NEW 3-DAY MEETING. EXPERIENCE.

SCIENTIFIC SESSIONS

PREVIEW & PRELIMINARY PLANNER

So much to see and do at Scientific Sessions 2018. Highlights include Late-Breaking Science, Frontiers in Science Summits, State of the Art Cardiovascular Care, Health Innovation Pavilion, Simulation Learning, Poster Sessions and much more.
Now digitally enhanced, the latest edition of the latest edition of the AHA Journals’ Trend Watch is available online and includes content across the spectrum of cardiovascular and cerebrovascular disease. This issue of AHA Journals’ Trend Watch features a collection of top-trending articles published between April 2017 and March 2018, specifically those with high Altmetric scores. These articles—from across the entire AHA Journals’ portfolio—are generating buzz and have people talking on social media, in blogs, and in the news.

THE ISSUE IS ORGANIZED BY TOPIC TO MAKE FINDING RELEVANT CONTENT QUICK AND EASY!

- Heart Failure and Cardiomyopathies
- Cardiac Development, Structure, and Function
- Prevention Health and Wellness
- Epidemiology and Big Data
- Women and Special Populations
- Hypertension and Nephrology
- Dyslipidemia and Treatments
- Neuroscience and Stroke
- ATVB [Basic and Clinical]
- Electrophysiology and Arrhythmias
- Intervention
- Imaging and Nuclear Medicine
- Genetics and Genomics
- Critical and Emergency Care
Dear Colleagues:

It is my pleasure to invite you to attend the American Heart Association Scientific Sessions 2018 in Chicago, IL. This important event will provide a new dimension of cardiovascular discovery and clinical practice for clinicians, basic scientists and researchers. The new three-day format will include unparalleled opportunity to network with and learn from the preeminent leaders. Learn and interface with your colleagues from around the world in innovative, interactive sessions that feature cutting-edge topics across an array of specialties.

This annual event features many opportunities to learn and network with colleagues from around the world in an exciting environment. The scope and quality of the scientific exchange makes AHA Scientific Sessions the premier cardiovascular research and instructional meeting in the world. This events feature three days of the best in cardiovascular clinical practice and scientific content covering all aspects of basic, clinical, population and translational content.

Scientific Sessions is the AHA’s largest meeting of the year and features:

• Exciting Late-Breaking Science that will feature the latest breakthroughs in patient care
• A breakout Main Event session featuring the cutting-edge topics in CV science
• A three-day Health Tech Summit highlighting impactful innovations in the healthcare arena
• Compelling educational area for original science presentations in the Science and Technology Hall
• 26 tracks covering cardiovascular basic, translational, clinical and population science
• Over 800 sessions including thought-provoking Main Event programming and 4,000 abstracts

For these reasons and many more, I hope you’ll join me in Chicago this November.

Sincerely yours,

Eric Peterson, MD, MPH, FAHA
Chair, Committee on Scientific Sessions Program
What will everyone be talking about THIS year?

Witness the most highly anticipated, late-breaking cardiovascular trial announcements of 2018 in person. Then, explore lively conversations with colleagues (almost) as brilliant as you. The whole cardiovascular community is assembling. Are you coming?

REGISTER NOW at ScientificSessions.org
5 Reasons to attend Scientific Sessions

Scientific Sessions is a critical experience you should attend every year as a cardiovascular professional. You don’t want to miss this practice-changing programming that will impact patient outcomes through:

1. **2018 Cholesterol Clinical Practice Guidelines**
   Guideline release that will change the way practitioners evaluate and manage cholesterol in their patients.

2. **Department of Health and Human Services’ Physical Activity Guidelines for Americans**

3. **Health Tech Summit**
   3-day summit with innovative and scalable solutions through advanced technology to improve patient outcomes.

4. **State of the Art Cardiovascular Care Seminar**
   One-day seminar with the latest recommendations in clinical cardiovascular care.

