American Heart Association. life is why™
SCIENTIFIC SESSIONS 2017

DailyNews

SATURDAY, NOVEMBER 11
November 11-15 | Anaheim, California

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7 Partnership awards two $1.5 million grants for extracellular matrix research

AHA grants expanding reach to smaller academic institutions

The AHA Institutional Research Enhancement Award program recently announced its first round of grants to faculty members from 13 academic institutions to support small-scale research projects related to cardiovascular diseases and stroke.


Audrey Vasauskas, PhD

The grant will allow Audrey Vasauskas, PhD, and her students at the Alabama College of Osteopathic Medicine in Dothan to continue their research into the role of FKBP51 in pulmonary arterial hypertension.

"By including students in research projects such as this one, they gain a deeper understanding of evidence-based medicine, which I believe really solidifies their training as future physicians," said Vasauskas, assistant professor of physiology and molecular medicine.

The AHA created AIREA to expose more students to cardiovascular research by extending grants to smaller academic centers that historically receive little government funding.

Vasauskas and her students are investigating the molecular mechanisms involved in the remodeling of pulmonary vessels characteristic of PAH. The research looks at novel cell-signaling pathways that link changes in BMPR2 signaling with transforming growth factor β that may induce the reprogramming of pulmonary artery endothelial cells to a constrictive, occlusive, smooth muscle phenotype.

Pulmonary arterial hypertension is characterized by the disruption of vascular structural integrity leading to arterial remodeling, increased resistance and ultimately death.

"Thus, there is a critical need to better understand the mechanisms underlying

AHA GRANTS continued on page 14

Pivotal research, cutting-edge cardiac science featured at Scientific Sessions

With exciting new offerings, updated and enhanced attendee favorites and even more cutting-edge science, this year's Scientific Sessions features comprehensive programming for cardiovascular basic scientists, researchers and clinicians of all career stages.

"Nearly 18,000 cardiovascular scientists and clinicians from more than 100 countries will share in the opportunity to network, collaborate and learn about the most current science and best practices in cardiovascular medicine," said Eric D. Peterson, MD, MPH, FAHA, chairman of the Committee on Scientific Sessions Program.

To help attendees plan their time and find sessions of interest, the scientific program is organized into three broad educational tracks — Basic Science, Clinical Care and Population Science — encompassing 26 educational "communities" covering the complete spectrum of cardiac science and clinical care. More than 4,000 abstracts will be presented at Sessions, including 33 late-breaking science abstracts covering the most recent results from some of the world's most important clinical trials and registries.

"Beginning Sunday afternoon, these late-breaking science sessions will feature pivotal research results and breakthroughs that will significantly impact the future of clinical practice," Peterson said.

A series of four in-depth Frontiers in Science summits will cover the world's most pioneering research in arrhythmia, thrombosis, stem cells and vascular disease. Another highlight is Monday's featured series of presentations covering

SCIENTIFIC SESSIONS continued on page 14

Partnership increases opportunities for physician-scientists from historically disadvantaged backgrounds

The AHA and the Robert Wood Johnson Foundation's Harold Amos Medical Faculty Development Program are partnering to increase diversity in the fields of cardiology and stroke.

Together, they're providing four-year postdoctoral research awards to physicians from historically disadvantaged backgrounds.

"Our program aims to address the unmet needs of underrepresented minority physician-scientists in academia," said David Wilkes, MD, program director of the AMFDP. "To have a partnership with a highly visible, effective organization such as the AHA helps us expand the mission and vision of the Amos Medical Faculty Development Program."

Award recipients participate in intensive mentoring programs and leadership-development training to help them achieve senior rank in academic medicine, dentistry or nursing. They're also expected to be role models for students and faculty of similar backgrounds.


David Wilkes, MD


Gregory Payne, MD, PhD

"This creates a ripple effect, which will support our 'culture of health' goal into the future," Wilkes said.

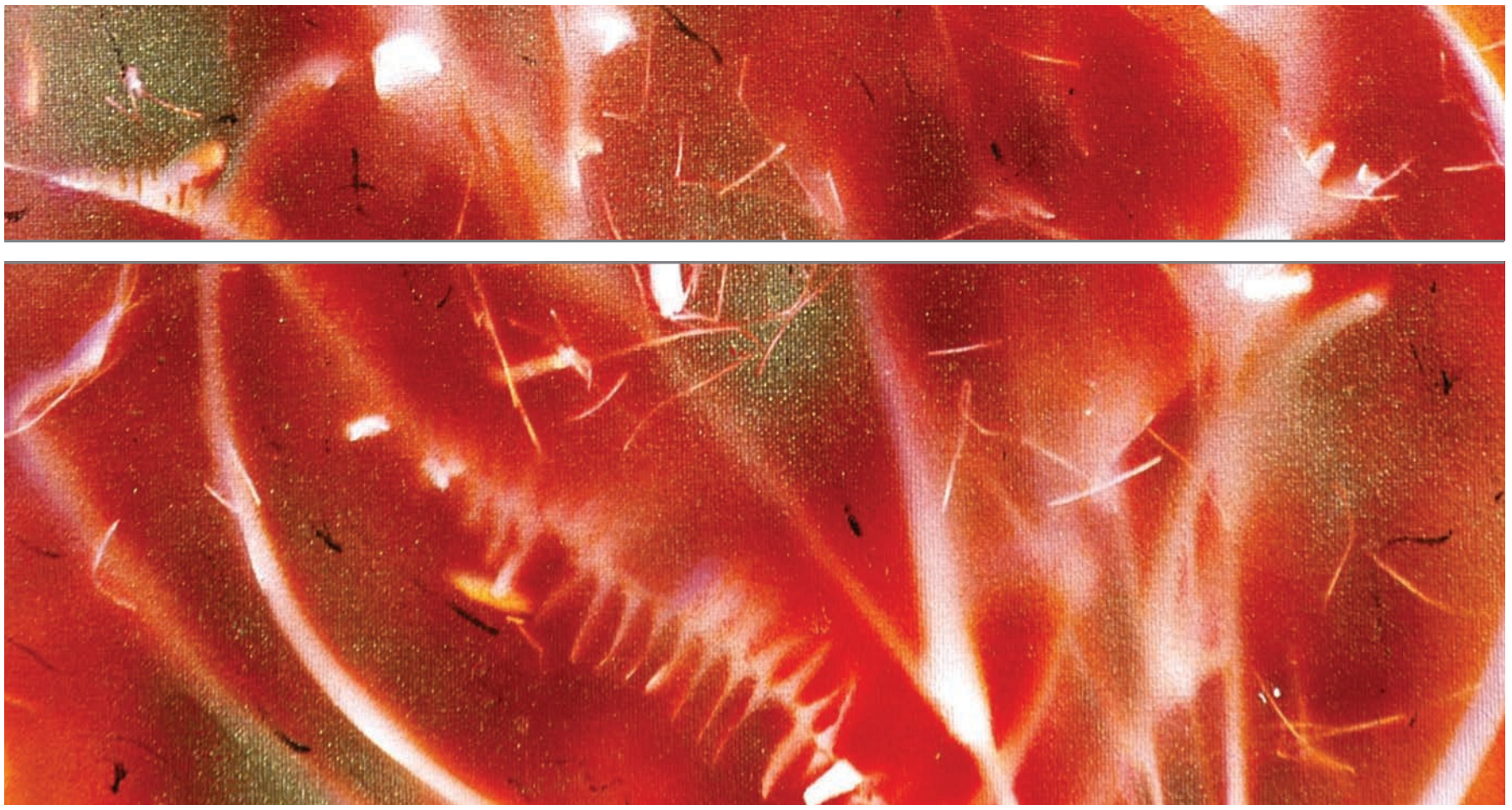
Gregory Payne, MD, PhD, a University of Alabama-Birmingham research fellow studying the extracellular matrix, recently received an AHA-AMFDP award.

