the change, please go to **precision.heart.org**. **V** 

Join Us

Vascular Inflammation in Atherosclerosis: Clinical Implications

#### George Abela, MD, MBA, MSc, FACC, FAHA, FNLA

Professor of Medicine Chief, Division of Cardiology Cardiology Fellowship Director Michigan State University Department of Medicine, Cardiology East Lansing, Michigan

#### Roxana Mehran, MD, FACC, FACP, FAHA, FESC, FSCAI

Professor of Medicine (Cardiology) Professor of Population Health Science and Policy Director of Interventional Cardiovascular Research and Clinical Trials, The Zena and Michael A. Wiener Cardiovascular Institute Icahn School of Medicine at Mount Sinai Chief Scientific Officer Cardiovascular Research Foundation New York, New York

#### Sunday, November 12, 2017 | 3:00–3:45 PM | Booth 2701 Anaheim Convention Center | Anaheim, California

This event is not part of the official Scientific Sessions 2017 as planned by the AHA Committee on Scientific Sessions Program. Sponsored by Novartis Pharmaceuticals Corporation





# - Welcoming Special Guest -Queen Latifah

HF Caregiver & Spokesperson

Hear her story at Opening Session. Sunday, November 12, 1 p.m.

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#### PRESIDENT continued from page 1

Warner will discuss key insights from his personal story and professional journey in cardiology and hospital leadership, including many vital opportunities that clinicians and researchers have to improve and extend lives.

These opportunities are particularly important, he notes, because of recent statistics that show heart disease and stroke mortality stalling and even reversing course after many decades of progress.

"Some would say the picture is grim, and maybe it is," Warner said. "But we are all here because of our commitment to improving this picture."

Warner will describe the importance

#### of expanding personal horizons and getting involved with groups like the AHA at a time when decades of progress to reduce cardiovascular mortality rates are slowing and political leaders are waffling on healthcare legislation.

Warner will describe how he has challenged himself throughout his career to consider how he could improve the health of more people.

A scholarship athlete in college, Warner will discuss how teamwork has been at the foundation of his entire career — and how it's crucial in the effort to save and improve lives. ▼

#### ADVANCED LIFE SUPPORT continued from page 1

According to Fukuda, there are several reasons that could explain the advantages of physicianperformed ALS. All EMS personnel in Japan perform CPR according to the Japanese CPR guidelines, although EMS personnel have different authorization levels depending on their level of training.

A small percentage of municipalities have physician-staffed ambulances, but most ambulances include at least one emergency life-saving technician (ELST) certified to insert an intravenous line and a supraglottic airway device. Specially trained ELST who have completed an extensive training program can administer epinephrine and insert an endotracheal tube.

"There might be differences in proficiency in ALS procedures between physicians and EMS personnel," Fukuda said. "In addition, the interventions, which only physicians could perform — surgical airway, chest drain, pericardial drain or thoracotomy — might have a greater impact on survival after traumatic OHCA. Unfortunately, the information on such interventions could not be obtained from the Japanese OHCA registry data." ▼

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The AHA would also like to thank the following companies for their support of Scientific Sessions 2017. This support was provided in the form of educational grants:

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PAID ADVERTISEMENT Please Join Us for a Cardiovascular Expert Theater at the American Heart Association Scientific Sessions 2017 Clinical Data and **Real-World Evidence** to Support NVAF & DVT/PE Treatment Decision Making Sunday, November 12, 2017 11:15 ам – 12:00 рм Dharmesh Patel, MD, MBBS, FACC Anaheim Convention Center Cardiovascular Expert Theater Cardiologist Stern Cardiovascular Foundation Booth 2701 Memphis, Tennessee Anaheim, California **Program Description** This lecture will discuss treatment options for patients with deep vein thrombosis and pulmonary embolism, and how they can reduce the risk of recurrent thrombotic events. It will also present options for reducing the risk of stroke in patients with nonvalvular atrial fibrillation

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This event is not part of the official Scientific Sessions as planned by the AHA Committee on Scientific Sessions Programming.