5. **Main Event Sessions**
   Including “Bending the Curve in #CVD Mortality Colloquium: Bethesda + 40” and “Cutting Edge in Cardiovascular Care.”
26 Programming Communities help you focus your learning by specialty:

- Acute Coronary Syndromes
- Arteriosclerosis, Thrombosis, Vascular Biology
- Cardiac Development, Structure and Function
- Cardiometabolic Health and Diabetes
- Cellular Biology
- Congenital Heart Disease and Pediatric Cardiology
- Drug Discovery
- Electrophysiology and Arrhythmias
- Epidemiology, Big Data and Precision Medicine
- Genetics and Genomics
- Health Tech
- Heart Failure and Cardiomyopathies
- Hypertension and Nephrology
- Imaging and Nuclear Medicine
- Interventional Treatments
- Lifestyle & Behavioral Medicine
- Metabolism and Physiology
- Nursing Research and Clinical
- Prevention, Health and Wellness
- Pulmonary Hypertension and Critical Care
- Quality of Care
- Signaling
- Stroke & Neuroscience
- Surgery & Anesthesia
- Vascular Disease and Thrombosis
- Women and Special Populations

Whether your interest is Basic Science, Clinical Science or Population Science, Scientific Sessions 2018 has you covered.
As a member you can benefit from access to:

• Choosing up to three scientific councils*
• 11 online journals*
• Savings for online and in-person learnings
• Grant and research opportunities
• Access to the latest research
• Savings on Sessions OnDemand

and much more.

*depends on membership tier.

Join us in improving heart and brain health for today and tomorrow’s future.
AMP UP
YOUR
SCIENTIFIC SESSIONS
EXPERIENCE

More can’t-miss opportunities
• EP Central
• Interventional Central
• Health Innovation Pavilion
• Simulation Zone
• Complimentary coffee breaks
• Lunch in Cardiovascular Expert Theaters
• AHA HeartQuarters
• Posters integrated throughout the Science & Technology Hall
• Engage with nearly 200 exhibitors
• Hands-Only CPR training
• AHA Bistro
• Complimentary professional photos taken
• Charging Lounge

SCIENCE & TECHNOLOGY HALL HOURS
Saturday, Nov. 10: 11 a.m.-5 p.m.
Sunday, Nov. 11: 10 a.m.-4:30 p.m.
Monday, Nov. 12: 10 a.m.-3 p.m.
Frontiers in Science Summits Present Pre-Publication Science

It doesn’t get much more cutting-edge than this! The Four Frontiers in Science Summits bring together early, mid- and senior investigators to debate the most impressive pre-publication science in the areas of:

Arrhythmia Research
Explore therapeutic innovations in the mechanisms, diagnosis and management of arrhythmias.

Thrombosis
Learn about the most recent progress in thrombosis research, bridging from basic to clinical science.

Therapeutic Discovery
Uncover innovations in precision medicine, stem cells and genetics as well as learn the latest in classical drug development.

Vascular Disease
Participate in an intimate setting for intense open scientific discussion that encourages “cross-pollination,” shares proven methodologies that may apply more broadly across specialty areas and inspires scientific collaboration.
Your peers, colleagues, mentors and friends will be at Scientific Sessions 2018. Will you?

Thousands of cardiovascular professionals from across the globe will converge in Chicago this November for the American Heart Association’s renowned annual conference. At Scientific Sessions 2018, you will discover groundbreaking research, experience hands-on learning, explore best practices with peers, hear inspiring speakers and meet colleagues facing similar challenges.

GET STARTED at ScientificSessions.org
Scientific Sessions

BY THE NUMBERS

15.5 hours of Early Career programming

Whether you’re a Fellow in Training or in the early stages of your career, Scientific Sessions is the best way to take your career to the next level.

100 countries

Physicians, cardiology professionals, research scientists and non-healthcare professionals from around the world will convene in Chicago.

41% International

59% Domestic

Collaborating with both U.S. and international partners and attendees is what makes Scientific Sessions a can’t-miss event.

Improve patient outcomes with nearly 200 exhibitors

You’ll find an incredible array of technologies, treatments and services you can bring back to your practice and ultimately improve patient outcomes.

4 Frontiers in Science Summits

Each Frontiers in Science Summit dedicates one full day to profile scientific advances in quick, lightning-speed sessions focused on presenting the latest breakthroughs and pre-publication discoveries.