"Support from the AHA and AMFDP will provide outstanding financial and professional assistance for my early career development, and I anticipate that it will expose me to some of the most impactful leaders in medicine," Payne said. "I have no doubt this award will accelerate my growth as a physician-scientist and leader in cardiology."

Payne is studying how remodeling of the extracellular matrix contributes to inflammation in several cardiovascular diseases. His research team recently identified a bioactive extracellular matrix fragment that may be a mediator of vascular inflammation and acute cardiac transplant rejection.

"Support from the AHA-AMFDP will allow us to further investigate how these fragments contribute to cardiac transplant graft failure, as well as explore how the ECM may directly contribute to cardiovascular disease," Payne said.

The AHA-AMFDP partnership also funded Marwah Abdalla, MD, MPH, assistant professor of medicine at Columbia University Medical Center in New York. Abdalla is the director of education for the cardiac intensive care unit and a clinical cardiologist in the Center for Behavioral Cardiovascular Health at Columbia University. Her research focuses on cardiovascular manifestations of hypertension. ▼



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HIGHLIGHTS FROM THE PROGRAM CHAIR

By Eric D. Peterson, MD, MPH, FAHA, Committee on Scientific Sessions Program Chair

Eric D. Peterson, MD, MPH, FAHA

Welcome to Anaheim and day one of the 2017 American Heart Association Scientific Sessions. From late-breaking clinical results to hands-on interactive experiences, the Committee on Scientific Sessions Program has assembled a world-class educational program covering the spectrum of basic, clinical and population science.

We'll begin with the Early Career Opening General Session at 9 a.m., then have Early Career Day that features a comprehensive program of specialty science and career development sessions for the up-and-coming generation of cardiac care clinicians and researchers (see schedule below). Each session will be led by experienced educators and mentors.

Reflecting a theme woven throughout Scientific Sessions, the Early Career Day schedule includes several sessions devoted to precision medicine and individualized patient care. At 1 p.m., we'll have the first of the two-part session "Precision Medicine in Cardiovascular and Stroke Nursing." Also at 1 p.m., two sessions will explore the use of big data to deliver precision medicine: "Cutting Edge Methods in Big Data and Beyond" and "Tackling Big Data: Network Systems Analysis for High-Throughput Data Interpretation."

At 3:10 p.m., "Using AHA's Precision Medicine Platform and the Type 2 Diabetes Knowledge Portal to Search and Analyze Data" will introduce early career scientists to the platform and provide a hands-on opportunity to see how it can enhance and expand research capabilities.

The annual Resuscitation Science Symposium also begins today. This three-day program brings together resuscitation clinicians and researchers from around the world to exchange ideas and learn about the most recent advances in resuscitation science.

Today's ReSS highlights include presentations of the Lifetime Achievement Award in Cardiac Resuscitation Science, the Lifetime Achievement Award in Trauma Resuscitation Science and the Ian G. Jacobs Award for International Group Collaboration to Advance Resuscitation Science. All three will be presented at 9:30 a.m. in rooms 154-158, ACC North. The best oral abstract presentations and the Best Abstract Awards for Cardiac and Trauma Resuscitation Science will follow at 10:30 a.m.

This is just a sampling of what's happening today — and a taste of what's in store over the next five days. No matter your specialty, area of interest or career level, this year's program has a lot to advance your scientific knowledge and improve your clinical practice.

Download the Mobile Meeting Guide to your phone or tablet or check the Scientific Sessions Program Book to get the most up-to-date information on all the great sessions, events and activities this week. ▼

