

# Daily News

Sunday, November 8

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## Creager to call on profession to increase awareness, treatment for PAD

**Mark A. Creager, MD, FAHA, will urge** investigators and clinicians to expand efforts to address the epidemic of peripheral artery disease in his American Heart Association presidential address Sunday.

Creager's 20-minute address — "The Crisis of Vascular Disease and the Journey to Vascular Health" — officially kicks off the association's 2015 Scientific Sessions at 1 p.m. in Hall D.



Mark A. Creager, MD, FAHA

Creager will remind attendees that PAD is not simply a disease of the legs, but a clinical manifestation of a systemic disease that often coexists with coronary artery disease and cerebrovascular disease.

"The risk of death is at least double for patients with PAD compared to patients who do not have it," said Creager, director of the Heart and Vascular Center at Dartmouth-Hitchcock Medical Center and professor of medicine at the Geisel School of Medicine at Dartmouth in Lebanon, New Hampshire. "And the risks of myocardial infarction, stroke and cardiovascular death among people with PAD are at least as great as in those patients who have already had a heart attack or stroke."

Physicians often fail to diagnose or adequately treat PAD, Creager said.

"In one survey, physicians were aware that their patients had PAD only 50 percent of the time," he said. "When my research group examined the NHANES database, we found risk-factor modifying therapies and

PRESIDENT continued on page 13

## PCORI, AHA to crowdsource key research for cardiovascular disease

**T**he AHA and the Patient-Centered Outcomes Research Institute (PCORI) are launching a joint initiative that combines the outreach power of crowdsourcing with the lure of prizes to speed the identification of critical research needed to improve care for cardiovascular disease.

AHA Chief Executive Officer Nancy Brown will announce the initiative during Sunday's Opening Session, which begins at 1 p.m. in Hall D.

"The pressure from patients is mounting as expectations rise for more evidence-based resources to help make informed health decisions and for more precise medicine," Brown said. "The AHA and PCORI will capitalize on this unprecedented opportunity to address a critical challenge and accelerate research. We look forward to working with PCORI and communities interested in making a difference by identifying critical questions that can transform the research paradigm and set the stage for innovative comparative effective cardiovascular disease research."

The new program, the Precision Medicine Advances using Nationally Crowdsourced CER, or PRANCCER, will use crowdsourcing techniques to draw on the collective wisdom of millions of CVD patients, clinicians, family caregivers and researchers.

The initiative will seek input on critical gaps in the evidence about which CVD prevention, diagnostic and treatment approaches work best for which patients based on their needs and circumstances. Those are the types of questions that PCORI-funded comparative clinical effectiveness research, or CER, is designed to answer. It also will serve the AHA's commitment to advancing precision cardiovascular medicine, which seeks to refine care for patients based on their particular characteristics.

Cash prizes will be offered for the most scientifically rigorous and patient-centered research ideas.



Joe Selby, MD, MPH

"This exciting initiative advances PCORI's patient- and stakeholder-driven approach to clinical research, which engages end-users of study results in all phases of the research process, including identifying research needs and topics," said PCORI

Executive Director

Joe Selby, MD, MPH. "We're delighted to partner with the AHA and its network of more than 30 million lay advocates and professional members in this initiative. By optimizing the use of a crowdsourced challenge model as a way to hone in on the greatest unmet needs in cardiovascular disease, we'll also learn how we can best apply this model to a range of other conditions."

CROWDSOURCE continued on page 13

## ECPR plus cooling associated with improved neurologic outcomes in OHCA patients

**New data from Japan suggest** that extracorporeal cardiopulmonary resuscitation (ECPR) plus therapeutic hypothermia is associated with improved neurologic outcomes for out-of-hospital cardiac arrest patients.

Results of the SAVE-J trial presented Saturday during the Resuscitation Science Symposium show that therapeutic hypothermia for between 24 and 48 hours with a median of 39 hours using a target temperature of 33°C is most likely to improve 30-day neurologic outcomes for patients undergoing ECPR for a ventricular fibrillation cardiac arrest.

"The results of SAVE-J show that even if the ventricular fibrillation cardiac arrest patient cannot be restored to spontaneous circulation in the field using conventional CPR, the combination of ECPR and therapeutic hypothermia can still be successful and some patients can have a favorable neurologic outcome at 30 days," said Ken Nagao, MD, PhD, from the

cardiovascular center at Nihon University Hospital, Tokyo, who presented the trial results.

ECPR is widely used in Japan, Nagao said, and therapeutic hypothermia has been shown to improve neurological intact survival for comatose patients with return of spontaneous circulation following ventricular fibrillation cardiac arrest. But there are many questions surrounding therapeutic hypothermia, including optimal cooling duration and target core temperature, patient selection, rewarming protocols and the potential effects of combination with ECPR.

SAVE-J was a prospective, multicenter observational study of advanced cardiac life support for patients with ventricular fibrillation cardiac arrest outside a hospital setting. All of the patients failed



Ken Nagao, MD, PhD

conventional CPR and met the criteria of the SAVE-J trial following out-of-hospital cardiac arrest.

The researchers identified 274 patients with out-of-hospital ventricular fibrillation cardiac arrest who failed conventional CPR and underwent ECPR. Of that initial group,

ECPR continued on page 13



Turn to page 4 to read about the Vascular Disease Thought Leaders Summit Report 2015

TODAY AT SESSIONS

Don't miss today's highlighted presentations and events. For the complete schedule, download the Mobile Meeting Guide, see the Final Program or view the online program at [scientificsessions.org](http://scientificsessions.org).

- 8–9:30 a.m.**

ReSS Poster Session, Day 2

Valencia Ballroom – W415CD
- 9–11 a.m.**

ABIM Learning Session—Cardiovascular Disease, 2015 Update (Early February Release)

W330ABC
- 9:30–10:30 a.m.**

ReSS Year in Review

Valencia Ballroom – W415AB
- 1–3 p.m.**

Opening Session

Hall D
- 3:30–5:30 p.m.**

ABIM Learning Session—Clinical Cardiac Electrophysiology, 2015 Update (Late March Release)

W330ABC
- 3:45–5 p.m.**

Advances in Structural Heart Disease Interventions for the Clinician

Chapin Theater
- 3:45–5 p.m.**

Affordable Care Act Effects on Patients, Clinicians, and Scientists

W109
- 3:45–5 p.m.**

Late-Breaking Clinical Trials I: Failure is Not an Option: New Drugs and Systems of Care

Hall D
- 5:15–6 p.m.**

Case Theater: Coronary Case—Severe Calcification

Hall A1, Case Theater

PROGRAM CHANGE

Yesterday we reported that NIH Director Francis S. Collins, MD, PhD, would present a special lecture on Monday. Unfortunately, an unexpected personal issue has prevented Collins from attending Sessions. In his place, Gary H. Gibbons, MD, director of the National Heart, Lung, and Blood Institute, will present a lecture on precision medicine at 9 a.m. Monday in Hall D.

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HIGHLIGHTS FROM THE PROGRAM CHAIR

By Frank W. Sellke, MD, FAHA, Committee on Scientific Sessions Program Chair

Today looks to be an outstanding day

at Scientific Sessions. The highlight will be the Opening Session, which begins at 1 p.m. in Hall D. AHA President Mark A. Creager, MD, FAHA, will preside and present the annual Presidential Address.

Also during the session, the Chairman's Award will be presented to Timothy J. Gardner, MD, FAHA, past president of the AHA, for his continued exemplary work with the American Heart Association. The recipients of the AHA Distinguished Scientist Awards also will be recognized for their achievements (see page 10 to read about those achievements.) The Basic Research Prize will be presented to Glenn I. Fishman, MD, the Clinical Research Prize will be awarded to Jackson T. Wright, MD, PhD, and the Population Research Prize will be presented to Gregory L. Burke, MD. This year's Eugene Braunwald Academic Mentorship Award will be presented to Michael H. Criqui, MD, MPH, FAHA. The Research Achievement Award goes to Harry C. Dietz, MD, and the Joseph A. Vita Award will be presented to Joseph C. Wu, MD, PhD. The Opening Session will conclude with the annual Lewis A. Conner Lecture, which will be delivered by Andrew J. Conrad, PhD, head of Google X's Life Sciences team.

The day actually begins at 9 a.m. with poster and oral sessions. This year we have continued the use of Poster Professors for all poster sessions, optimizing interactions, networking and knowledge transfer. We have an outstanding day of programing with many excellent oral sessions and presentations in basic, clinical and population science. The Committee of Scientific



Frank W. Sellke, MD, FAHA

Sessions Program has put together outstanding educational programs in almost every area. You can learn about the latest drugs and devices when the exhibit hall opens at 11 a.m.

This year we have a record number of outstanding Late-Breaking Clinical Trials, which will be presented in six sessions over the next four days. The first Late-Breaking Clinical Trials session, “Failure is Not an Option: New Drugs and Systems of Care,” begins at 3:45 p.m. today in Hall D. The session will include reports from the FIGHT, NEAT-HFpEF, SOCRATES-REDUCED, BEAT-HF and COSMIC-HF trials.

This afternoon's Special Session, “Advances in Structural Heart Disease Interventions for the Clinician,” begins at 3:45 p.m. in the Chapin Theater.

The session's presentations will cover the state of the art and current challenges of TAVR, the latest in percutaneous mitral valve repair, current perspectives and future directions of inter-atrial septal closure, alcohol septal ablation for hypertrophic cardiomyopathy and the current status of left atrial appendage occlusion for AF.