26 Programming Communities

Sessions are organized by 26 education communities — structured areas of interest meant to help you better navigate the meeting.
Take some science home

Pick up your complimentary copy of the Abstracts on USB in the Science & Technology Hall, Booth 1219.

Supported by Sanofi Regeneron
1 Three days designed with you in mind

You said, “shorter.” You got shorter. Five days shrunk to a schedule-friendly three days. And with the precision of a heart surgeon, the AHA has lovingly recrafted the event to deliver equivalent value in a more concise package.

You said, “easier.” You got easier. Programming is neatly arranged by science type and specialty. Locate your preferred sessions easily and quickly.

- Nov. 10 and 11
  Clinical and Population Science
- Nov. 11 and 12
  Basic Science
- Nov. 10 through 12
  Early Career

2 Advance your career

If you are looking for a position working in cardiology, visit the Science & Technology Hall at Scientific Sessions 2018 to gain access to the AHA Career Fair. The Career Fair provides you an opportunity to meet face-to-face with hiring representatives in all subspecialties and at all levels of training for hospitals and research facilities that have job openings, fellowships and other specialty programs.

This is your opportunity to make connections with colleagues and recruiters looking to hire cardiovascular professionals like you. Browse recruitment materials at your leisure in a no-pressure environment and meet one-on-one with representatives of top employers. There is no additional fee to participate; the AHA Career Fair is included in your registration.

3 State-of-the-Art Cardiovascular Care

Saturday, Nov. 10

This one-day seminar is dedicated to physicians, nurses and other health professionals to communicate the latest advances in clinical cardiovascular care. Session topics will provide recommendations and updates that can be incorporated into your everyday practice. You’ll have the chance to ask thought leaders your questions about state-of-the-art cardiovascular care.

4 Health Innovation Pavilion and Health Tech Summit

Tech-savvy cardiovascular professionals should put this new area on their must-visit list. The Health Innovation Pavilion is where you can see game-changing technologies, products and services in action and explore their roles in the treatment and prevention of cardiovascular disease. This learning destination will also feature an educational program developed by leaders from AHA’s Center for Health Technology and Innovation.

The pavilion also hosts the Health Tech Competition, which offers health startup finalists an opportunity to pitch their companies, “Shark Tank”-style, to venture capitalists and AHA VIPs who can help them reach the next level.

5 2018 AHA/ACC Cholesterol Clinical Practice Guidelines release

Introducing a new age in cholesterol management and evaluation.
WORLD-RENOVISED KEYNOTE

You’ve reached the top of your game by learning from researchers, scientists and doctors who were at the top of their games. We’ve lined up recognized professionals in their respective fields to share their knowledge with you in Chicago.

(Turn to page 24 for a complete list of faculty for Scientific Sessions 2018.)

**Basic**

**Stefanie Dimmeler, PhD, FAHA**
Institute of Cardiovascular Regeneration
Frankfurt, Germany

**Junichi Sadoshima, PhD, MD, FAHA**
Rutger, New Jersey

**Clinical**

**Robert Harrington, MD, FAHA**
Stanford
San Francisco, California

**John McMurray, MD, FAHA**
University of Glasgow
UK Glasgow, United Kingdom

**Lynne Warner Stevenson, MD, FAHA**
Vanderbilt University
Boston, Massachusetts

**Clyde Yancy, MD, MSc, FAHA**
Northwestern University
Chicago, Illinois
SPEAKERS

Population

Michelle Albert, MD, MPH, FAHA
University of California – San Francisco
San Francisco, California

John Spertus, MD, FAHA
Mid America Heart Institute
Kansas City, Missouri

Neil Stone, MD, FAHA
Northwestern University
Chicago, Illinois

Nursing

Tamilyn Bakas, PhD, RN, FAHA
University of Cincinnati
Cincinnati, Ohio

Gia Mudd-Martin, PhD, MPH, RN, FAHA
University of Kentucky
Lexington, Kentucky

Erin Ferranti, PhD, FAHA
Emory University
Atlanta, Georgia

Learn from TOP LEADERS

Scientific Sessions is jam-packed with educational sessions featuring the world’s top leaders in the areas of cardiovascular disease and treatment.
Networking and Collaboration Opportunities

Scientific Sessions brings together researchers and clinicians from across the globe. There’s no better way to network with your peers and thought leaders. Visit our specialized lounges for targeted networking and collaboration opportunities.
Early Career and FIT Lounge
Are you early career or a Fellow in Training (or soon to be one)? This is the place to meet with leading healthcare experts, gather career-building resources and network with your peers. This lounge will host educational sessions about conducting research, social media presence, peer-reviews, meeting journal editors and AHA leadership.