EARLY CAREER PROGRAM SATURDAY, NOV. 11

SESSION NUMBER	SESSION TITLE	LOCATION	TIME
AHA.EC.01	Early Career Opening General Session: Transitions	Ballroom B	9 a.m.-Noon
CLCD.EC.01	Launch your Cardiology Career: Pearls from the Mentors	Ballroom B	1-2 p.m.
CVSA.EC.01	CVSA Part 1: What is the Future of Cardiac Surgery?	207D	1-2:15 p.m.
CVSN.EC.01	Precision Medicine in Cardiovascular and Stroke Nursing	207C	1-2:40 p.m.
ATVB.EC.01	BCVS/ATVB Joint Early Career Programming	253AB	1-3 p.m.
EQL.EC.01	Cutting Edge Methods in Big Data and Beyond	213A	1-3 p.m.
FGTB.EC.01	Tackling Big Data: Network Systems Analysis for High-Throughput Data Interpretation	304CD	1-3 p.m.
CVDY.EC.01	Innovations in Pediatric Cardiology	202AB	1-4 p.m.
CVRI.EC.01	CVRI Imaging Boot Camp	304AB	1-5 p.m.
CLCD.EC.02	Considering Electrophysiology as a Specialty	204C	2:15-3 p.m.
CVSA.EC.02	CVSA Part 2: Tips for Early Career Surgeons: What You Do Not Learn in Residency	207D	2:30-3:30 p.m.
3CPR.EC.01	Emerging Science from the 3CPR Early Career Committee	210C	3-5 p.m.
CVSN.EC.02	Precision Medicine in Cardiovascular and Stroke Nursing: Part 2	207C	3-5 p.m.
FGTB.EC.02	Using AHA's Precision Medicine Platform and the Type 2 Diabetes Knowledge Portal to Search and Analyze Data	304CD	3:10-5:10 p.m.
CLCD.EC.03	How I Got Here: A Panel Discussion on the Different Types of EP Career Options	204C	3:15-4:30 p.m.
ATVB.EC.02	BCVS/ATVB Joint Early Career Programming: Part 2	253AB	3:15-5 p.m.
EQL.EC.02	Cutting Edge Methods in Big Data and Beyond: Part 2	213A	3:15-5 p.m.
CVSA.EC.03	CVSA Part 3: The Surgeon Scientist is Very Much Alive	207D	3:45-5 p.m.
CLCD.EC.04	Early Career EP Clinical Session	204C	4:15-6:15 p.m.

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.**

8:15-9:30 a.m.
Outcomes of Cardiac Arrest Survivors with ICDs
Rooms 154-158, ACC North

9:30-10:15 a.m.
2017 Awards for Lifetime Achievement in Cardiac Resuscitation Science and Trauma Resuscitation Science, and Presentation of the Ian G. Jacobs Award for International Group Collaboration to Advance Resuscitation Science
Rooms 154-158, ACC North

10:30-11:45 a.m.
ReSS Best Oral Abstract Presentations and Presentation of the Best Abstract Awards for Cardiac and Trauma Resuscitation Science
Rooms 154-158, ACC North

1:15-2:45 p.m.
ReSS Poster Session
Rooms 155-159, ACC North

2-3:15 p.m.
Samuel A. Levine Young Clinical Investigator Award Competition
Ballroom B, 3rd Level, Main Building

2:45-4 p.m.
Prognostication After Resuscitation
Rooms 155-158, ACC North

3:45-5 p.m.
Laennec Young Clinician Award Competition
Ballroom B, 3rd Level, Main Building

4:30-5:30 p.m.
Late-Breaking Resuscitation Science Session
Rooms 155-158, ACC North

HEARTY HUMOR by Jonny Hawkins

"The surgery shouldn't be any problem. I've seen it done once."

SCIENTIFIC SESSIONS BY THE NUMBERS

5 days of unparalleled learning

2 Million medical professionals participating virtually via live streaming

17,000 attendees including **6,200** international attendees from more than **100** countries

More Than **5,000** presentations from the world's leaders in cardiovascular science

26 educational communities divided into basic, clinical and population programming

More than **200** exhibitors showcasing the latest cardiovascular technology and resources

40 international joint sessions with **41** countries participating

Research grant is catalyst for nutritional investigator's involvement with AHA

An AHA Scientist in Development grant in 2004 did more than provide critical funding for Marie-Pierre St-Onge, PhD — it was a stepping stone for her career and the evolution of her involvement with the AHA.

"It seems like the AHA has been there for me at all the major transitions of my career, and I am very grateful for their support," said St-Onge, who was transitioning from a post-doctoral fellow to an assistant professor when she received her first AHA grant.

Today, St-Onge co-directs the AHA's Go Red For Women Strategically Focused Research Network Center, where she's a principal investigator for an SFRN grant she received in 2016.

She's also been involved with the AHA in numerous other ways, including as chair of the Communications and Membership Committee and as a member of the Obesity Committee for the Council on Lifestyle and Cardiometabolic Health.

She currently serves on the council's Nutrition and the Spring Meeting Planning committees and was recently appointed to the Science Advisory and Coordinating Committee.

"I thoroughly enjoy being an active member of my council and volunteering in council committees as well as at the national level," said St-Onge, associate professor of nutritional medicine at Columbia University Medical Center in New York.

St-Onge, who joined the AHA in 2003 to present her doctoral research findings at Scientific Sessions, said getting involved on an AHA scientific council has not only helped her career trajectory, but it's also been enjoyable.

"I love being involved in cutting-edge research and science and having a role in disseminating scientific knowledge to the medical community and the general public," she said. "Being an active council member provides opportunities to interact with scientists of varied backgrounds — all working towards a common goal to understand, prevent, treat and manage heart disease.

"Thanks to the AHA, I've worked with great people I never would have worked with otherwise. To advance in academia, you have to have a broad network that extends beyond your institution. Getting involved in the AHA helps you to expand your network and gain exposure for your research."

St-Onge encourages new and early career members to attend career activities and speak to more senior members during Scientific Sessions.

"Getting involved is easy," she said. "In my experience, the AHA — and the Council on Lifestyle and Cardiometabolic Health in particular — is full of friendly individuals who are easily approachable."

In addition to continuing to participate on her council, St-Onge said she plans to support efforts to give back to the association.

"Since receiving my SFRN award, I've recognized how much work goes into raising money to support research," she said. "My group makes an active effort to give back to the AHA and to assist in fundraising in any way possible. I have participated in events at my AHA affiliate that have given me a new appreciation and understanding of the AHA's efforts to support and advocate for heart disease research." ▼

Claiming CME/CE at Scientific Sessions

Healthcare professionals attending Scientific Sessions can claim and print CME/CE certificates when they have attended all of the sessions for the meeting. **Physicians, nurses and EMS must claim credit by May 15, 2018. Pharmacists must claim credit by Dec. 15, 2017. ABIM MOC credit is available and must be claimed by Dec. 15, 2017.**

1. Go to **learn.heart.org**.
2. Click "Activities in Progress" in the left-hand navigation. You will be prompted to sign in using your American Heart Association username and password. You can create an account if you don't have one.
3. Review the "Activity Overview and "Activity Material" tabs.
4. Complete the evaluation.
5. Claim your credit(s).