March 2017

## 2017 Unofficial Satellite Events

#### Sunday, Nov. 12

6-8 a.m. Industry-supported Symposium Intensifying Lipid-Lowering Therapy with **PCSK9** Inhibitors Sponsored by American Academy of CME, Inc.

and Spire Learning Supported by Amgen The Clarion Anaheim Hotel, Orangewood Ballroom Registration: www.regonline.com/lipids2017

#### 6:30-8 a.m.

Industry-supported Symposium Managing Dyslipidemia in Special Populations, A Collaboration Between the National Hispanic Medical Association and the National Lipid Association Sponsored by National Lipid Association Supported by Amgen Anaheim Marriott, Salon F Registration: lipid.org/rsvpanaheim

#### 6:30-9:30 p.m.

Industry-supported Symposium The Important Role of Lipoprotein(a) in Cardiovascular Disease: Present & Future **Therapeutic Options** Sponsored by AcademicCME Supported by Amgen Inc. Hilton Anaheim, California Ballroom D Registration: academiccme.com/LPa

#### 6:30-10 p.m.

Industry-supported Symposium Advances in the Treatment of Stable **Coronary Artery Disease and Peripheral Artery Disease** Sponsored by EMCREG-International Supported by Janssen Pharmaceuticals

Anaheim Marriott, Marquis Ballroom South Registration: www.emcreg.org

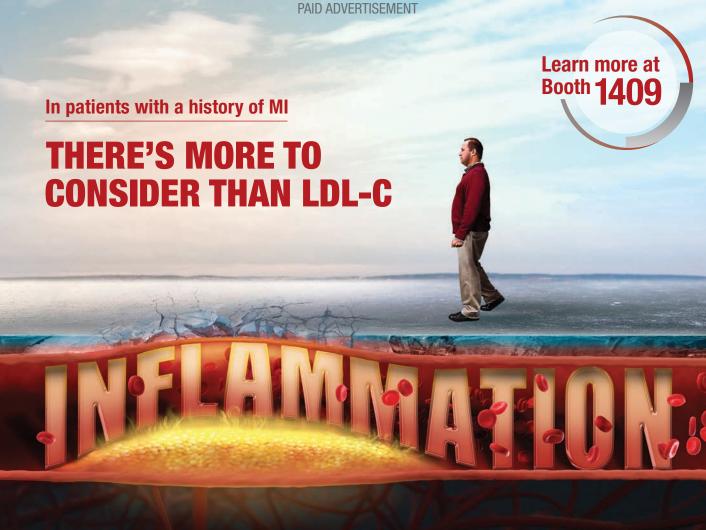
#### 7-8:30 p.m.

Industry-supported Symposium **Recognizing Residual Inflammatory Risk: Emerging Approaches to Preventing Recurrent Events in Patients with** Atherosclerotic Cardiovascular Disease Sponsored by Med-IQ Supported by Novartis Hilton Anaheim, California Ballroom C Registration: www.cvent.com/d/ktqkqq

#### 7-9 p.m.

Industry-supported Symposium Elevated CV Risk in Patients with Diabetes: Causes, Implications, and New Management Strategies

Sponsored by Vindico Medical Education Supported by Boehringer-Ingelheim Pharmaceuticals, Inc. and Lilly USA, LLC Anaheim Marriott, Platinum Ballrooms 5 & 6 Registration: VindicoCME.com/111217



Even when treated with optimal LDL-C-lowering therapies, patients remain at risk for recurrent CV events. One of the reasons is due to inflammation<sup>1-3</sup>—a significant CV risk factor.<sup>4</sup>

CV, cardiovascular; LDL-C, low-density lipoprotein cholesterol; MI, myocardial infarction.