Women in Science and Medicine Lounge
Are you a woman in the field? Exchange stories and strategies from female clinicians and researchers around the world in all stages of their career. Educational sessions will be available from the Women in Science and Medicine Task Force.

FAHA Lounge
Have you achieved Fellow of the American Heart Association status? This lounge is open to the members of AHA who have earned their designation as FAHAs. Enjoy the planned networking activities, comfortable seating and multiple amenities that will make this area your home while at Scientific Sessions.

EP Central
Are you an electrophysiologist? Making its debut in 2015, this lounge quickly became an attendee favorite. Engage with fellow electrophysiologists and others interested in EP in this networking and learning hub devoted to the specialty. This year we have an expanded schedule of non-CME accredited education, career development activities and information relevant to the EP community.

Interventional Central
Do you specialize in interventional cardiology? This is your home base. This year, we have an expanded schedule of programming topics like challenging cases, career development, hot topics, and more. While here, you can network and exchange information with peers, and gather career-building resources.

Simulation Zone
Do you like to roll up your sleeves and get hands-on experience? Head to the interactive area in the Science & Technology Hall during scheduled sessions or at your convenience to test your cardiac knowledge, skills and critical thinking.

Posters
Are you interested in the latest research? This is the place to learn about the latest original research. We’ll feature six categories: Clinical, Population, Basic Science and Best of Specialty.
## SCIENTIFIC SESSIONS 2018 PROGRAM AT A GLANCE

### SATURDAY
- **Clinical/Pop/Programming**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
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<tbody>
<tr>
<td>7:15-8:45 AM</td>
<td>Community Programming</td>
</tr>
<tr>
<td>9:00 AM-NOON</td>
<td>Main Events, Late Breaking Science and Community Programming</td>
</tr>
<tr>
<td>2:00-5:00 PM</td>
<td>Science &amp; Technology Hall 11:00 AM-5:00 PM</td>
</tr>
<tr>
<td>5:00-7:00 PM</td>
<td>Community Programming</td>
</tr>
<tr>
<td>6:30-10:00 PM</td>
<td>Industry Events</td>
</tr>
</tbody>
</table>

### ADDITIONAL PROGRAMS
- State of the Art in Cardiovascular Care
- Health Tech Summit
- Frontiers ARS
- Early Career
- Frontiers Vascular Disease

### SUNDAY
- **Clinical/Pop/Basic/Programming**

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### ADDITIONAL PROGRAMS
- Clinical Nursing Symposium
- Health Tech Summit
- Early Career

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**Educational Sessions**

**Science & Technology Hall**

**AHA Events and Meetings**
Our Mission
To be a relentless force for a world of longer, healthier lives.
DON’T MISS THE CARDIOVASCULAR EXPERT THEATER SESSIONS

Enjoy a complimentary lunch* while learning the latest advances in cardiovascular practices, services and technologies.