As in the past, we have many joint sessions with other organizations. Today's joint programming includes sessions with the Preventive Cardiovascular Nurses Association, the International Society of Cardiovascular Disease Epidemiology and Prevention, the Brazilian Society of Cardiology, the Chinese Society of Cardiology, the Japanese Circulation Society and many more.

Whatever your specialty or interests, Scientific Sessions has an outstanding selection of programs to learn cutting-edge science, new clinical techniques and procedures, and the results of the latest clinical trials. ▼

Late-Breaking Clinical Trials — LBCT.01

3:45–5 p.m. Sunday | Hall D

Failure is Not an Option: New Drugs and Systems of Care

TRIAL	DESCRIPTION
A Randomized Trial of Liraglutide for High-Risk Heart Failure Patients With Reduced Ejection Fraction (FIGHT: Functional Impact of GLP-1 for Heart Failure Treatment)	A randomized, double-blinded, placebo-controlled clinical trial of treatment with liraglutide versus placebo for six months in high-risk HF patients with reduced ejection fraction (LVEF ≤ 40 percent) and recent hospitalization.
Nitrate's Effect on Activity Tolerance in Heart Failure With Preserved Ejection Fraction (NEAT-HFpEF)	This trial was designed to evaluate the effect of isosorbide mononitrate on activity tolerance in heart failure with preserved ejection fraction.
Oral sGC Stimulator Vericiguat in Patients with Worsening Chronic Heart Failure and Reduced Ejection Fraction — The SOLuble guanylate Cyclase stimulaTOR in heArT failurE patientS With REDUCED EF (SOCRATES-REDUCED) Study	Phase II dose-finding trial of the once daily sGC stimulator vericiguat added to standard therapy in patients with worsening chronic HF and reduced ejection fraction over 12 weeks.
Remote Patient Management After Discharge of Hospitalized Heart Failure Patients: The Better Effectiveness After Transition — Heart Failure Study (BEAT-HF)	BEAT-HF is a comparative effectiveness randomized control trial that evaluated a remote patient management care transition approach to reduce readmissions for hospitalized heart failure patients aged 50 years and over.
Chronic Oral Study of Myosin Activation to Increase Contractility in Heart Failure (COSMIC-HF): Final Results from a Double-blind, Randomized, Placebo-controlled Multicenter Study	The primary objectives of COSMIC-HF were to select an oral, modified-release formulation and dose for chronic, twice-daily dosing in patients with HFrEF (escalation phase), and to characterize pharmacokinetics over 20 weeks of treatment (expansion phase).

Special Session — SS.01

3:45–5 p.m. Sunday | Chapin Theater

TRIAL	DESCRIPTION
Advances in Structural Heart Disease Interventions for the Clinician	<p>Presentations:</p> <ul style="list-style-type: none"><li>• TAVR: State of the Art and Current Challenges</li><li>• The Latest in Percutaneous Mitral Valve Repair (MitraClip)</li><li>• Inter-Atrial Septal Closure: Current Perspectives and Future Directions</li><li>• What is New in Alcohol Septal Ablation for HCM?</li><li>• Current Status of Left Atrial Appendage Occlusion for Atrial Fibrillation</li></ul>



# The AHA Institute for Precision Cardiovascular Medicine to 'provide bold answers to bold questions'

**T**he American Heart Association Institute for Precision Cardiovascular Medicine, an umbrella for the AHA's precision medicine initiatives, was launched in October in Washington, DC, with leaders in clinical medicine, federal health and the pharmaceutical industry.

The association has pledged \$30 million over five years, with a tentative pledge to commit an additional \$30 million within another five years. A fundraising campaign will seek to add an additional \$100 million in three years.

"With our interactions across all stakeholders, the American Heart Association is uniquely poised to lead the way in precision cardiovascular medicine and to provide bold answers to bold questions," said CEO Nancy Brown. "The AHA has an unparalleled commitment to cardiovascular research and 30 million volunteers, which define its brand, science and grassroots. Patients and families alike look to the AHA for a bolder outlook."

Precision medicine is a fast-growing approach to disease prevention and treatment that seeks more precise

care by combining scientific research with detailed information about a patient's genes, environment and lifestyle. One goal is to collect large troves of health data that researchers can analyze to identify patterns and specific ways to diagnose and treat individuals.

Attendees at the October meeting began plotting a 20-year plan to set the institute's research agenda for precision cardiovascular medicine. The group also discussed how to start building the infrastructure for opening and accessing data.

The institute will provide the leadership and funding support for the development of precision cardiovascular medicine. It will also catalyze, coordinate and integrate multiple activities across big data platforms to lead to the generation of a data discovery portal. And it will bring stakeholders together and serve



Nancy Brown

as an "honest broker" to balance the interests of competing parties. Data sharing will be permitted under rules and regulations to be established.

Short-term, the institute will include data from paired genotype-phenotype datasets such as longitudinal studies and health systems biobanks to help

provide access to a large, highly diverse set of the most valuable CV data for researchers. In the future, it will include a much wider set of CV-related data, including data from registries, patients, omics, EHR, clinical trials and regulatory databases.

The institute has already announced the funding of 10 Discovery grants funded at \$160,000 per year, eight Pathway grants at \$500,000 for two years and two Grand Challenge grants at \$2 million each over four years. ▼



## MEMBER SPOTLIGHT

**Professor Kerry-Anne Rye, BSc(Hons), PhD, FAHA**

*Head of Lipid Research, School of Medical Sciences, Faculty of Medicine, University of New South Wales Sydney, Australia*

### How long have you been an AHA/ASA Professional Member?

I joined the AHA in 1987 soon after I completed my PhD. I became a FAHA in 1990.

### Why did you join?

The AHA provides unlimited opportunities for networking and getting to know people in and outside your areas of interest. This is very important for everyone involved in cardiovascular disease research, but especially for people living on the other side of the world, as I do. My interactions with other investigators at AHA events have led to some productive, cutting-edge collaborative efforts over the years. The positive outcomes of these studies have demonstrated in the best possible way that geographical location is irrelevant when it comes to advancing knowledge.

### Are you involved in AHA councils?

I have been involved in the Council on Arteriosclerosis, Thrombosis and Vascular Biology (ATVB) for more than seven years. I am a past chair of the council's Women's Leadership Committee and I am currently the ATVB Council Chair for the Committee on Scientific Sessions. I also act as the liaison between the ATVB Council and the International Atherosclerosis Society.

### What do you enjoy most about these roles?

They provide a lot of opportunities to get involved in new processes and initiatives, and to link up with people that share my interests. Many of these activities also move me out of my comfort zone, which is a very good thing.

### How else are you involved with the AHA?

In 2011, I set up an ATVB Council mentoring program for early career investigators. This program matches scientists and physicians who are just starting out in their careers with a senior ATVB Council member who acts as their mentor. It has been a highly successful initiative and it is tremendously exciting seeing several of the mentees who have joined the program obtain their first faculty positions and grant funding.

### Why is membership valuable to you?

In addition to hearing about the latest and greatest science here at Sessions, as well as at the ATVB Council spring meeting, it makes it easy to keep in close touch with like-minded people. I always leave these events with an impossibly long list of new ideas and renewed enthusiasm for what I do on a day-to-day basis.

### What message would you like to convey to your colleagues about being an AHA member?

If you are interested in becoming part of a vibrant and energized community, the AHA is for you. It can provide you with unlimited networking opportunities and access to people who are acknowledged leaders in their fields. It also gives you an opportunity to present the outcomes of your latest work to an attentive audience that really wants to know what you are doing right now, and what you plan to do next. ▼

## CAREER PROGRESSION

### SAM O. ZAIDAT, MD, MS, FAAN, FAHA

As a neurology resident in the 1990s, Sam Zaidat's passion for stroke and neurointervention was piqued when he watched an interventional neurologist remove a clot by navigating a catheter through a blocked brain artery.

"That was uncommon at the time. Seeing it had a strong impact on me," said Zaidat, MD, the neuroscience and stroke director at St. Vincent Mercy Hospital in Toledo, Ohio. "Learning to do it became a challenge that I wanted to achieve. It was my dream to become an interventional neurologist and reverse the brain damage caused by stroke. We could give our stroke patients their lives back."

Zaidat tells a story that illustrates his passion for stroke care. As a neurology resident at Case Western Reserve University in Cleveland, Ohio, he recalls rushing a patient to get a hyperacute MRI in the middle of the night when he crashed his own head into a door. He cared for the patient before getting the seven stitches he needed.

"For me, stroke care is a passion and love," Zaidat said. "At the time, I was a stroke neurologist and



neurointensivist, but I told my boss I needed neurointerventional training. I wanted to take the catheter up to the brain and remove the clot myself."

Zaidat found a mentor and got involved with the American Stroke Association early in his career. Ten years later, he has built one of the busiest neurointerventional

programs in the country and is a principal investigator of two clinical trials.

The ARISEII (Analysis of Revascularisation in Ischemic Stroke with EmboTrap) trial is an international prospective acute ischemic stroke trial. Zaidat's European co-principal investigator is Tommy Anderson, MD, PhD. The Neuroform ATLAS FDA IDE trial is a national prospective trial testing the next-generation Neuroform stent system to treat cerebral aneurysm. He is co-principal investigator of the trial with Brian Jankowitz, MD.

"For the next two years, my focus will be on completing these trials and presenting the results," Zaidat said. "I hope my colleagues and I will be ready to present our findings at the International

Each day, we're profiling an investigator at a different career stage, from early career to distinguished veteran.

Stroke Conference in 2018."

Zaidat credits his early involvement in the American Stroke Association with helping him achieve his clinical and research goals.