References: 1, Armitage J. Bowman L, Wallendszus K, et al: Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine (SEARCH) Collaborative Coroup, Intensive lowering of LDL cholesterol with 80 mg versus 20 mg simvastatin daily in 12,064 survivors of myocardial infarction: a double-bill (and and mised trial. Lancet. 2010;376(9753):1658-1669. 2. Sabatine MS, Giugliano RP, Keech AO, et al; FOURIER Steering Committee and Investigators. Evolocumab and clinical outcomes in patients with after acute coronary syndromes. N Engl J Med. 2017;376(18):1713-1722. **3.** Canon CP, Blazing MA, Giugliano RP, et al; IMPROVE-IT Investigators. Ezetimibe added to statin therapy after acute coronary syndromes. N Engl J Med. 2015;372(25):2387-2397. **4.** Sabatine MS, Morrow DA, Jablonski KA, et al; PEACE Investigators. Prognostic significance of the Centers for Disease Control/American Heart Association high-sensitivity C-reactive protein cut points for cardiovascular and other outcomes in patients with stable coronary artery disease. Circulation. 2007;115(12):1528-1536.



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XMI-1349216

Monday, Nov. 13

6:30-8:30 a.m. Industry-supported Symposium

Getting to the Heart of Type 2 Diabetes Care: Seeking Better Outcomes in Patients with **Cardiovascular Disease** Sponsored by Paradigm Medical Communications, LLC Supported by Novo Nordisk Inc. Hilton Anaheim, Pacific Ballroom A Registration: www.paradigmmc.com/649

#### 6:30-9:30 p.m.

Industry-supported Symposium Applying PCSK9 Inhibitors to Optimize **Outcomes in Patients with Dyslipidemia** Sponsored by AcademicCME and the Elsevier Office of Continuing Medical Education Supported by Amgen Inc. Hilton Anaheim, California Ballroom D Registration: academiccme.com/PCSK9

#### 7-9 p.m.

Industry-supported Symposium Providing Quality Care for Patients with Heart Failure Sponsored by Vindico Medical Education Supported by Novartis Pharmaceuticals Corporation Anaheim Marriott, Platinum Ballrooms 5 & 6 Registration: VindicoCME.com/111317

#### 7-9 p.m.

Social Event University of Iowa Reception Sponsored by University of Iowa Hospitals and Clinics Supported by University of Iowa Hospitals and Clinics Hyatt Regency Orange County

#### 7-9:30 p.m.

Industry-supported Symposium From Clinical Trials to Clinical Practice: Applying Cardiovascular Outcome Trial Data to Real World T2DM Management Sponsored by Creative Educational Concepts Supported by AstraZeneca Anaheim Marriott, Marquis Ballroom Northeast Registration: www.ceconcepts.com/live/278

#### 7-9:30 p.m.

Industry-supported Symposium The Role of the Cardiologist for Successfully **Managing Atrial Fibrillation Patients** Sponsored by AtriCure

Supported by MediaSphere Medical Anaheim Marriott

Registration: www.innovationsincrm.com/aha

#### 7-10 p.m.

Nonprofit Symposium Machine Learning Vulnerable Patient Project Sponsored by SHAPE Hilton Anaheim

#### Registration: shapesociety.org

#### 7:30-9 p.m.

Industry-supported Symposium Preventing Pulmonary Embolism and Stroke: A New Era of Enhanced DOAC Efficacy and Safety Sponsored by Medscape Education Supported by Portola Pharmaceuticals, Inc. Anaheim Marriott, Grand Ballroom E & F Registration: www.medscape.org/townhall/ preventing-pe-and-stroke

#### Tuesday, Nov. 14

#### 6:30-8:30 a.m.

Industry-supported Symposium Severe Hypocholesterolemia: Review of **Clinical Trials to Improve Outcomes** Sponsored by Potomac Center for Medical Education and Rockpointe Supported by Amgen Anaheim Marriott, Platinum Ballroom 3 & 4 Registration: www.cvent.com/d/wtq951