### SATURDAY

<table>
<thead>
<tr>
<th>BOOTH</th>
<th>SESSION START/END TIME</th>
<th>SUPPORTER</th>
<th>TITLE</th>
</tr>
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<tbody>
<tr>
<td>250</td>
<td>Noon-12:45 p.m.</td>
<td>Janssen Biotech, Inc.</td>
<td>Clinical Information For Patients With Thrombotic Risk</td>
</tr>
<tr>
<td></td>
<td>1:15-2 p.m.</td>
<td>Amgen, Inc.</td>
<td>Repatha® (evolocumab) Putting it Into Practice</td>
</tr>
<tr>
<td></td>
<td>3:15-4 p.m.</td>
<td>Boehringer Ingelheim Corp.</td>
<td>Embolic Stroke of Undetermined Source</td>
</tr>
<tr>
<td>2002</td>
<td>Noon-12:45 p.m.</td>
<td>Sanofi Regeneron</td>
<td>PRALUENT (Alirocumab) Injection – The Time to Treat is Now</td>
</tr>
<tr>
<td></td>
<td>1:15-2 p.m.</td>
<td>Novartis Pharmaceuticals Corp.</td>
<td>HF/EF AND SUDDEN CARDIAC DEATH: INSIGHTS FROM A LARGE HF OUTCOME STUDY</td>
</tr>
<tr>
<td>2038</td>
<td>Noon-12:45 p.m.</td>
<td>Amgen, Inc.</td>
<td>Understanding the Spectrum of LDL-C in CV Disease: A Focus on Low LDL-C</td>
</tr>
<tr>
<td></td>
<td>1:15-2 p.m.</td>
<td>Boehringer Ingelheim Corp.</td>
<td>Jardiance® (empagliflozin) tablets: Evolving Clinical Development</td>
</tr>
</tbody>
</table>

### SUNDAY

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<tbody>
<tr>
<td>250</td>
<td>10:15-11 a.m.</td>
<td>Amarin Corp.</td>
<td>Does VASCEPA® (icosapent ethyl) Prevent Cardiovascular Disease? New data from REDUCE-IT™</td>
</tr>
<tr>
<td></td>
<td>Noon-12:45 p.m.</td>
<td>Amgen, Inc.</td>
<td>Who Are The Highest Risk CV Patients &amp; How Do We Manage Them?</td>
</tr>
<tr>
<td></td>
<td>1:15-2 p.m.</td>
<td>Novartis Pharmaceuticals Corp.</td>
<td>To Be Announced</td>
</tr>
<tr>
<td></td>
<td>3:15-4 p.m.</td>
<td>Janssen Pharmaceuticals, Inc.</td>
<td>Long-Term Results of Treatment Across a Broad Range of Patients With Type 2 Diabetes</td>
</tr>
<tr>
<td>2002</td>
<td>Noon-12:45 p.m.</td>
<td>Novartis Pharmaceuticals Corp.</td>
<td>Expert Conversations in Heart Failure With Preserved Ejection Fraction</td>
</tr>
<tr>
<td></td>
<td>1:15-2 p.m.</td>
<td>BMS Pfizer</td>
<td>Diagnosing Atrial Fibrillation: Current Challenges and the Future Connected World</td>
</tr>
<tr>
<td>2038</td>
<td>Noon-12:45 p.m.</td>
<td>Janssen Biotech, Inc.</td>
<td>Clinical Information For Patients With Thrombotic Risk</td>
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<td>Amgen, Inc.</td>
<td>Repatha® (evolocumab) Putting it Into Practice</td>
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### MONDAY

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<tr>
<th>BOOTH</th>
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<th>TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>Noon-12:45 p.m.</td>
<td>Amarin Corp.</td>
<td>Cardiovascular Risk Reduction with VASCEPA® (icosapent ethyl): Data from REDUCE-IT™</td>
</tr>
</tbody>
</table>

*Provided to attendees by the American Heart Association. This event is not part of the official Scientific Sessions as planned by the AHA Committee on Scientific Sessions Programming.
3 DAYS PACKED WITH LEARNING

Here are just a few of the can’t-miss sessions we have lined up for you.

SATURDAY, NOV. 10

MAIN EVENTS

9 a.m.-10:15 a.m.
Cutting Edge in Cardiovascular Science

9 a.m.-10:15 a.m.
The Future of Your Aortic Valve

10:45-Noon
2018 Cholesterol Clinical Practice Guidelines

10:45 a.m.
Hey Doc, My Wristband Says I Have AF, What Do I Do Now?

10:45 a.m.
Prevention Beyond the Guidelines: What to Do Next

2 p.m.
Structural Heart Disease, 3D Imaging and Artificial Intelligence

3:45 p.m.
Shocking Controversies From the Edge! Saving the Sickest Against All Odds

3:45 p.m.
You Are What You Eat: The Intestinal Microbiome and Cardiometabolic Disease

5:30 p.m.
State of the Heart for Women: Top 10 Advances in Gender-Specific Medicine

EARLY CAREER

7:15 a.m.
Big Data, Small Data: David & Goliath

9 a.m.
Navigating Early Career Waters: Mentors, Funding and Life Balance?