"For many physicians, nurses, trainees, researchers and others who are interested in stroke, the American Stroke Association is one of the most important organizations in the field," he said. "I became active in the ASA and the AHA early in my training because I was able to have access to cutting-edge research, and it provided me with networking opportunities. The connections, competitiveness and friendships I've experienced have been an integral part of my career."

In addition to attending the AHA/ASA International Stroke Conference for 17 years, Zaidat has participated in AHA's Scientific Sessions the past three years. He has served on the International Stroke Conference planning committee, and as chair of the Stroke Session Group representing the Stroke Council on the AHA Committee on the Scientific Sessions Program. He has also served in multiple leadership capacities on the Stroke Council. ▼

# Vascular disease summit meeting monograph now available

Three key areas of focus are identified in the vascular disease summit meeting monograph that was released Friday, Nov. 6, by the American Heart Association.

“Improving Vascular Disease Prevention, Detection and Treatment: A Vascular Disease Thought Leaders Summit Report” will be cited in an address by AHA President Mark Creager, MD, FAHA, during Sunday’s Opening Session. The monograph, based on an August gathering of vascular disease experts, patients and caregivers, includes specific recommendations to improve vascular disease awareness, prevention, detection and treatment.

“The knowledge gap between heart disease and vascular disease among the

public and healthcare providers is quite dramatic,” Creager said.

Vascular disease affects more than 8 million people in the U.S., yet awareness in healthcare providers and the public is lacking. Not recognizing vascular disease, ignoring or misdiagnosing its symptoms — such as recurring leg pain during walking that improves with rest — can put patients at increased risk for amputation, heart attack and stroke.

Key areas of focus identified include peripheral artery disease, venous thrombosis, including venous thromboembolism and deep vein thrombosis, and abdominal aortic aneurysm.

PAD is a disease of the peripheral vasculature and can be among the first

symptoms of systemic atherosclerosis. Although public and provider awareness of atherosclerosis as a coronary disease is high, few nonspecialists recognize that if arteries are clogged in one part of the body, they are likely to be clogged in other areas.

“Plaque build-up in patients’ legs, the problem that causes peripheral artery disease, typically affects arteries all over, including those in the heart and those that go to the brain,” Creager explained. “If someone has peripheral artery disease, they’re at significant risk for heart attack or stroke if they don’t start addressing the problem.”

Untreated PAD increases the risk for cardiac and cerebral vascular events, including heart attack and stroke. It can also

lead to impaired wound healing, gangrene and limb amputation.

Awareness of venous thromboembolism, which includes deep vein thrombosis or blood clots in the legs, is also lacking. Once seen as a disease affecting patients who are bedridden following major surgery, it’s now understood that a far broader population is at risk. Risk factors include prolonged inactivity, including long plane flights or simply sitting too long, as well as smoking, diet, obesity and diabetes.

In addition to the direct impairment of circulation in the affected limb, deep vein thrombosis increases the risk of another form of venous thromboembolism: pulmonary embolism. Clots formed in the legs can break free into the blood circulation, passing through the heart to lodge in the lungs. Pulmonary embolism can lead to severe shortness of breath and death.

Abdominal aortic aneurysm is a weakening and ballooning of the aortic wall as it descends through the abdomen. Rupture of the weakened aorta causes severe internal bleeding that frequently leads to death. The risk of these aneurysms is high in men over age 65 who have ever smoked, and in those who have first-degree relatives with this condition.

In addition to focusing public and provider awareness on vascular disease, the AHA is intensifying its efforts in research and reimbursement.

“Primary care physicians have a lot on their plates today,” Creager said. “They’re dealing with so many medical issues that sometimes it’s hard for them to recognize when a patient is at risk for vascular disease or already has it, and they should. If they’re not sensitive to vascular disease or focusing on it, they’re going to miss it.”

The monograph is available to Sessions attendees and online at <http://scientificsessions.org/VascularDiseaseReport>. ▼

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## Sanofi and Regeneron Expert Lectures Series

Join us at **Booth 1328** to learn about PCSK9 inhibition and the unmet need in patients with poorly controlled LDL-C

### Nov 8th

12:00 PM - 12:30 PM **Efficacy, Safety, and Tolerability With PCSK9 Inhibition**  
*Harold Edward Bays, MD, FTOS, FACC, FACE, FNLA*

3:15 PM - 3:45 PM **Efficacy, Safety, and Tolerability of PCSK9 Inhibition in Special Populations**  
*Michael Koren, MD, FACC*

### Nov 9th

1:00 PM - 1:30 PM **Efficacy, Safety, and Tolerability With PCSK9 Inhibition**  
*Norman Lopor, MD, FACC*

### Nov 10th

10:30 AM - 11:00 AM **Efficacy, Safety, Tolerability, and Dosing Options With PCSK9 Inhibition**  
*Paul Thompson, MD*

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### Nov 8th

Booth 1559

11:15 AM - 12:00 PM **PCSK9 Inhibition: Long-term Safety and Efficacy**  
*Michael Davidson, MD*

### Nov 9th

Booth 1601

12:00 PM - 12:45 PM **PCSK9 Inhibition: Efficacy and Safety With Two Dosing Options**  
*Yehuda Handlesman, MD, FACP, FACE, FNLA*

**LDL-C** = low-density lipoprotein cholesterol; **PCSK9** = proprotein convertase subtilisin/kexin type 9.

**SANOFI**  **REGENERON**



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# Seminar will explore use of 3D printing in cardiovascular care

Although it's still in its infancy, 3D printing for medical use is emerging as an educational tool that promises to offer more benefits as it develops.

Six experts will discuss the latest advances in this emerging technology during Sunday's Cardiovascular Seminar, "3D Printing in Cardiovascular Care." The session begins at 5:30 p.m. in W305.

Moderators Vincent B. Ho, MD, chair and professor of radiology and radiological sciences at Uniformed Services University of the Health Sciences in Bethesda, Maryland, and Alexander Seifalian, MD, PhD, department head and professor of nanotechnology and regenerative medicine at University College London, agree that 3D printing could revolutionize cardiovascular care.

"One day we could potentially personalize devices, such as stents, for use surgically," Ho said. "I can see a time in the future when we're able to customize a stent for a specific patient's needs."

So far, 3D printing has been used primarily to print structures. But Ho also sees a future for 3D bioprinting, with researchers printing tissue for specific patients. Seifalian said researchers are beginning experiments with printing cells and scaffolds for heart valve tissue engineering or cardiac patches, but bioprinting applications won't be ready for clinical use for years.

"However, 3D printing technology is improving every day with higher resolution and better precision," he said. "At the same time, many new biomaterials are coming out, which may one day be used for 3D printing of cardiovascular structures."

3D printing has already proven valuable for training and education. Researchers have created models to look at interesting anatomical relationships — especially in young children with complex congenital heart lesions, Ho said.

"It's difficult to understand the orientation of the various chambers and the connections of the chambers to the arteries and veins," he explained. "Having a model of a heart or the aorta that you can hold in your hand helps you to understand the anatomic relationships of the various structures. It is helpful for surgeons and their patients to see things in three dimensions."



Vincent B. Ho, MD



Alexander Seifalian, MD, PhD

In the United Kingdom, Seifalian said 3D printing is rapidly being integrated into clinical practice to assist with planning, decision making and delivery of cardiovascular implants.

Residents and trainees have also used 3D models to practice procedures before they perform surgery. This is especially important with minimally invasive percutaneous transcatheter procedures, Ho said.

Researchers have also used 3D models to simulate the physiology of the heart and examine it during experiments.

"You can actually take a heart and model what it looks like now and what it should look like after it has been repaired to see how the physiology changes," Ho said. "So if someone has a congenital heart lesion, you can perform the proposed repair and actually see what the potential post-op results will be."

Equally important, he said, is how the technology has been used to educate patients as well as parents of young patients.

"Using a 3D model, you can explain exactly what you're going to do so everyone can understand," Ho said.

Today's session will review several 3D printing applications, including 3D printing for physiology flow simulations, 3D printing in congenital heart disease surgical planning, and the use of 3D printing in transcatheter aortic valve replacement.

Seifalian urged researchers and clinicians alike to attend the session.

"3D printing is an affordable and fairly easy tool to use," he said. "One day, every hospital will print models of organs to help with treatment planning as well as education and training of junior clinicians. 3D printing will also play a large role in future research as an important tool in the laboratory." ▼

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RESEARCH

ACCELERATING SCIENCE FOR EXTRAORDINARY IMPACT

### Join us for our Annual Awardee Group Photo at Scientific Sessions

- Photo taken with AHA President Mark Creager, MD, FAHA and other officers
- Monday, November 9 at 1:40 PM
- Level 3, Chapin Theater Lobby
- Participants will receive a special lapel pin!





# Heart disease survivor donates \$5 million to fund research center for heart disease in women

**Y**ears ago, when Sally Soter was diagnosed with atrial fibrillation, she told her doctor she was determined to conquer heart disease — and help other women facing it too.

Her commitment to fighting the No. 1 killer of women became even clearer in May when she and her husband Bill donated \$5 million for a new research center studying the prevention and treatment of heart disease in women.

The Sarah Ross Soter Center for Women's Cardiovascular Research is part of the American Heart Association's Go Red For Women Research Network, which is one of

a series of Strategically Focused Research Networks. The association's research networks are made up of several elite research institutions collaborating to address specific areas of heart disease or stroke.

"To be able to fund something that could help women and heart disease is very rewarding," said Soter, an active community volunteer who's passionate about improving healthcare for women by accelerating science. "There's so much we still don't know. It could mean so much for research."