#### 7:30-9 a.m.

Industry-supported Symposium **Renal Denervation and Blood Pressure** Control: A Clinical Trial Update Sponsored by Cardiovascular Research Foundation Supported by Medtronic Hilton Anaheim, Pacific A Registration: rdn-htn.com

#### 7-9 p.m.

Industry-supported Symposium **Cornerstones in Cardioprevention:** Rediscovering the Utility of Aspirin Sponsored by Medscape, LLC Supported by Bayer Consumer Health Anaheim Marriott, Platinum Ballroom 5 & 6 (Ground Floor) Registration: www.medscape.org/townhall/ aspirin-benefits

#### **REPATHA®** (evolocumab)

**BRIEF SUMMARY OF PRESCRIBING INFORMATION** Please see package insert for full Prescribing Information

#### 1. INDICATIONS AND USAGE

1.1 Primary Hyperlipidemia

REPATHA is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C)

#### 1.2 Homozygous Familial Hypercholesterolemia

REPATHA is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C. 1.3 Limitations of Use

The effect of REPATHA on cardiovascular morbidity and mortality has not been determined.

#### 4. CONTRAINDICATIONS

REPATHA is contraindicated in patients with a history of a serious hypersensitivity reaction to REPATHA [see Warnings and Precautions (5.1)]. 5. WARNINGS AND PRECAUTIONS

#### 5.1 Allergic Reactions

Hypersensitivity reactions (e.g., rash, urticaria) have been reported in patients treated with REPATHA, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with REPATHA, treat according to the standard of care, and monitor until signs and symptoms resolve.

#### 6. ADVERSE REACTIONS

The following adverse reactions are also discussed in other sections of the label:

• Allergic Reactions [see Warnings and Precautions (5.1)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Adverse Reactions in Patients with Primary Hyperlipidemia and in Patients with Heterozygous Familial Hypercholesterolemia REPATHA is not indicated for use in patients without familial hypercho-

lesterolemia or atherosclerotic CVD [see Indications and Usage (1.1)]. The data described below reflect exposure to REPATHA in 8 placebocontrolled trials that included 2651 patients treated with REPATHA, including 557 exposed for 6 months and 515 exposed for 1 year (median treatment duration of 12 weeks). The mean age of the population was 57 years, 49% of the population were women, 85% White, 6% Black, 8% Asians, and 2% other races.

Adverse Reactions in a 52-Week Controlled Trial

In a 52-week, double-blind, randomized, placebo-controlled trial (Study 2), 599 patients received 420 mg of REPATHA subcutaneously (range: 22 to 75 years), 23% were older than 65 years, 52% women, 80% White, 8% Black, 6% Asian, and 6% Hispanic. Adverse reactions reported in at least 3% of REPATHA-treated patients, and more frequently than in placebo-treated patients in Study 2, are shown in Table 1. Adverse reactions led to discontinuation of treatment in 2.2%of REPATHA-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to REPATHA treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for REPATHA and placebo, respectively).

Table 1. Adverse Reactions Occurring in Greater than or Equal to 3% of REPATHA-treated Patients and More Frequently than with Placebo in Study 2

	Placebo (N=302) %	REPATHA (N=599) %
Nasopharyngitis	9.6	10.5
Upper respiratory tract infection	6.3	9.3
Influenza	6.3	7.5
Back pain	5.6	6.2
Injection site reactions <sup>†</sup>	5.0	5.7
Cough	3.6	4.5
Urinary tract infection	3.6	4.5
Sinusitis	3.0	4.2
Headache	3.6	4.0
Myalgia	3.0	4.0
Dizziness	2.6	3.7
Musculoskeletal pain	3.0	3.3
Hypertension	2.3	3.2
Diarrhea	2.6	3.0
Gastroenteritis	2.0	3.0

#### fincludes ervthema, pain, bruising

Adverse Reactions in Seven Pooled 12-Week Controlled Trials In seven pooled 12-week, double-blind, randomized, placebocontrolled trials, 993 patients received 140 mg of REPATHA subcutaneously every 2 weeks and 1059 patients received 420 mg of REPATHA subcutaneously monthly. The mean age was 57 years (range: 18 to 80 years), 29% were older than 65 years, 49% women, 85% White, 5% Black, 9% Asian, and 5% Hispanic. Adverse reactions reported in at least 1% of REPATHA-treated patients, and more frequently than in placebo-treated patients, are shown in Table 2.