International attendees can obtain their attendance verification certificate at the registration center. For a full list of conference accreditation statements and credit hours, visit **scientificsessions.org**.

Seminar focuses on delivery of care by general practitioners

A full-day seminar Saturday will review the latest advances in clinical cardiovascular care for primary care physicians, nurses and other general practitioners.

The "State of the Art Cardiovascular Care 2017," which begins at 9:30 a.m. in Ballroom A, 3rd Level (Main Building), will cover a wide range of topics, including cardiovascular screening of asymptomatic patients, atrial fibrillation, hypertension, heart failure, dyslipidemia, diabetes and metabolic syndrome, and genetics and pharmacogenomics.

"We developed this seminar in response to feedback we received from Scientific Sessions attendees looking for more programming geared toward internists, family medicine physicians and nurses, who are often the front-line providers for patients with cardiovascular disease," said Kiran Musunuru, MD, PhD, MPH, chair of the committee that planned the seminar. "The goal is to provide general practitioners with the most current information on diagnosis, treatment and prevention."

The seminar will include a discussion of evidence-based cardiovascular therapies for patients with diabetes or metabolic syndrome. Previous generations of medications were either effective for diabetes but didn't affect cardiovascular risk, or treated diabetes successfully but increased cardiovascular risk, Musunuru said. However, several large studies in the past few years evaluated drugs found to reduce cardiovascular risk in patients with diabetes.

"Those are some relatively new findings that the general practitioner may not be very familiar with yet," said Musunuru, assistant professor of stem cell and regenerative biology at Harvard University and associate physician at Brigham and Women's Hospital in Boston.

The seminar includes two AF presentations focusing on emerging research findings that can be applied to patients now, he said.

The first will review initial treatment considerations and provide tips for primary care providers for patients when they are first diagnosed with AF. The second talk will review more advanced forms of the disease, including recommendations for referring to a cardiologist or cardiac electrophysiologist.


Kiran Musunuru, MD, PhD, MPH

The seminar will be videotaped and available as an online course with self-assessment material.

"Our hope is that this seminar will become an annual event and set the stage for additional future programming at Scientific Sessions directed toward general practitioners," Musunuru said. ▼

GENE EXPRESSION ANALYSIS OF SMOKING, ASPIRIN AND CV RISK

Using a cohort of the PREDICT Trial, researchers examined whether gene expression levels associated with the biological effects of smoking and aspirin were associated with an increased risk of cardiovascular events.

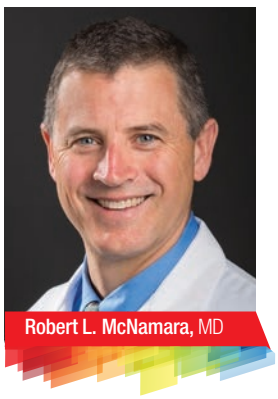
The study's results will be presented on poster board 1230 during an abstract poster session at 3:15 p.m. Sunday in the Science and Technology Hall.

Pennsylvania hospital becomes first accredited Cardiovascular Center of Excellence

The nation's first hospital to achieve accreditation under a new AHA and American College of Cardiology program was announced in September.

Commonwealth Health Regional Hospital of Scranton in Pennsylvania was designated a Cardiovascular Center of Excellence for integrating evidence-based science, quality initiatives, clinical best practices, patient-centered care and the latest ACC/AHA guidelines into its cardiovascular care processes.

Hospitals must achieve coordination of care in at least three of four accreditation areas developed by the ACC — chest pain, atrial fibrillation, heart failure and cardiac catheterization services — to receive accreditation.


Robert L. McNamara, MD

"The AHA and ACC have been dedicated to improving cardiovascular health and cardiovascular care for decades — both as individual organizations and collaboratively," said Robert L. McNamara, MD, chair of the AHA Hospital Accreditation Cardiovascular Subcommittee and associate professor of medicine at Yale School of Medicine in New Haven, Connecticut. "The new Cardiovascular Center of Excellence designation will help further those efforts."

Accredited hospitals must be equipped to meet the care needs — diagnosis, treatment, rehabilitation, support and education — of the most complex cardiac patients in the hospital and beyond. The key, McNamara said, is for hospitals to coordinate high-quality care from an institutional standpoint.

Commonwealth Health Regional Hospital of Scranton showed that it met the accreditation criteria after a thorough evaluation of the facility's multidisciplinary teams and processes.

"The staff at Scranton displayed a commitment to work with all levels of the community to emphasize cardiovascular disease prevention, early recognition and treatment, and rehabilitation for an improved quality of life," McNamara said. "Having accredited hospitals equipped to collaborate with their communities to address the needs of patients with life-threatening heart conditions is key to improving quality of life and survival for all patients."

For more information, visit **heart.org/cardiacaccreditation.** ▼

10 Years of Mission: Lifeline

Launched by the American Heart Association in 2007, the Mission: Lifeline program continues to improve care for patients experiencing heart attack, cardiac arrest and stroke. These high-risk, time-sensitive emergencies require high-quality care at every link in the chain of survival. Mission: Lifeline works to ensure there are no weak links.

The program has grown from focusing on a single type of deadly heart attack and rural areas to a broader focus nationwide, including major metro areas. About 800 hospitals were honored this year for meeting various standards of excellence — up from 77 in 2010, the first year of the award program. Some of the program's accomplishments include:

- Faster response times for certain types of lifesaving care
- More than 85 percent of the country is now covered under the system of care for ST segment elevation myocardial infarction, or STEMI, an often-deadly heart attack the program initially targeted.
- Expansion into highly populated cities, including New York, Philadelphia, Atlanta and Seattle

DailyNews

The American Heart Association's Scientific Sessions 2017 *Daily News* is published by TriStar Publishing, Inc., as a service to American Heart Association Scientific Sessions attendees.

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Partnership awards two $1.5 million grants for extracellular matrix research


Suneel Apte, MB, BS


Jeffrey Holmes, MD, PhD

The AHA and the Paul G. Allen Frontiers Group have awarded two $1.5 million grants to study the extracellular matrix.