Soter's gift will make a major impact on the AHA's research program, which funds more heart and stroke research than any organization outside the U.S. government.

"The American Heart Association is so grateful for Sally's commitment to improving women's heart health and to correcting the disparities that so many women face when it comes to accessing the care they deserve," AHA CEO Nancy Brown said. "We are eager for this important new research to begin, and for the improvements that will follow in prevention, treatment and care for all women."



Sally Soter

Research continues to show differences in heart disease among women and men, yet gaps remain in how to best diagnose, treat and prevent it. These gaps mean a lack of information about whether women react differently to heart disease, if diagnostic methods work as well in women as in men, and if women respond differently to treatment, according to the AHA.

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## What more is there to learn about platelet activation and aggregation?

Find out at

# Booth 701



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Soter hopes the new research center can help get to the bottom of what's still unknown about women's hearts. She recalled feeling upset about her own heart when her doctor diagnosed her 17 years ago.

"I was angry that I had it," said Soter, who had two ablations to treat the atrial fibrillation. "I felt that I had taken care of myself. I was just plain determined that I wasn't going to have it forever."

Soter's gift is the latest event in her long history of volunteerism and advocating for women's heart health. Soter established the first-ever endowed chair exclusively for women's heart health at Ohio State University Medical Center. She has a particular interest in fighting healthcare disparities, ensuring that "rich or poor, regardless of gender, ethnicity and income, you would have a chance at a different life."

Soter also helped the AHA launch Teaching Gardens in Palm Beach County, Florida, getting the pleasure of seeing kids who'd never eaten vegetables enjoy them.

"It has meant a great deal to me to see these children and know that they're learning in their work," she said. "I was raised to know that one should give back to the community and I really believe in teaching." ▼



### OHCA in elderly MI survivors

Using linked data from the NCDR ACTION Registry-GWTG and the Centers for Medicare and Medicaid Services, researchers examined the association between out-of-hospital cardiac arrest and mortality or all-cause readmission in elderly survivors of myocardial infarction. Learn their findings during an oral abstract session at 3 p.m. Sunday in W414CD.



# AHA research center guiding tobacco regulations

**S**tudies are underway by researchers participating in the American Heart Association's Tobacco Regulation and Addiction Center (A-TRAC), a virtual center conducting tobacco-related research.

A-TRAC was created with a five-year, \$19.7 million grant in 2013 from the National Institutes of Health and the U.S. Food and Drug Administration's Tobacco Regulatory Science program. The center has experts at various sites researching tobacco issues to inform the regulatory arm of the U.S. Food and Drug Administration.

“Within A-TRAC, we have a number of the best universities and best investigators in the world working on tobacco-related research,” said Rose Marie Robertson, MD, chief science officer of the American Heart Association and a co-director of A-TRAC.

Three major research projects at the center involve: Identifying measurable markers of body function, for example changes in the urine, that will give information about how tobacco products are toxic to the heart and blood vessels; finding new ways such as imaging to detect early cardiovascular injury caused specifically by tobacco use; and discovering how people in vulnerable

populations' perception of tobacco use can influence their efforts to stop smoking.

“We have all known for several decades that smoking is injurious for cardiovascular health, but we don’t know why,” said Sanjay Srivastava, PhD, professor of medicine at the University of Louisville in Kentucky, who is leading research on the toxic effects of smoking.

Srivastava's team is looking for markers in the body that indicate how tobacco exposure harms the heart and blood vessels. This can help track down the most harmful parts of tobacco products.

"It's really important to understand the mechanisms by which smoking causes cardiovascular injury," said Michael Blaha, MD, a cardiologist and researcher in clinical

epidemiology at Johns Hopkins Bloomberg School of Public Health in Baltimore.

Imaging now provides insights not available 20 years ago.

"I think the most interesting thing is moving smoking research into the modern era of imaging, so we can actually look at the behavior of blood vessels with imaging tests to see how smoking affects those measures," he said.

Thomas Payne, PhD, professor in the department of otolaryngology and communicative sciences at the University of Mississippi Medical Center in Jackson, is looking at how people think about using tobacco.

“A lot of people use tobacco now, obviously, and use a variety of methods to

quit. But very, very few use the resources that have been developed to specifically assist with that," he said.

Payne's research aims to improve media messaging so people will be encouraged to take advantage of proven treatments to help them quit.

“Because tobacco use continues to be the No. 1 cause of preventable disease and death in the United States, more research on its impact is absolutely essential,” said American Heart Association CEO Nancy Brown. “Together, we can strengthen our understanding of the health risks of tobacco products that can inform, shape and support meaningful regulation and protect the public from tobacco-related disease and death.” ▼

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# 2015 Scientific Sessions Exhibitors

## Science & Technology Hall Hours

Sunday	11 a.m.–4 p.m.
Monday	10 a.m.–4 p.m.
Tuesday	10 a.m.–2:30 p.m.

## Lunch Break

Sunday	11 a.m.–1 p.m.
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Tuesday	Noon–2 p.m.

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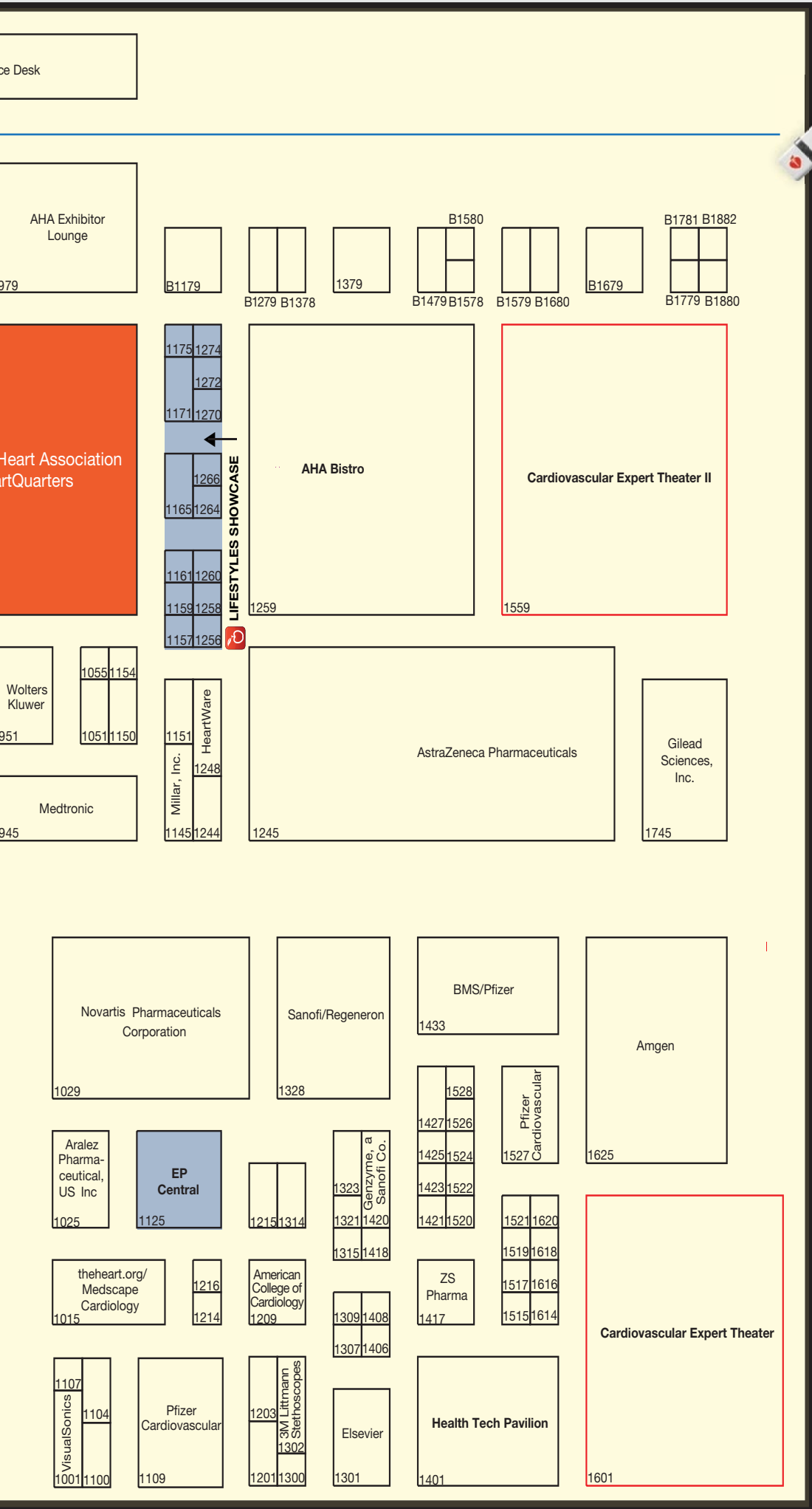
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IN THE SCIENCE &  
TECHNOLOGY HALL**

**Emerging Science & Technology Showcase**  
Stop by this area to visit companies currently in the early stages of product development or the product-approval process, giving you a sneak peek at the future of cardiovascular disease prevention, diagnosis and treatment.

**Lifestyle Showcase**  
Here you will find health- and nutrition-focused exhibitors. Join the AHA by calling on all people to live longer, more heart-healthy lives by supporting the products that drive health and nutrition awareness.

**Public Service Showcase**  
This area features associations, non-profit service providers, universities and other organizations who strive to promote heart health.

**Research & Discovery Zone**  
Visit this one-stop shop for the newest research and features from research labs around the world.