Table 2. Adverse Reactions Occurring in Greater than 1% of REPATHA-treated Patients and More Frequently than with Placebo in Pooled 12-Week Studies

	Placebo (N=1224) %	REPATHA <sup>†</sup> (N=2052) %
Nasopharyngitis	3.9	4.0
Back pain	2.2	2.3
Upper respiratory tract infection	2.0	2.1
Arthralgia	1.6	1.8
Nausea	1.2	1.8
Fatigue	1.0	1.6
Muscle spasms	1.2	1.3
Urinary tract infection	1.2	1.3
Cough	0.7	1.2
Influenza	1.1	1.2
Contusion	0.5	1.0

†140 mg every 2 weeks and 420 mg once monthly combined Adverse Reactions in Eight Pooled Controlled Trials (Seven 12-Week Trials and One 52-Week Trial)

The adverse reactions described below are from a pool of the 52week trial (Study 2) and seven 12-week trials. The mean and median exposure durations of REPATHA in this pool of eight trials were 20 weeks and 12 weeks, respectively.

#### Local Injection Site Reactions

Injection site reactions occurred in 3.2% and 3.0% of REPATHA-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. The proportions of patients who discontinued treatment due to local injection site reactions in REPATHA-treated patients and placebo-treated patients were 0.1% and 0%, respectively

#### Allergic Reactions

Allergic reactions occurred in 5.1% and 4.7% of REPATHA-treated Anlergic reactions occurred in 5.1% and 4.7% of REPATHA-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for REPATHA and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).

#### Neurocoanitive Events

In placebo-controlled trials, neurocognitive events were reported in less than or equal to 0.2% in REPATHA-treated and placebo-treated patients. Low LDL-C Levels

In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1988 patients treated with REPATHA had at least one LDL-C value < 25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and REPATHA dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by REPATHA are unknown.

#### Musculoskeletal Events

Musculoskeletal adverse reactions were reported in 14.3% of REPATHAtreated patients and 12.8% of placebo-treated patients. The most common adverse reactions that occurred at a rate greater than placebo were back pain (3.2% versus 2.9% for REPATHA and placebo, respectively), arthralgia (2.3% versus 2.2%), and myalgia (2.0% versus 1.8%) Adverse Reactions in Patients with Homozygous Familial Hypercholes-

<u>terolemia</u>

In a 12-week, double-blind, randomized, placebo-controlled trial of 49 patients with HoFH (Study 4), 33 patients received 420 mg of REPATHA subcutaneously once monthly [see Clinical Studies (14.3)]. The mean age was 31 years (range: 13 to 57 years), 49% were women, 90% White, 4% Asian, and 6% other. The adverse reactions that occurred in at least two (6.1%) REPATHA-treated patients, and more frequently than in placebo-treated patients, included:

Upper respiratory tract infection (9.1% versus 6.3%)
Influenza (9.1% versus 0%)

Gastroenteritis (6.1% versus 0%)
Nasopharyngitis (6.1% versus 0%)

#### 6.2 Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The immunogenicity of REPATHA has been evaluated using an electrochemiluminescent bridging screening immunoassay for the detection of binding anti-drug antibodies. For patients whose sera tested positive in the screening immunoassay, an in vitro biological assay was performed to detect neutralizing antibodies.

In a pool of placebo- and active-controlled clinical trials, 0.1% of patients treated with at least one dose of REPATHA tested positive for binding antibody development. Patients whose sera tested positive for binding antibodies were further evaluated for neutralizing antibodies; none of the patients tested positive for neutralizing antibodies.