The grants will help investigators uncover the next breakthrough in heart-health research by studying the role the ECM may play in everything from tissue repair to cell-to-cell communication.

The 2017 AHA-Allen Distinguished Investigators are Suneel Apte, MB, BS, a researcher at the Lerner Research Institute at the Cleveland Clinic in Ohio, and Jeffrey Holmes, MD, PhD, professor of biomedical engineering and founding director of the Center for Engineering in Medicine at the University of Virginia in Charlottesville.

"Given that cardiovascular disease remains an unsolved mystery and a tremendous burden to society, we were pleased to work with the world's leading heart association to hopefully solve this difficult problem," said Tom Skalak, PhD, executive director of the Paul G. Allen Frontiers Group in Seattle, Washington.

"The AHA shares our passion for exploring new territory in science. In funding these two AHA-Allen Distinguished Investigators, we believe that the information content of the extracellular matrix can be decoded and used to define new therapies and heart-health measures."

Apte's research is focused on a class of enzymes called proteases that work like molecule scissors to remodel the extracellular matrix.

"That kind of activity is not visible on the surface or in a snapshot," Apte said. "We have to dig deep for it, but it is important because cutting ECM molecules affects their function in a significant way."

Apte and his team will define the extensive ECM remodeling that occurs by cataloging as many cut molecules in the heart and blood vessels as possible. They will also delete a protease and track changes in the extracellular matrix.

"This is truly fundamental knowledge with considerable potential for treating human disease," Apte said. "That's why the commitment to studying the ECM by the AHA and the Allen Group is important. This is an unexplored frontier that needs to attract greater awareness, more scientists and increased funding. This grant allows us to embark on ambitious projects that might not have been readily supported by other initiatives or agencies."

Holmes' research was inspired by the realization that the extracellular matrix turns over much more slowly than the cells that inhabit it or their parts. For example, the half-life of the actin and myosin in a myocyte is about one week, but collagen and elastin can last an entire lifetime.

"We think the implication of this simple fact is that much of the information about long-term processes such as aging is stored in the extracellular matrix and read back by cells to help direct their behavior," Holmes said. "Our goal is to image this turnover in both space and time, so we can watch cells deposit and modify the ECM, and then see how other cells access that information."

Holmes is studying heart mechanics, growth and remodeling. He is particularly interested in the scar that forms after a heart attack.

"Our work has led us into modeling and measuring extracellular matrix turnover in the heart and made us appreciate how important the cardiac extracellular matrix is for nearly everything that happens in normal heart development as well as in disease," he said.

"The most exciting thing about the AHA-Allen partnership is that they asked us to think big — to propose something truly novel even if it's risky. An opportunity to take a big leap instead of a single step is not only valuable, it's fun." ▼

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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Welcome, New 2017 American Heart Association Fellows

As a Fellow of the American Heart Association/ American Stroke Association, you are a part of one of the world's most eminent organizations of cardiovascular and stroke professionals. The American Heart Association recognizes your scientific and professional accomplishments and volunteer leadership and service.

Fellows, stop by the FAHA Lounge, located in Hall D, Level 1 to relax, network and recharge.

Stop by if you are interested in Fellowship!

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Waimei A. Tai, MD FAHA
Takenori Yamaguchi, MD PhD FAHA

Innovation, new editors highlight scientific journals' year

Editor-in-chief announcements and the launch of an innovative issue and article summary formats marked another remarkable year for the American Heart Association/American Stroke Association scientific journals. Here's a review of the top achievements and a look at what's in store:

EDITOR-IN-CHIEF TRANSITIONS AND CELEBRATIONS

On July 1, Nancy K. Sweitzer, MD, PhD, began her tenure as editor-in-chief of *Circulation: Heart Failure*, and Paul J. Wang, MD, as editor-in-chief of *Circulation: Arrhythmia and Electrophysiology*. Kiran Musunuru, MD, PhD, MPH, will become editor-in-chief of *Circulation: Genomic and Precision Medicine* (currently *Circulation: Cardiovascular Genetics*) on Jan. 1, 2018.

Joseph A. Hill, MD, PhD, celebrated his first anniversary as editor-in-chief of *Circulation* in July. Hill has continued the journal's legacy of excellence, while enhancing it with more editorials with unique perspectives and "On My Mind" essays on hot topics.

JOURNALS ON THE GO

"*Circulation* on the Run," the weekly *Circulation* podcast series, celebrated its first anniversary in July. Downloads of the journal podcast series exceeded 60,000 within the year. In addition, "*Circulation: Arrhythmia and Electrophysiology* on the Beat" launched this year. Subscribe to each podcast on iTunes and Google Play.

Visual abstracts for at-a-glance understanding of key articles are included in *Arteriosclerosis, Thrombosis, and Vascular Biology (ATVB), Circulation: Arrhythmia and Electrophysiology,* and *Circulation: Cardiovascular Quality and Outcomes*.

IN-DEPTH LEARNING

Circulation Research published three new compendia, collections of themed articles offering a comprehensive assessment of a cardiovascular disease or pathological condition. The 2017 issues include "Cardiomyopathy," edited by Eugene Braunwald; "Congenital Heart Disease," edited by Ali J. Marian; and "Stroke" edited by Marc Fisher, Costantino Iadecola and Ralph Sacco.

▶ http://circres.ahajournals.org/content/circulation-research-compendia

Clinical cases, presented during *Hypertension* Clinical-Pathological Conferences and hosted at meetings around the world in 2014-17, are available to watch online. Each video includes an expert panel discussion with *Hypertension* editors.

▶ http://hyper.ahajournals.org/content/clinical-pathological-conferences

SCIENTIFIC STATEMENTS AND CLINICAL PRACTICE GUIDELINES

Updated guidelines for managing heart failure and syncope were among 45 scientific statements and clinical practice guidelines published in fiscal year 2016-17. Download the AHA/ASA's mobile app "AHA Guidelines On-The-Go" and enjoy the benefits of staying up to date.