2 p.m.
The Next Steps in Your Cardiology Career: An Interactive Session With Mentors

While every effort is made to ensure the accuracy of data within this publication, the publisher cannot be held responsible for errors or omissions.

Data current as of Aug. 31, 2018.
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Data current as of Aug. 31, 2018.
3:45 p.m.
3CPR: Shark Tank Style

5:30 p.m.
Tackling Big Data: Network Systems Analysis for High Throughput Data Interpretation

5:30 p.m.
Communication: Pearls and Perils

MONDAY, NOV. 12

MAIN EVENTS

9 a.m.
Trending Topics in Clinical Science

9 a.m.
Trending Topics in Population Science

10:45 a.m.
Unpacking the Cardiovascular Biology of Violence

3:45
Trending Topics in Basic Science

FRONTIERS IN THROMBOSIS

7:15 a.m.
Inflammatory Mechanisms in Thrombosis

9 a.m.
Cancer and Thrombosis

10:45 a.m.
Urgent Diagnosis and Management of Aggressive Thrombosis Syndromes

THERAPEUTIC DISCOVERY SUMMIT

7:15 a.m.
Stem Cells and Their Derivatives as Therapeutics

9:00 a.m.
Genetics and Precision Medicine

10:45 a.m.
Nucleotide-based Therapies

2:00 p.m.
Innovations in Classical Drug Development

3:45 p.m.
Therapeutic Discovery Summit: Biomaterials & Engineered Tissues

5:30 p.m.
Emerging Topics in Therapeutic Discovery

Programming is subject to change. Please check http://bit.ly/AHA18ProgramPlanner
SEE THE LATEST AND GREATEST

Stop by and visit the Health Innovation Pavilion (Booth 214) and learn about health innovations and medical technology. A variety of companies and start-ups will be showcasing their products and services during Sessions.

EDUCATIONAL PROGRAMMING:

- Health Tech in the Home
- Health Tech Inside the Health System
- Machine Learning for Dummies
- Machine Learning Demonstration Showcase
- The Future: How Will Data Science Improve Health Care?
- Tech-Enabled Clinical Trials

Join us for the 2018 HEALTH TECH COMPETITION

Saturday, Nov. 10 | 1 p.m.

Watch as start-up finalists “pitch” their companies to a panel of judges, and then vote for your favorites!
Follow these steps for seamless registration:
From Sept. 5 to Oct. 10, you will receive the advance rate.
From Oct. 11 to Nov. 16, the standard rate applies.

Visit ScientificSessions.org to REGISTER TODAY.

We’ve got a comfy room waiting for you. Book now!
The AHA has negotiated special rates and added-value benefits
with 42 partner hotels in Chicago.

Visit ScientificSessions.org to select to SELECT AND BOOK YOUR HOTEL.
Meet the AHA Scientific Sessions 2018 Faculty