**Retail Row**  
Visit these exhibitors to shop for a variety of leisure products.

**Health Tech Competition  
2:15–3:15 p.m. Monday  
Location: Cardiovascular Expert Theater 1601**  
Watch seven medical tech startups demonstrate a broad spectrum of cardiac healthcare innovations before a panel of distinguished cardiologists, venture capitalists and industry thought leaders.

**Sunday's Theater  
Demonstrations**

**Cardiovascular Expert Theaters**

**Booth 1601**  
**11:15 a.m.–Noon**  
**A Treatment Approach for Patients With Chronic Systolic Heart Failure**  
Amgen  
**12:30–1:15 p.m.**  
**Exploring Risk Reduction in Thrombosis**  
Janssen Pharmaceuticals, Inc.

**Booth 1559**  
**11:15 a.m.–Noon**  
**PRALUENT® (alirocumab): Long-term Safety and Efficacy**  
Sanofi Regeneron  
**12:30–1:15 p.m.**  
**Repatha™ (evolocumab): Product Overview**  
Amgen

**Booth 163**  
**11:15 a.m.–Noon**  
**Understanding the Role of VASCEPA® (icosapent ethyl) as Add-on to Statins in Patients With Persistent High Triglyceride Levels (≥200 to <500 mg/dL)**  
Amarin Pharma  
**12:30–1:15 p.m.**  
**The Myth of the Clinically Stable Patient With Heart Failure**  
Novartis Pharmaceuticals Corporation

**HeartQuarters Theater**

**Booth 859**  
**11:15 a.m.–Noon**  
**Collaboration Station**  
*Presenter: Lora Burke, Chair of Council Operations Committee*  
**12:15–12:45 p.m.**  
**Introduction to New My American Heart Website Using the Professional Online Network**  
*Presenter: Kerstin Wiggins*

**12:45–1:30 p.m.**  
**Hypertension CPC Case: Hypertensive Encephalopathy and Renal Failure in a Young Man**  
*Presenters: Robert W. Hunter, Royal Infirmary of Edinburgh; Neeraj Dhaun, British Heart Foundation*

**1:40–2 p.m.**  
**E-College Heart Failure Interactive Experience**  
*Presenter: Steve Dentel, BSN, RN, CPHQ, National Consultant, Quality and Systems Improvement, American Heart Association*

**2:15–3 p.m.**  
**Video**

**3:15–4 p.m.**  
**Improving Patient Outcomes Takes a Need for Speed**  
*Presenter: Courtney Nicolato, CPHIT, Senior Advisor & Director, New Business Initiatives, American Heart Association*



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# Distinguished Scientists to be honored during Opening Session

The American Heart Association will honor six researchers as 2015 Distinguished Scientists during the Opening Session, which begins at 1 p.m. Sunday in 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 91 past honorees. They are:

## Samuel Z. Goldhaber, MD, FAHA

Director of the thrombosis research group at Brigham and Women's Hospital in Boston, Massachusetts, Goldhaber is a principal investigator for a broad range of randomized clinical trials and observational studies related

to the prevention, treatment and epidemiology of venous thromboembolism, stroke prevention in atrial fibrillation and the prevention of recurrent myocardial infarction.

Through a series of clinical trials, Goldhaber has shown that right ventricular dilatation and hypokinesia predict an adverse prognosis in acute pulmonary embolism. His research has also shown that systemic and catheter-based, ultrasound-facilitated thrombolytic therapy restores normal right ventricular function more rapidly than heparin.



Samuel Z. Goldhaber, MD, FAHA

In addition, he conducted a randomized trial demonstrating that electronic medical alerts for high-risk inpatients not receiving venous thromboembolism prophylaxis reduced symptomatic DVT and pulmonary embolism rates by more than 40 percent.

Goldhaber is also professor of medicine at Harvard Medical School and section head of vascular medicine in the Cardiovascular Medicine Division at Brigham and Women's Hospital. He serves as chair of the steering committee of the National Heart, Lung, and Blood Institute-sponsored ATTRACT Trial of DVT, which is testing pharmacomechanical low-dose thrombolysis against standard anticoagulation to prevent post-thrombotic syndrome. He serves on the steering committees of the GARFIELD Atrial Fibrillation and GARFIELD-Venous

Thromboembolism cohort studies and is national coordinator of participating U.S. sites.

Goldhaber is also president and founding director of the North American Thrombosis Forum, a nonprofit organization.

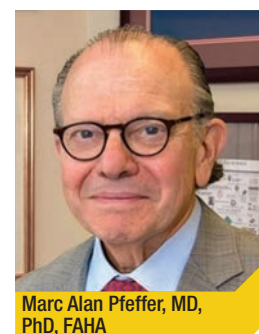
## Marc Alan Pfeffer, MD, PhD, FAHA

Along with his late wife, Dr. Janice Pfeffer, and Eugene Braunwald, MD, Pfeffer is credited with introducing the concept that ACE inhibitors could attenuate adverse ventricular remodeling following myocardial infarction, resulting in extended survival among other clinical benefits. Since this initial discovery, Pfeffer has had a principal role in several practice-changing clinical trials, including SAVE, CARE, VALIANT, CHARM, PEACE, ARISE, TREAT, ALTITUDE, RED-HF, TOPCAT and ELIXA.

Pfeffer, who is the Dzaou Professor of Medicine at Harvard Medical School and senior physician in the Cardiovascular Division at Brigham and Women's Hospital in Boston, Massachusetts, has developed a reputation as a team builder who helps trainees and junior faculty advance academically. He is known for sharing data and assisting others in developing meaningful scholarly works from study databases.

An internationally known expert in the field of cardiology, *Science Watch* recognized Pfeffer for having the most cited papers in clinical medicine. He was also cited as one of the most influential biomedical researchers in 1996-2011 in the *European Journal of Clinical Investigation*.

Pfeffer has also received the AHA's Clinical Research Prize and the James B. Herrick Award. He is also senior associate editor of *Circulation* and serves on the data safety monitoring boards of multiple international trials.



Marc Alan Pfeffer, MD, PhD, FAHA

## Barbara Riegel, PhD, RN, FAHA

A well-known nurse scientist, Riegel's research focuses on adults with cardiovascular disease, particularly self-care of older adults with chronic heart failure. She recently expanded her research to include multimorbidity, a common phenomenon in adults with heart failure.

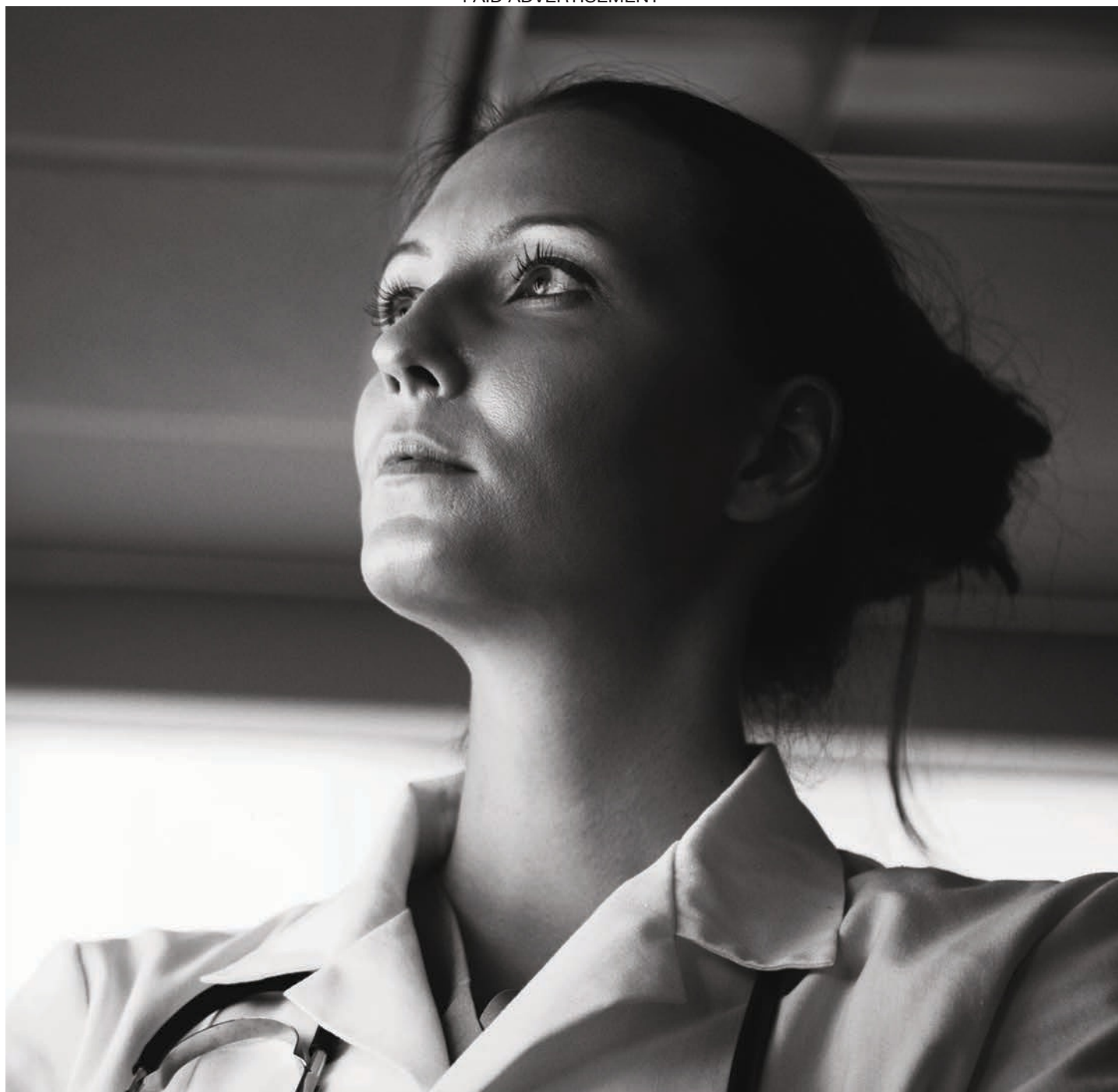
In researching medication adherence and decision making in response to symptoms, Riegel has demonstrated that poor medication adherence is a primary contributor to hospitalization for heart failure. She has also identified intentional and unintentional factors associated with poor medication adherence and developed an approach to improve it.