▶ http://professional.heart.org/statements

NEW CURATED ISSUE OF TOP-TRENDING ARTICLES

The most talked-about articles were published in the third issue of the *AHA/ASA Journals' Trend Watch*. Pick up a copy at AHA HeartQuarters (booth 355), Wolters Kluwer (booth 439) or Wiley (booth 545). Current and pass issues can be accessed online and feature 450-plus freely available articles.

▶ www.ahajournals.org/content/trend-watch

COMING IN 2018

The *JAHA – Journal of the American Heart Association* will be published twice monthly. As the AHA/ASA's online-only Open Access journal, all content is free to read, download and share.

▶ http://jaha.ahajournals.org

One Brave Idea settles into new home

With four pairs of oversized gold scissors snipping a wide red ribbon, the One Brave Idea Science Innovation Center officially opened for business in Boston.

That business: Finding a new way to solve the age-old problem of heart disease.

One Brave Idea is a $75 million research enterprise that is attacking the No. 1 killer in the world in ways that haven't been tried. The project itself is a bit of an experiment because of how much it upends the typical formula for scientific research.

Instead of giving a smaller amount of money for one institution to seek incremental progress, the AHA, Verily and biopharmaceutical company AstraZeneca each contributed $25 million and their other vast resources to support a team of specialists from various backgrounds and institutions. The team is led by Calum MacRae, MD, PhD, and guided by his overarching vision.

MacRae's vision is essentially creating an "early warning system." He wants to figure out the causes of heart disease long before any symptoms appear. While that may seem like prevention, he considers it a precursor to that.

"What we're really doing is moving from prevention back to that boundary of where heart disease first develops," said MacRae, chief of cardiovascular medicine at Brigham and Women's Hospital in Boston. "If we can identify those first transitions, we can maintain wellness longer."

MacRae is eager to examine areas, such as the skin, that scientists have never considered as possible clues to heart problems. He's also using new tools, ranging from those his team creates to those that exist but have never been used to study cardiovascular diseases.

"We look at One Brave Idea almost like a startup company," said Nancy Brown, CEO of the AHA and chair of One Brave Idea's oversight committee. "It's really helping us at this critical intersection of technology and science to find cures for patients and hope for families."

One Brave Idea experiments are already under way at clinics and labs around Boston and across North America. Think of those locations as the spokes of a wheel and the Science Innovation Center as the hub.

The Innovation Center, located on the seventh floor of the Longwood Center, opened Oct. 3. The state-of-the-art life sciences building in Boston's medical research area has a unique vibe to it, a sense that Verily CEO Andy Conrad described as being "Google-esque."

"There's an energy here you can just feel," said Greg Keenan, AstraZeneca's U.S. Head Medical Officer and a member of the project's oversight committee. "This space actually represents the innovative nature that One Brave Idea is in general."

MacRae, Chief Scientific Officer Stan Shaw and others have offices at the headquarters. There are a variety of conference rooms and workspaces of all sizes.

"This center provides an opportunity for the scientists, researchers, young investigators, mathematicians and data scientists who are all working together to find an end to coronary heart disease to have a single location where they can collaborate, while also recognizing and appreciating the virtual nature of the team," Brown said.

MacRae had been thinking about an early warning system for years, but doubted he'd have a chance to explore it – mainly because of how different it is from traditional research. Then the One Brave Idea initiative was announced during Scientific Sessions in November 2015.

Last summer, MacRae was picked over 348 other applicants and immediately went to work.

He built a team of scientists, mathematicians, engineers and even a venture capitalist. They came up with all sorts of pilot projects and went into them with the technology world's approach of being willing to fail fast and move on to the next-best thing. Three of these projects were showcased at the opening of the One Brave Idea Science Innovation Center.

AHA CEO Nancy Brown (in red), Greg Keenan of AstraZeneca, Andy Conrad of Verily and One Brave Idea leader Calum MacRae cut the ribbon on the One Brave Idea Science Innovation Center.

The AHA's $25 million investment is its largest in a single science project in the organization's 93-year history. The organization has spent more than $4.1 billion on research, including more than $100 million annually since 1996. ▼

2017 Unofficial Satellite Events

Saturday, Nov. 11

10 a.m.-2 p.m.
Industry-supported Symposium
Improving Health Care Access for Minority and High Risk Populations
Sponsored by Association of Black of Cardiologists
Supported by Amgen Inc.
Anaheim Marriott
Registration: www.abcardio.org

6:30-9 p.m.
Nonprofit Symposium
What a Clinician Needs to Know About Diagnosis & Management of Heart Disease in Women
Sponsored by Washington University School of Medicine, Continuing Medical Education
Supported by Washington University and Barnes-Jewish Heart & Vascular Center
Hilton Anaheim, 2nd Floor, Pacific Ballroom
Registration: barnesjewish.org/anaheim2017

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

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

SATELLITE EVENTS continued on next page

Scientific statement raises concerns about CV health of African-Americans

While heart disease and stroke — and deaths from those diseases — have declined in the United States in recent decades, those advances have not been shared equally in the African-American community. A panel of experts has been trying to find out why.

The result is a new American Heart Association scientific statement about cardiovascular health in African-Americans that examines the challenges and proposes solutions.

"We still see higher rates of heart disease and risk factors such as obesity, high blood pressure and diabetes in African-Americans as compared to whites, and higher death rates from heart attack and stroke," said Mercedes Carnethon, PhD, associate professor of preventive medicine at Northwestern University's Feinberg School of Medicine and chair of the group that wrote the new statement. "We thought it was important to pull together all the information."

The scientific statement points to cardiovascular disease as a prime cause of the gap between expected life spans of blacks and whites — more than three years for both men and women — and identifies a number of factors for the continuing disparity. The first, Carnethon said, transcends race.

"What we see for all ethnic groups is notable differences by socioeconomic status," she said. "High socioeconomic status provides access to health-promoting resources, access to a culture that promotes the ability to make healthy lifestyle choices, access to healthy foods and exercise, even the ability to prioritize good sleep."

But even among different groups at the same economic level, she said, African-Americans lag behind. "We've got the information, we've got better therapies than ever," she said. "So why aren't they either received by all people or as effective?"

Age, the statement said, is one key. Many African-Americans are developing risk factors, particularly obesity, earlier in life, which leads to high blood pressure and diabetes — and subsequently heart attacks and strokes — at younger ages than other groups.