A
Antonio Abbate
Jinnette Abbott
Marwah Abdalla
Dale Abel
Evan Dale Abel
Willie Abel
Charbel Abi Khalil
Jamil Aboulhosn
Daryl Abrams
Tushar Acharya
Stephan Achenbach
Jonathan Afilalo
Amrita Ahluwalia
Faraz Ahmad
Zahid Ahmad
Ernesto Aiello
Elena Aikawa
Masanori Aikawa
Olujimi Ajijola
Fadi Akar
Takashi Akasaka
Junya Ako
Jassim Al suwaidi
George Alba
Gregory Albers
Christine Albert
Michelle Albert
Denilson Albuquerque
Pilar Alcaide
Sana Al-Khatib
Rasha Al-Lamee
Larry Allen
Norrina Allen
Matthew Allison
Alvaro Alonso
M. Chadi Alraies
Amrut Ambarekdar
Nicholas Amoroso
Sonia Anand
Douglas Anderson
Jeffrey Anderson
Mark Anderson
Dominick Antiglillo
John Angle
Shiva Annamalai
Sameer Ansari
Fabrice Antigny
Elliott Antman
Charles Antzenевич
Lawrence Appel
Elena Arbelo
Eloisa Arbustini
Stephen Archer
Reza Ardehali
Aimee Armstrong
Donna Arnett
Herbert Aronow
Wilbert Aronow
Pankaj Arora
Kent Arrell
Nancy Artinian
Shipra Arya
Anita Asgar
Aarti Asnani
Karen Aspy
Pavan Atluri
Brett Atwater
Scott Auerbach
Eric Austin
Leon Axel
David Axelrod
Dawn Aycock
Shyam Bansal
Wei Bao
Ana Barac
Adrian Baranchuk
Dianna Bardo
John Barnard
Geoffrey Barnes
Kelly Baron
Weimar Barroso
Gregory Barsness
Carlo Bartoli
Monica Baskin
Sukhdeep Basra
Eric Bates
Katherine Bates
Seth Baum
Lisa Baumann Kreuziger
Iris Baumgartner
Joseph Bavaria
Jeroen Bax
Blaise Baxter
Antonio Bayes De Luna
Garth Beache
Andrea Beaton
Theresa Beckie
Joshua Beckman
Elijah Behr
Natalie Bello
John Beltrame
Wilson Lam  
Hildo Lamb  
Linda Lambert  
Rachel Lampert  
Fernando Lanas  
Andrew Landstrom  
John Lane  
Irene Lang  
Tamara Langeberg  
Joe Lau  
Yuk Law  
Patrick Lawler  
Jennifer Lawton  
Nhat-Tu Le  
Miguel Leal  
Scott Lear  
Linda Leatherbury  
Guillaume Lebreton  
Agnes Lee  
Anson Lee  
Christopher Lee  
Barbara Leeper  
Nicholas Leeper  
David Lefer  
Leslie Leinwand  
Lawrence Leiter  
Carrie Lenneman  
Terry Lennie  
Steven Lentz  
Jane Leopold  
Edgar Lerma  
Alexander Leung  
Florian Leuschner  
Scott Levick  
Benjamin Levine  
Glenn Levine  
Jerrod Levy  
Thorsten Lewalter  
E. Douglas Lewandowski  
Eldrin Lewis  
Megan Lewis  
Sandra Lewis  
Tene Lewis  
Klaus Ley  
Chuanfu Li  
Ji Li  
Song Li  
Mingyu Liang  
Peter Libby  
Alice Lichtenstein  
Brian Lima  
Jooa Lima  
Jennie Lin  
JoAnn Lindenfeld  
Merry Lindsey  
Mark Link  
Diana Litmanovich  
Sheldon Litwin  
Bo Liu  
Donald Lloyd-Jones  
Cecilia Lo  
Deborah Lockwood  
Alexander Logan  
Chris Longenecker  
Gary Lopaschuk  
Patricia López-Jaramillo  
Angela Lorts  
Joseph Loscalzo  
Jimmy Lu  
Steven Lubitz  
Burkard Ludwig  
Russell Luepker  
Tom Lumbers  
Thomas Lüscher  
Aldons Luís  
Daniel Lustgarten  
Esther Lutgens  
Alicia Lyle  
Karen Lyons  
Pedro Mata  
Kunihiro Matsushita  
David Mattson  
C. David Mazer  
Mjaye Mazwi  
Robert McBane  
Michael McConnell  
Keith McCrae  
Brian McCrindle  
Peter McCullough  
George McDaniel  
Mary McDermott  
Doff McElhinney  
John McEvoy  
Francis McGowan  
Anthony McGuire  
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William McKenna  
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EXHIBITORS

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Data current as of Aug. 31, 2018.
REPATRA® (evinacumab) injection, for subcutaneous use

**BRIEF SUMMARY OF PRESCRIBING INFORMATION**

Please see package insert for full Prescribing Information.

**INDICATIONS AND USAGE**

1. Prevention of Cardiovascular Events in adults with established atherosclerotic cardiovascular disease. REPATRA® is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization.

2. Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia)

REPATRA® is indicated as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C).