Riegel has also identified factors that impair the ability of heart failure patients to accurately perceive and interpret their symptoms, including age-related changes in interoception and illness-related changes in the brain. She has



Barbara Riegel, PhD, RN, FAHA

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published a situation-specific theory of heart failure self-care and a middle-range theory of self-care of chronic illness. These theories are the basis of various self-report research measures used worldwide to study the self-care behaviors of chronically ill people.

Riegel is the Edith Clemmer Steinbright Professor of Gerontology in the school of nursing at the University of Pennsylvania, Philadelphia. She is also co-editor of the *Journal of Cardiovascular Nursing*, the official journal of the Preventive Cardiovascular Nurses Association.

#### Howard A. Rockman, MD, FAHA

An internationally recognized basic scientist, Rockman has made seminal discoveries in understanding the molecular mechanisms of cardiac hypertrophy and heart failure, with emphasis on the role of G protein-coupled receptors in the development and therapy of heart disease. He pioneered the use of mice as a model system by developing miniaturized technologies to study murine cardiac pathophysiology. This work laid the foundation for using genetically engineered mice to study molecular mechanisms of disease.

In a landmark study, Rockman disproved a long-standing theory that normalization of wall stress was critical in preventing heart failure. His work resulted in a paradigm shift in understanding how the heart responds to pathological stress. Rockman also discovered that phosphoinositide 3-kinase has protein kinase activity, and identified an endogenous substrate for the enzyme and role in receptor endocytosis. He recently discovered how  $\beta$ -adrenergic and angiotensin receptors in the heart can be selectively activated to induce cardioprotective signaling, which has led to the development of a new class of drugs known as biased ligands.

Rockman is the Edward S. Orgain Professor of Cardiology and professor of medicine, cell biology and molecular genetics at Duke University in Durham, North Carolina. He is editor-in-chief of the *Journal of Clinical Investigation*.

#### Jeffrey L. Saver, MD, FAHA

A leader in cerebrovascular research and clinical care, Saver has served as director of the Comprehensive Stroke Center at the University of California, Los Angeles, since its inception in 1995. His research focuses on acute stroke treatment, stroke prevention, neuroimaging, clinical trial design and the neurocognitive consequences of stroke.

Saver has had numerous leadership positions in neurovascular and translational science organizations, including chair of the AHA/ASA Stroke Council, founding chair of the AHA/ASA Stroke Scientific Statements Oversight Committee and founding chair of the AHA/ASA Stroke Performance Measures Oversight Committee.



Howard A. Rockman, MD, FAHA

Saver has also served as co-chair of the NIH-NINDS Common Data Elements Stroke Task Force. He was principal investigator of the NIH-NINDS Field Administration of Stroke Magnesium (FAST-MAG) phase 3 clinical trial and principal investigator of NIH-NINDS UCLA Specialized Program of Translational Research in Acute Stroke (SPOTRIAS). He was global principal investigator of the Solitaire with the Intention for Thrombectomy as Primary Endovascular Treatment for Acute Ischemic Stroke (SWIFT PRIME) pivotal clinical trial.

Saver is also professor of neurology at UCLA's David Geffen School of Medicine. He has served on the editorial boards of numerous journals and is associate editor at the *Journal of the American Medical Association* and consulting editor for the journal *Stroke*.



Jeffrey L. Saver, MD, FAHA

#### Russell P. Tracy, PhD, FAHA

Tracy's research focuses on coagulation, inflammation and adaptive immune systems in cardiovascular disease and other chronic diseases. He has made major contributions to the understanding of inflammation in atherosclerosis and as a major cause of cardiovascular disease and non-cardiovascular disease morbidity and mortality in "well-controlled" HIV-infected people. Most recently, he has studied the role of chronic infections, including cytomegalovirus, HIV and hepatitis C, in the regulation of adaptive immunity and the implications for cardiovascular disease.

NIH-funded since 1984, Tracy is involved in many molecular and genetic epidemiological studies, including the



Russell P. Tracy, PhD, FAHA

Cardiovascular Health Study, Multi-Ethnic Study of Atherosclerosis, National Heart, Lung, and Blood Institute's Heart Failure Network, NHLBI's HIV-CVD Consortium and NHLBI's Exome Sequencing Program.

Tracy is professor of pathology and laboratory medicine and biochemistry

at the University of Vermont College of Medicine in Burlington. He is also director of the college's laboratory for clinical biochemistry research.

He serves on the NIH Office of AIDS Research Working Group on HIV and Aging, and has participated in many NHLBI, National Institute on Aging and National Institute of Allergy and Infectious Diseases workshops and planning sessions. ▼

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# Family stories fuel donors' philanthropy

Heart disease showed no mercy when heart attacks hit brothers Harry and Chuck Sublett on the same day.

Chuck survived, but Harry didn't.

"That morning when I got up I would've said there was no heart disease in my family, and three hours later, I would say it's rampant," said their brother and longtime American Heart Association supporter Jim Sublett.

Jim knew he should get his own heart checked out. Soon there was more bad news. An artery was 100 percent blocked.

"It was a fluke that I was alive," Sublett said. Over the years, Jim's body had slowly grown collateral circulation to compensate for the reduced blood flow. It did him a big favor by diverting the flow around the blockage and reducing his risk of heart attack. He started taking statins to manage his cholesterol.

A few years later, in 2010, heart disease caught up with Jim's wife Donna. She was sitting at her computer when she felt intense pressure — like a mammogram machine was coming down on her chest. An artery was 65 percent blocked. After a stent, her doctor wished her well and said he didn't think he'd see her for a decade. He was off by about six years. In May 2014, Donna had more chest pains, another blocked vessel, another stent.

The Subletts had been AHA supporters since 1998, but they wanted to do even more after Donna's heart attack. They've



Jim and Donna Sublett

made a major donation to the AHA to fund five grants that focus on cardiovascular advances for women. They hope their support will help spare families the heartache their family has suffered.

"It was such a shock to us," said Donna. They'd always worried about Jim's heart, not hers, and she hadn't given much thought to her mom and dad's histories of heart disease and stroke. "I didn't have high blood pressure. I didn't have high cholesterol. I wouldn't have been the one that we picked."

Research, they know, is the key to the future.

The Subletts attend Scientific Sessions as honored guests. "It's very energizing — what they're doing and how they're going to change our lives," Jim said.

Each of the five grants the Subletts are funding is focused on heart disease and women because they feel research involving women has been overlooked. The studies will:

- Examine how to counteract some of the negative side effects of statins with a natural supplement derived from dark chocolate;
- Identify a new class of drugs to mimic statins using a different genetic target;
- Look for a new drug to treat plaque build-up in the arteries by examining how low oxygen levels at the buildup can trigger the production of more cholesterol;
- Determine if a specific molecule within a cell could be a new therapeutic target to lower LDL, or "bad" cholesterol;
- Uncover why women are disproportionately affected by congestive heart failure.

The Subletts call it a "no brainer" to support early researchers. In talking to researchers, they hear the same thing time and again, Donna said. "My first grant came from the AHA. I wouldn't be where I am today without them." ▼

## Unofficial Satellite Events

### SUNDAY, NOV. 8

7–9 p.m.

University/Nonprofit Symposium  
**Cardio-Oncology: A New Era, An Evolving Discipline**  
Sponsored by Mayo Clinic Division of Cardiovascular Diseases  
Supported by Mayo Clinic Division of Cardiovascular Diseases  
Rosen Centre Hotel, Grand A Ballroom  
Registration: 6:30–7 p.m.

7–9 p.m.

Industry-supported Symposium  
**New Tools for Managing Hyperkalemia: Cases in Heart Failure and Renal Disease**  
Sponsored by ZS Pharma  
Supported by ZS Pharma  
Rosen Centre Grand Ballroom D

7–9:15 p.m.


Industry-supported Symposium  
**Optimizing LDL-Targeted Cardiovascular Risk Reduction**  
Jointly Provided by the University of Massachusetts Medical School and CMEducation Resources, LLC  
Supported by an Independent Educational Grant from Sanofi and Regeneron Pharmaceuticals  
Hyatt Regency Orlando, Plaza Ballroom D-G  
Registration: [www.reg-LDL.com](http://www.reg-LDL.com)

7–10 p.m.

Industry-supported Symposium  
**AF Spotlight: Using NOACs Safely**  
Sponsored by Postgraduate Institute for Medicine and Medtelligence  
Supported by Boehringer Ingelheim Pharmaceuticals, Inc. and Daiichi Sankyo, Inc.  
Hyatt Regency Orlando, Windermere Ballroom W, Convention Level  
Registration: <http://events.medtelligence.net/ha2015.html>

7–10 p.m.


Industry-supported Symposium  
**Repatha™ (evolocumab): Product Overview**  
Sponsored by Amgen  
Supported by Amgen  
Hyatt Regency Orlando, Windermere X Room


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# PLAY 9 TO WIN!