There was no evidence that the presence of anti-drug binding antibodies impacted the pharmacokinetic profile, clinical response, or safety of REPATHA, but the long-term consequences of continuing REPATHA treatment in the presence of anti-drug binding antibodies are unknown.

of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to REPATHA with the incidence of antibodies to other products may be

There are no data available on use of REPATHA in pregnant women to inform a drug-associated risk. In animal reproduction studies, there were no effects on pregnancy or neonatal/infant development when monkeys were subcutaneously administered evolocumab from organogenesis through parturition at dose exposures up to 12 times the exposure at the maximum recommended human dose of 420 mg every month. In a similar study with another drug in the PCSK9 inhibitor antibody class, humoral immune suppression was observed in infant monkeys exposed to that drug in utero at all doses. The exposures where immune suppression occurred in infant monkeys were greater than those expected clinically. No assessment for immune suppression

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was conducted with evolocumab in infant monkeys. Measurable evolocumab serum concentrations were observed in the infant monkeys at birth at comparable levels to maternal serum, indicating that evolocumab. like other IoG antibodies, crosses the placental barrier DA's experience with monoclonal antibodies in humans indicates that they are unlikely to cross the placenta in the first trimester; however, they are likely to cross the placenta in increasing amounts in the second and third trimester. Consider the benefits and risks of REPATHA and possible risks to the fetus before prescribing REPATHA to pregnant women.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

#### Animal Data

Data

In cynomolgus monkeys, no effects on embryo-fetal or postnatal development (up to 6 months of age) were observed when evolocumab was dosed during organogenesis to parturition at 50 mg/kg once every 2 weeks by the subcutaneous route at exposures 30- and 12-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. No test of humoral immunity in infant monkeys was conducted with evolocumab

#### 8.2 Lactation

#### **Risk Summary**

There is no information regarding the presence of evolocumab in human milk, the effects on the breastfed infant, or the effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for REPATHA and any potential adverse effects on the breastfed infant from REPATHA and any the underlying maternal condition. Human IgG is present in human milk, but published data suggest that breast milk antibodies do not enter the neonatal and infant circulation in substantial amounts.

#### 8.4 Pediatric Use

The safety and effectiveness of REPATHA in combination with diet and other LDL-C-lowering therapies in adolescents with HoFH who require additional lowering of LDL-C were established based on data from a 12-week, placebo-controlled trial that included 10 adolescents (ages 13 12-week, placeob-controlled that that included to addresserits (ages 15 to 17 years old) with HoFH [see Clinical Studies (14.3)]. In this trial, 7 addressents received REPATHA 420 mg subcutaneously once monthly and 3 adolescents received placebo. The effect of REPATHA on LDL-C was generally similar to that observed among adult patients with HoFH. Including experience from open-label, uncontrolled studies, a total of 14 addresseries with HoFH have been treated with REPATHA with a median adolescents with HoFH have been treated with REPATHA, with a median exposure duration of 9 months. The safety profile of REPATHA in these adolescents was similar to that described for adult patients with HoFH. The safety and effectiveness of REPATHA have not been established in

pediatric patients with HoFH who are younger than 13 years old The safety and effectiveness of REPATHA have not been established in pediatric patients with primary hyperlipidemia or HeFH.

#### 8.5 Geriatric Use

In controlled studies, 1420 patients treated with REPATHA were  $\geq 65$ years old and 171 were  $\geq 75$  years old. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

#### 8.6 Renal Impairment

No dose adjustment is needed in patients with mild to moderate renal impairment. No data are available in patients with severe renal impairment [*see Clinical Pharmacology (12.3)*].

#### 8.7 Hepatic Impairment

No dose adjustment is needed in patients with mild to moderate hepatic impairment (Child-Pugh A or B). No data are available in patients with severe hepatic impairment [see Clinical Pharmacology (12.3)].