High rates of hypertension and less effective disease management are major contributors to the disparity, according to the report, as are the disadvantages of living in poor, underserved neighborhoods.

"The takeaway is we still face a significant problem," Carnethon said. "We need to find ways to create a culture of health in the African-American community and prioritize a healthy lifestyle to prevent heart disease."

To accomplish that, the scientific statement highlights the need for progress at every level of healthcare, from individuals to healthcare providers to policymakers. Among the recommendations is to invest in environments that promote healthy lifestyles, such as safe spaces for physical activity and supermarkets offering affordable, nutritious food that are often lacking in poorer neighborhoods.

Also advised in the scientific statement are programs that promote healthy diets and lifestyles, particularly through churches and other faith-based institutions, to raise awareness of cardiovascular risk factors and the need to lower them. Increased funding of medical research to help tailor treatment to African-Americans is also recommended, as are efforts to create a more diverse workforce in healthcare to enhance trust in the medical community.

"This is a call to action," said Ivor Benjamin, MD, director of the Medical College of Wisconsin's Cardiovascular Center and president-elect of the AHA.

"It recognizes the complexity of the problem," he said. "It's not just about patients and healthcare providers. It's about the public health system. It's about the whole community, local health departments and legislatures. All of them should be actively engaged in improving cardiovascular health." ▼

SATELLITE EVENTS

continued from page 12

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

SCIENTIFIC SESSIONS continued from page 1

the latest innovations in digital healthcare solutions and health information technology.

Perhaps the most anticipated event of the meeting is the release of the 2017 Hypertension Clinical Practice Guidelines. A variety of user-friendly sessions will follow the release of the guidelines Monday afternoon.

"These sessions will feature experts who will discuss the scope of the guidelines and how they should impact current clinical care," Peterson said.

Recognizing the growing emphasis on individualized care, Monday's Precision Medicine Summit will feature sessions focusing on big data initiatives, "omics" research and technologies, and improving diagnostic precision in cardiomyopathies and heart failure. Scientific Sessions attendees can also learn about the AHA Institute for Precision Cardiovascular Medicine at the Recharge Institute Lounge. Located in Hall D, the lounge features daily demonstrations of AHA's Precision Medicine Platform and My Research Legacy.

A symposium celebrating the 50th year of the Fogarty International Center will be held Tuesday afternoon. "Fogarty, NHLBI, NIH and the Future of Global Cardiovascular Health Research" will showcase programs that promote the global health agenda into the 21st century.

As always, the main Science and Technology Hall is where all of the latest products, tools and technologies in cardiac care are on display. The Science and Technology Hall will also be home to the Scientific Sessions poster area, which Peterson noted is always "a great place to meet and network with colleagues, and also ask questions and interact with the poster presenters."

The Science and Technology Hall opens at 11 a.m. Sunday in Hall ABC.

With so many sessions, events and activities to choose from, Peterson encouraged attendees to download the Scientific Sessions Mobile Meeting Guide for the most up-to-date meeting news, session schedules, city information and more. The mobile app is available at **scientificsessions.org/mobile.**

Also check out page 3 in each issue of the *Daily News*, where Peterson will highlight some of the day's top sessions and activities. ▼

AHA GRANTS continued from page 1

cellular alterations that lead to the eventual occlusion of vessels," Vasauskas said.

Vasauskas' research is a perfect example of how the AIREA program is helping the AHA connect with the next generation of physicians and researchers, said AHA Immediate Past-President Steven R. Houser, PhD, FAHA.


Steven R. Houser, PhD, FAHA

"It will take some time to see the results of the research we're funding, but we've already seen how the program has expanded our outreach," said Houser, director of the Cardiovascular Research Center at Temple University in Philadelphia. "We've reached into areas of the country we haven't been before. Some of the best and brightest students are at these schools, and we need to carry our message to them."

Houser, who trained at a small university that didn't have a lot of "big-time research," still found his way to cardiovascular science. He said the AHA wants to make sure that folks at smaller institutions don't have to rely on luck.

"A lot of great fundamental biology is taking place at small schools," he said. "The next cardiovascular or stroke scientist who makes a great impact on health may be at a small institution as we speak." ▼

2017 AIREA Recipients

Role of TRIM65 E3 Ligase in Endothelial Activation
Mingui Fu, PhD
University of Missouri, Kansas City

The Renal Cholinergic System and the AKI-CKD Nexus
Aaron Polichnowski, PhD
East Tennessee State University, Johnson City

Reelin Signaling in Coronary Vessel Formation
Cathy J. Hatcher, PhD
Philadelphia College of Osteopathic Medicine, Pa.

Impact of Clinical Mutations on Assembly of the NADH-module of Complex I
Steven B. Vik, PhD
Southern Methodist University, Dallas

Formation of a G-quadruplex Repair Complex by FANCJ and REV1: Toward Better Cardiovascular Health Through DNA Repair
Colin Wu, PhD
Oakland University, Rochester, Mich.

Volumetric Assessment of Epicardial Adipose Tissue Using Echocardiography
Jon Klingensmith, PhD
Southern Illinois University, Edwardsville

The Role of Osteopontin in Promoting West Nile Virus Neuroinvasion
Fengwei Bai, PhD
University of Southern Mississippi, Hattiesburg

The Role of FKBP51 in Pulmonary Arterial Hypertension
Audrey Vasauskas, PhD
Alabama College of Osteopathic Medicine, Dothan

Early Life Programming by Omega-3 Fatty Acids in Obesity-Associated Inflammation
Latha Ramalingam, PhD
Texas Tech University, Lubbock

Mas Receptor: A Target for Bone Marrow Mobilopathy and Vascular Repair in Diabetes
Yagna Jarajapu, PharmD, PhD
North Dakota State University, Fargo

A New Image-guided Approach for Cardiac Resynchronization Therapy
Weihua Zhou, PhD
University of Southern Mississippi, Hattiesburg

Cofilin and Inflammation after Hemorrhagic Brain Injury
Zahoor Shah, PhD
University of Toledo Health Science Campus, Ohio

Mitral Valve Tissue Engineering
Agneta Simionescu, PhD
Clemson University, Clemson, S.C.