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**PRESIDENT** continued from page 1

antiplatelet drugs were being prescribed for fewer than 20 percent of PAD patients who did not have previously established coronary or cerebrovascular disease."

Meanwhile, new antiplatelet drugs have the potential to reduce limb complications of PAD. Technology advances are leading to innovative imaging approaches using optical coherence tomography, intravascular ultrasound, PET computed tomography, contrast-enhanced magnetic resonance imaging and other modalities to image plaques and assess their vulnerability for rupture.

But new treatments only work if they're used, Creager said.

"We still have a long way to go in awareness, treatment and prevention to preserve vascular health," he said. "We must continually seek new and creative solutions."

One way the AHA is doing this is by "building a culture of health," Creager said. "We believe we can make a difference by helping people make healthy decisions wherever they are — at work, at school, at home and at play."

The AHA is working toward this goal by advocating for cigarette taxes, clean air laws, access to smoking cessation programs and a ban on marketing electronic cigarettes to children. On the local, state and national levels, the association also advocates for healthier nutrition and increased physical education in schools. In addition, it encourages companies to implement wellness programs that offer health education and supportive environments for employees. ▼

**ECPR** continued from page 1

206 (75 percent) also received therapeutic hypothermia. The 206 patients were stratified into three groups based on the duration of cooling: 24 hours or less (for a median of 24 hours), 24 to 48 hours (for a median of 39 hours) and more than 48 hours (for a median of 82 hours). The primary outcome was favorable 30-day neurologic assessment.

Any attempt at therapeutic hypothermia was associated with a larger proportion of patients with favorable 30-day neurologic outcomes — 15 percent — compared to ECPR alone at 1.5 percent ( $p=0.001$ ), Nagao said. The most favorable result was seen in patients who were cooled for 24 to 48 hours (25.4 percent), followed by cooling for more than 48 hours (19 percent) and less than 24 hours (8 percent,  $p=0.008$ ). The adjusted odds ratio for a favorable neurologic outcome at 30 days was 6.85 for therapeutic hypothermia for between 24 and 48 hours ( $p=0.001$ ), Nagao said.

The most effective core target temperature was 33°C, with an adjusted odds ratio of 5.26 for a favorable 30-day neurologic outcome ( $p=0.069$ ).

"The most important finding is that we should not give up on resuscitation," Nagao said. "We would like to see the addition of ECPR plus therapeutic hypothermia to the Japanese guidelines for CPR for patients with ventricular fibrillation cardiac arrest outside the hospital, based on these results. What we know now is that cooling for between 24 and 48 hours in combination with ECPR is associated with improved neurologic benefits. The next step will be to refine the inclusion criteria for this combined lifesaving procedure." ▼

**CROWDSOURCE** continued from page 1

The AHA is using PRANCCER to help fuel research advances that are expected to grow out of the new AHA Institute for Precision Cardiovascular Medicine. The institute is committed to creating novel grant and challenge opportunities and providing a rapidly growing portfolio of federated research data to cardiovascular and stroke researchers and bioinformaticians. The ultimate goal is to support the continuing development of precision medicine within a comparative effectiveness research framework. Improving comparative effectiveness research will enable clinicians and patients to gain useful information on the interventions that are the most effective for specific subsets of individuals. (See page 3 for more information about the

AHA Institute for Precision Cardiovascular Medicine.)

Crowdsourcing is a broad term that covers almost any type of outreach to large communities. Crowdsourcing funding has already seen significant success with the ALS Association Ice Bucket Challenge that raised awareness of amyotrophic lateral sclerosis in 2014. The challenge helped the ALS Association to increase its research funding from \$3.5 million and 21 projects to \$11.6 million and 58 projects.

In the biomedical sciences, crowdsourcing produced EyeWire, a game that allows anyone to help map the neuronal connectome in the brain. As gamers solve 3D puzzles, they construct 3D models of neurons at nanoscale resolution from electron microscopy images. ▼

**AHA professional website launching in February**

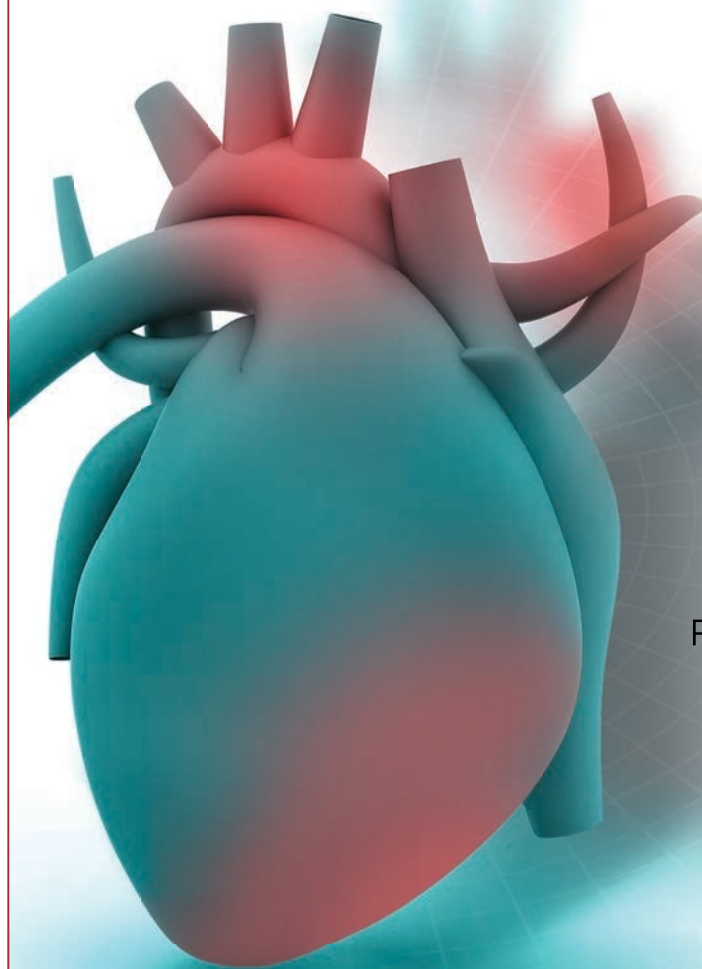
Look for a new site for professionals in February 2016. Professional Heart Daily, **Professional.heart.org**, aims to be the most authoritative, comprehensive web resource available to scientists, clinicians and healthcare providers.

The site, which is a benefit to AHA/ASA professional members, gives healthcare professionals a complete source of continually updated information. It will be better organized and easier to access. In the meantime, visit [my.americanheart.org](http://my.americanheart.org) for information on scientific statements, ACC/AHA practice guidelines, scientific meetings, research grants, council information and more.

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**Javed Butler, MD, MPH, MBA**  
Professor of Medicine, Chief of Cardiology  
Stony Brook University  
Stony Brook, New York

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# AHA supporters donate millions for research

Longtime American Heart Association supporters David and Stevie Spina are donating \$2.5 million to support research that would personalize ways to treat and prevent cardiovascular disease.

The donation, announced in early March, supports the Cardiovascular Genome-Phenome Study (CVGPS), which uses data from major studies to examine topics like cardiovascular aging and death in diverse populations, interactions between genes and diet in blood vessel problems, and genetic signatures of tobacco exposure.

David Spina has served in a variety of volunteer leadership positions and currently serves on the AHA's national board of directors. In 2003, after a heart attack and bypass surgery, his involvement became personal.

"Having a heart attack and observing the procedures to stabilize and restore my health allowed me to have a clearer understanding and appreciation of the knowledge and skill used by the medical team helping me," he said. "Today's knowledge is vastly more effective than the information available only 40 years ago, and the death rates from heart attack and stroke are much lower as a result."

Spina said he faced two kinds of challenges after his heart attack and bypass surgery — physical and emotional. He wrestled with diet and lifestyle changes while learning to keep up with doctors'

appointments and prescriptions. His sense of independence also took a hit.

"During my heart attack and bypass surgery, I felt a profound sense of dependency," Spina said. "I needed every bit of help I could get from the medical staff who cared for me. My personal challenge was to restore my sense of self-confidence to enable me to be confident about my future."

Spina's ordeal increased his desire to give back after "the help, skill and compassion that helped me when I needed it so much."

In total, the Spinas have donated more than \$6 million to the AHA. In 2008, they helped the association fund centers that research ways to improve outcomes for heart disease and stroke patients. The centers trained more than 20 postdoctoral fellows in outcomes research, 15 of whom have moved into faculty positions. More than 300 studies were published based on the centers' research.

The new donation adds to the Spinas' "already powerful legacy of philanthropy, which has benefited the American Heart Association mission in many important



David and Stevie Spina

ways," said organization CEO Nancy Brown. "All of us are inspired by their commitment to knowledge advancement and the discovery of unprecedented approaches to preventing and treating

cardiovascular diseases and stroke."

CVGPS researchers are accessing massive volumes of data from multiple studies, including the Framingham Heart Study, which has tracked cardiovascular disease in three generations of New Englanders, and the Jackson Heart Study, which focuses on cardiovascular diseases' impact on African-Americans. Spina believes CVGPS will make cardiovascular research even more effective in the future.