#### 13. NONCLINICAL TOXICOLOGY

**13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility** The carcinogenic potential of evolocumab was evaluated in a lifetime study conducted in the hamster at dose levels of 10, 30, and 100 mg/kg administered every 2 weeks. There were no evolocumab-related tumors at the highest dose at systemic exposures up to 38- and 15-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. The mutagenic potential of evolocumab has not been evaluated, however, monoclonal antibodies are not evened to the DMA or between potential of the set events of the DMA or between potential of the set events of the descent of the two potential of the set events of the descent of the set events of the descent of the descent of the set events of the descent of the desce not expected to alter DNA or chromosomes.

There were no adverse effects on fertility (including estrous cycling, sperm analysis, mating performance, and embryonic development) at the highest dose in a fertility and early embryonic developmental toxicology study in hamsters when evolocumab was subcutaneously administered at 10, 30, and 100 mg/kg every 2 weeks. The highest dose tested corresponds to systemic exposures up to 30- and 12-fold the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. In addition, there were no adverse evolocumab testers of the sector and the sector of the se were no adverse evolocumab-related effects on surrogate markers of fertility (reproductive organ histopathology, menstrual cycling, or sperm parameters) in a 6-month chronic toxicology, mistada dyenny, of spin monkeys subcutaneously administered evolocumab at 3, 30, and 300 mg/kg once weekly. The highest dose tested corresponds to 744- and 300-fold the recommended human doses of 140 mg every 2 weeks and 200 mg areas marthly recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC

**13.2 Animal Toxicology and/or Pharmacology** During a 3-month toxicology study of 10 and 100 mg/kg once every 2 weeks evolocumab in combination with 5 mg/kg once daily rosuvastatin in adult monkeys, there were no effects of evolocumab on the humoral immune response to keyhole limpet hemocyanin (KLH) after 1 to 2 months exposure. The highest dose tested corresponds to exposures 54- and 21-fold higher than the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. Similarly, there were no effects of evolocumab on the humoral immune response to KLH (after 3 to 4 months exposure) in a 6-month study in cynomolgus monkeys at dose levels up to 300 mg/kg once weekly evolocumab corresponding to exposures 744- and 300-fold greater than the recommended human doses of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC.

This Brief Summary is based on the REPATHA® Prescribing Information



RFPATHA® (evolocumab) Manufactured by: Amgen Inc. One Amgen Center Drive Thousand Oaks, California 91320-1799 U.S. License Number 1080 Patent: http://pat.amgen.com/repatha/

The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of semple added to according the methodology and the additional sectors.

### misleading.

#### 8. USE IN SPECIFIC POPULATIONS 8.1 Pregnancy

Risk Summary

### PAID ADVERTISEMENT Who can you help escape high LDL-C? Take the next step at **booth 321**, or today's presentation: Repatha<sup>®</sup>: Take the Next Step\* Repatha<sup>®</sup>: Take the Next Step\* with Irving Loh, MD, FACC, FAHA, FCCP, FACP with Seth J. Baum, MD, FACC, FACPM, FAHA, FNLA, FASPC on Sunday, November 12 from on Sunday, November 12 from 2:00 PM - 2:30 PM at booth 321 12:30 pm - 1:15 pmProduct Theater at booth 2467 Repatha<sup>®</sup> is the #1 prescribed PCSK9 inhibitor<sup>1,†</sup> TAND EXERCIS For adults with clinical ASCVD **HELP YOUR PATIENTS ESCAPE HIGH LDL-C STATIN THERAPY ADD REPATHA® AND** MAXIMIZE LDL-C LOWERING Repatha<sup>®</sup> every 2 weeks + statin delivered UP TO % ADDITIONAL LDL-C REDUCTION compared to placebo + statin<sup>2,3</sup> Results from a 12-week study in patients with ASCVD. At week 12, LDL-C was reduced by the AHA Committee on Scientific Sessions Program.