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 hypercholesterolemia or atherosclerotic CVD [*see Indications and Usage (1.1)*].

The data described below reflect exposure to REPATHA in 8 placebo-controlled 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 once monthly [*see Clinical Studies (14.1)*]. The mean age was 56 years (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†	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

†includes erythema, pain, bruising

Adverse Reactions in Seven Pooled 12-Week Controlled Trials

In seven pooled 12-week, double-blind, randomized, placebo-controlled 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† (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 52-week 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 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

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 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 and placebo, respectively), arthralgia (2.3% versus 2.2%), and myalgia (2.0% versus 1.8%).

Adverse Reactions in Patients with Homozygous Familial Hypercholesterolemia

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.

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 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 misleading.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

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 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 IgG antibodies, crosses the placental barrier. FDA'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.

Data

Animal 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 or from 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 to 17 years old) with HoFH [*see Clinical Studies (14.3)*]. In this trial, 7 adolescents 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 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 ≥ 65 years old and 171 were ≥ 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 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-related effects on surrogate markers of fertility (reproductive organ histopathology, menstrual cycling, or sperm parameters) in a 6-month chronic toxicology study in sexually mature 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 420 mg once monthly, respectively, based on plasma AUC.

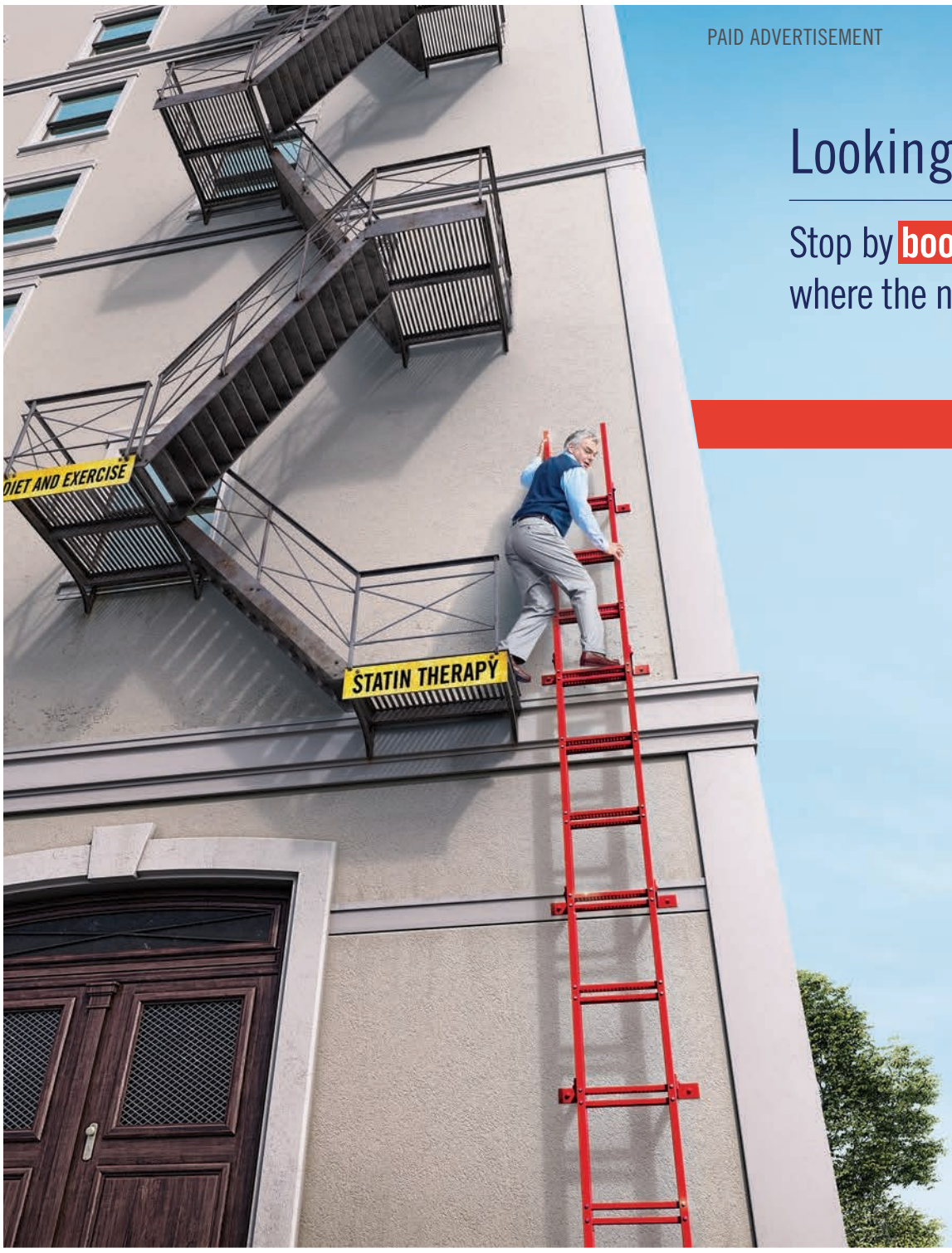
13.2 Animal Toxicology and/or Pharmacology

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 v3, 07/16

AMGEN®

REPATHA® (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/



Looking for an escape?

Stop by **booth 321** and play *CholesterBall* where the name of the game is: aim low!

Repatha® is the #1 prescribed PCSK9 inhibitor[1,*]

For adults with clinical ASCVD
on **maximally tolerated** statin therapy as an adjunct to diet[2]

HELP YOUR PATIENTS ESCAPE HIGH LDL-C

ADD REPATHA® AND MAXIMIZE LDL-C LOWERING

Repatha® every 2 weeks + statin delivered
UP TO **77%** **ADDITIONAL LDL-C REDUCTION**
compared to placebo + statin[2,3]

Results from a 12-week study in patients with ASCVD. At week 12, LDL-C was reduced 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.[2,3]

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

ASCVD = atherosclerotic cardiovascular disease;
PCSK9 = proprotein convertase subtilisin/kexin type 9.

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® 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®.
- **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®-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® 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® 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®.

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

Repatha® (evolocumab) injection 140 mg/mL

Visit **booth 321**
or www.RepathaHCP.com for more information