"I've learned the pivotal role the American Heart Association plays in translating scientific learning into daily use by doctors and hospitals, and the extensive work it does educating the public about heart health," he said. "My work let me develop a sense of confidence in the organization and its effectiveness in pursuing its mission. I hope my investment in CVGPS will encourage others to invest in the AHA too." ▼

## Google Life Sciences CEO to speak during Opening Session

Andrew Conrad, PhD, chief executive officer of Google Life Sciences, will present the Lewis A. Conner Memorial Lecture during Sunday's Opening Session, which takes



Andrew Conrad, PhD

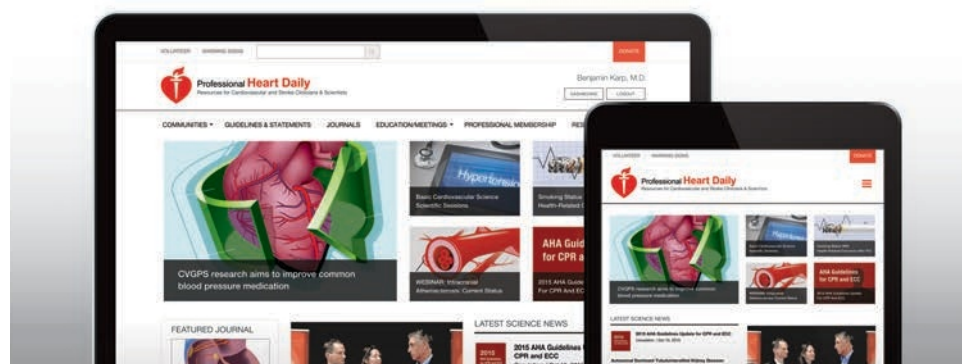
place from 1 to 3 p.m. in Hall D.

At Google Life Sciences, Conrad oversees more than 300 scientists working on a wide spectrum of healthcare projects. He's known for his efforts to shift the focus of U.S. healthcare from treatment to prevention, and for bringing researchers from a variety of backgrounds together to solve problems.

Conrad previously served as chief scientific officer of Laboratory Corporation of America (LabCorp). He co-founded the National Genetics Institute, where he served as chief scientific officer. Conrad also founded the California Health and Longevity Institute.

Conrad also serves as chief scientific advisor of the North Carolina Research Campus, an academic collaboration between Duke University, the University of North Carolina and North Carolina State University.

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**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 <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

<sup>†</sup>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.

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**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

<sup>†</sup>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

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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 v2, 09/15

**AMGEN®**

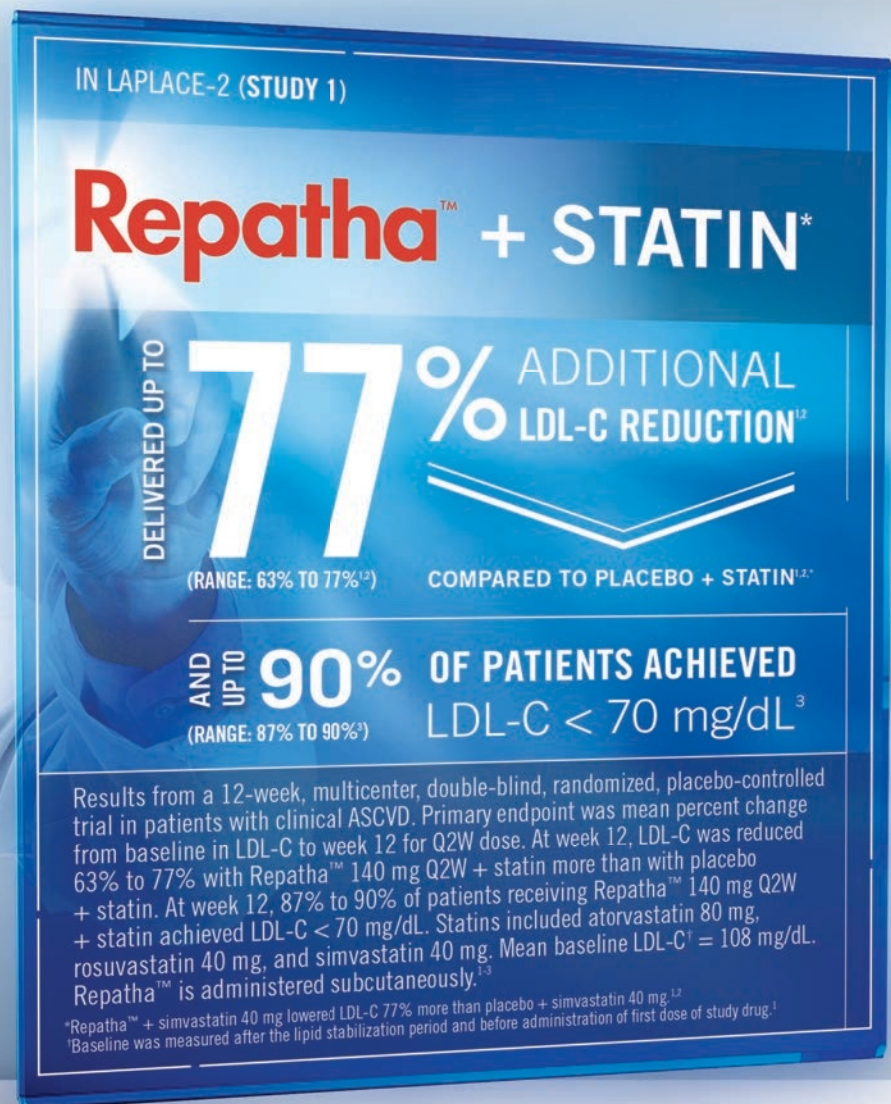
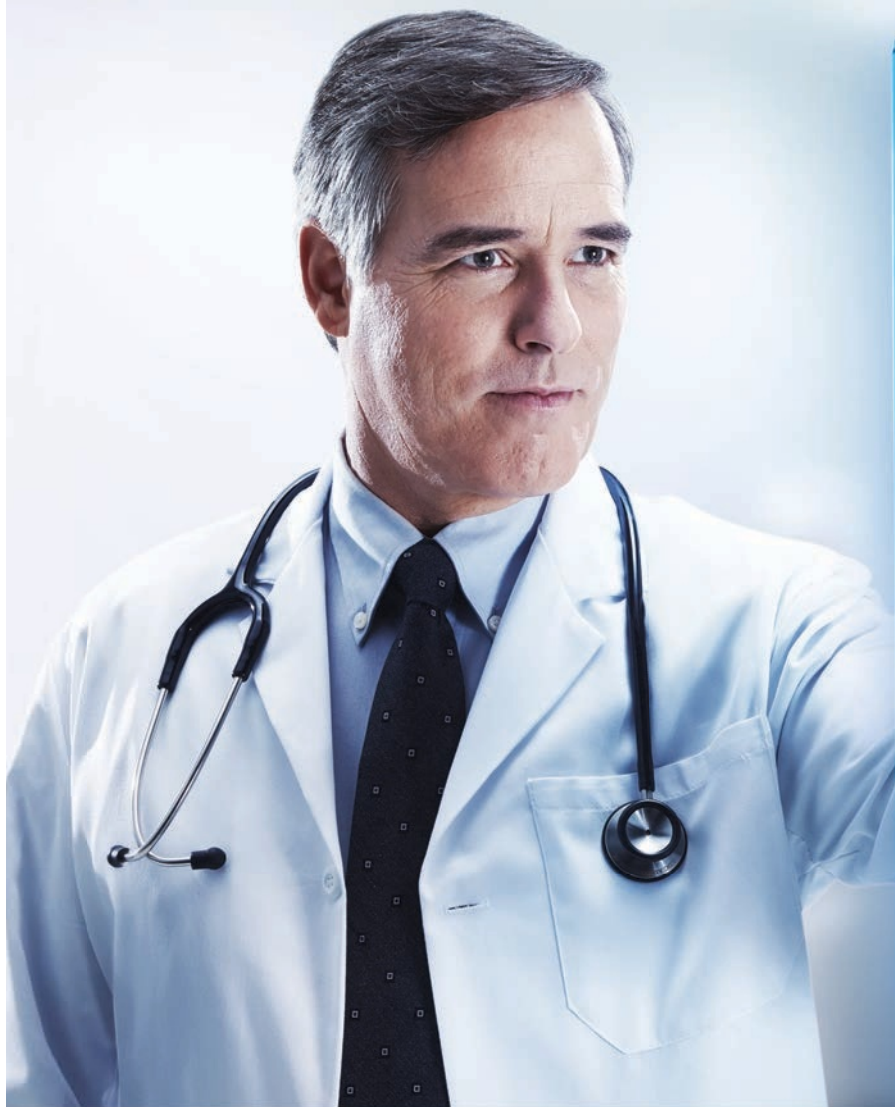
REPATHA™ (evolocumab)  
**Manufactured by:** Amgen Inc.  
One Amgen Center Drive  
Thousand Oaks, California 91320-1799  
U.S. License Number 1080  
Patent: http://pat.amgen.com/repatha/



**NOW APPROVED  
REPATHA™**

## A NEW PCSK9 INHIBITOR FOR INTENSIVE, PREDICTABLE LDL-C REDUCTION

in adults with clinical ASCVD or HeFH on maximally tolerated statin therapy as an adjunct to diet<sup>1</sup>



### Indication

- Repatha™ is a PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor antibody 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, who require additional lowering of LDL cholesterol (LDL-C).
- **Limitations of Use:** The effect of Repatha™ on cardiovascular morbidity and mortality has not been determined.

### 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, included: Local injection site reactions that 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. Repatha™ (evolocumab) Prescribing Information v2, Amgen. 2. Data on file, Amgen;[1]; 2015. 3. Data on file, Amgen;[2]; 2015.

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**AMGEN**  
Cardiovascular

 **Repatha™**  
(evolocumab) injection  
140 mg/mL