ASCVD = atherosclerotic cardiovascular disease;

#### Indication

- Repatha® is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).
- The effect of Repatha<sup>®</sup> on cardiovascular morbidity and mortality has been published. Inclusion of the results in the approved labeling is under evaluation with the FDA.

#### Important Safety Information

- Contraindication: Repatha® is contraindicated in patients with a history of a serious hypersensitivity reaction to Repatha<sup>®</sup>.
- Allergic reactions: Hypersensitivity reactions (e.g. rash, urticaria) have been reported in patients treated with Repatha®, including some that led to discontinuation of therapy. If signs or symptoms of serious allergic reactions occur, discontinue treatment with Repatha®, treat according to the standard of care, and monitor until signs and symptoms resolve.
- Adverse reactions: The most common adverse reactions (> 5% of Repatha<sup>®</sup>-treated patients and more common than placebo) were: nasopharyngitis, upper respiratory tract infection, influenza, back pain, and injection site reactions.

In a 52-week trial, adverse reactions led to discontinuation of treatment in 2.2% of Repatha®-treated patients and 1% of placebo-treated patients. The most common adverse reaction that led to Repatha® treatment discontinuation and occurred at a rate greater than placebo was myalgia (0.3% versus 0% for Repatha® and placebo, respectively).

 Adverse reactions from a pool of the 52-week trial and seven 12-week trials: Local injection site reactions occurred in 3.2% and 3.0% of Repatha®-treated and placebo-treated patients, respectively. The most common injection site reactions were erythema, pain, and bruising. The proportions of patients who discontinued treatment due to local injection site reactions in Repatha®-treated patients and placebo-treated patients were 0.1% and 0%, respectively.

Allergic reactions occurred in 5.1% and 4.7% of Repatha®-treated and placebo-treated patients, respectively. The most common allergic reactions were rash (1.0% versus 0.5% for Repatha® and placebo, respectively), eczema (0.4% versus 0.2%), erythema (0.4% versus 0.2%), and urticaria (0.4% versus 0.1%).

Neurocognitive events were reported in less than or equal to 0.2% in Repatha®-treated and placebo-treated patients.

In a pool of placebo- and active-controlled trials, as well as open-label extension studies that followed them, a total of 1,988 patients treated with Repatha® had at least one LDL-C value < 25 mg/dL. Changes to background lipid-altering therapy were not made in response to low LDL-C values, and Repatha® dosing was not modified or interrupted on this basis. Although adverse consequences of very low LDL-C were not identified in these trials, the long-term effects of very low levels of LDL-C induced by Repatha<sup>®</sup> are unknown.

Musculoskeletal adverse reactions were reported in 14.3% of Repatha®-treated patients and 12.8% of placebo-treated patients. The most common adverse reactions that occurred at a rate greater than placebo were back pain (3.2% versus 2.9% for Repatha<sup>®</sup> and placebo, respectively), arthralgia (2.3% versus 2.2%), and myalgia (2.0% versus 1.8%).

• Immunogenicity: Repatha® is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with Repatha<sup>®</sup>.

#### Please see Brief Summary of full Prescribing Information on adjacent page.

References: 1. Data on file, Amgen; 2017. 2. Repatha® (evolocumab) Prescribing Information, Amgen. 3. Data on file, Amgen; 2015.





**AMGEN**° Cardiovascular

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on **maximally tolerated** statin therapy as an adjunct to diet<sup>2</sup>

63% to 77% (mean 71%) with Repatha® 140 mg every 2 weeks + statin more than with placebo + statin. Maximum-dose statins used were atorvastatin 80 mg, rosuvastatin 40 mg, and simvastatin 40 mg.<sup>2,3</sup>

This event is not part of the official Scientific Sessions 2017 as planned

Based on IMS (TRx) data for the period of September 11, 2015 to June 2, 2017.

PCSK9 = proprotein convertase subtilisin/kexin type 9