3. Heterozygous Familial Hypercholesterolemia

REPATRA® is indicated in patients with a history of a serious hypersensitivity reaction to REPATRA® [see Warnings and Precautions (5.1)].

**5. WARNINGS AND PRECAUTIONS**

5.1 Allergic Reactions

Hypersensitivity reactions, including rash, urticaria, have been reported in patients treated with REPATRA®, including some that led to discontinue of treatment. If signs or symptoms of serious allergic reactions occur, discontinue treatment with REPATRA®, 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 in the clinical trials of a drug may not be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adverse Reactions in Adults with Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia)

The data described below reflect exposure to REPATRA® in 8 placebo-controlled trials that included 1,985 patients treated with REPATRA® and 1,957 patients treated with placebo. Most patients were randomized to REPATRA® or placebo for 26 weeks and 315 exposed for 1 year, median treatment duration of 12 weeks. The median age of patients in the pooled population was 57 years; 65% were older than 65 years. 57% of patients were women, 85% White, 6% Black, 8% Asian, and 2% other races.

Adverse Reactions in a 27-Week Controlled Trial

In a 27-week, double-blind, randomized, placebo-controlled trial (Study 3 DESCRIBES, NCT01375437), 399 patients received 300 mg REPATRA® subcutaneously every 2 weeks and 315 patients received REPATRA® subcutaneously once monthly [see Clinical Studies (14.2)]. The mean age was 56 years (range: 21-92 years), 63% were older than 65 years, 56% were women, 85% White, 6% Black, 8% Asian, and 5% other races. Adverse reactions reported in at least 2% of patients treated with REPATRA® or placebo are shown in Table 1. Adverse reactions led to discontinuation of treatment in 2.7% of REPATRA®-treated patients and 1% of placebo-treated patients.

Table 1. Adverse Reactions Occurring in Greater than or Equal to 2% of Placebo- and REPATRA®-treated Patients and More Frequently than Placebo in DESCRIBES Placebo (N=315) % REPATRA® (N=399) %

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Placebo (N=315)</th>
<th>REPATRA® (N=399)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>3.9</td>
<td>3.0</td>
</tr>
<tr>
<td>Back pain</td>
<td>2.2</td>
<td>2.0</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>2.0</td>
<td>1.8</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>1.6</td>
<td>1.4</td>
</tr>
<tr>
<td>Nausea</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Muscle spasm</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Urticaria</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>Gaugh</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Influence</td>
<td>1.1</td>
<td>1.2</td>
</tr>
<tr>
<td>Constipation</td>
<td>0.5</td>
<td>0.6</td>
</tr>
</tbody>
</table>

+140 mg every 2 weeks and 420 mg once monthly combined

Data

Animal Data

In cynomolgus monkeys, no effects on embryo-fetal or postnatal development up to 6 months of age were observed when evinacumab was dosed during organogenesis through the end of pregnancy. The subcutaneous route of administration at exposures 30- and 10-fold the human exposure during organogenesis did not result in teratogenic effects in the monkey. Human IgG is present in human milk, but published data suggest that breast milk antibodies do not enter the neonatal and intestinal circulation in substantial amounts.

Risk Summary

There is no information regarding the presence of evinacumab in human milk, the effects on the nursing infant, or the effects of milk production. The development and health benefits of breastfeeding should be considered along with the mother’s clinical need for REPATRA® and any potential adverse effects on the infant when repatrisocin or REPATRA® is the mother’s medication. Human IgG is present in human milk, but published data suggest that breast milk antibodies do not enter the neonatal and intestinal circulation in substantial amounts.

In controlled trials, 7,665 (41%) patients treated with REPATRA® were 65 years and older, and 1,500 (7%) were 75 years and older. 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 in the elderly and younger patients, but greater sensitivity to other adverse effects or altered drug dynamics in these older individuals cannot be ruled out.

8.6 Renal Impairment

No dose adjustment is needed in patients with renal impairment [see Clinical Pharmacology (12.7)].

8.7 Hepatic Impairment

No dose adjustment is needed in patients with mild to moderate hepatic impairment [see Clinical Pharmacology (12.7)].

12. NONCLINICAL TOXICOLOGY

12.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In 1-year, postnecrosis alcoholic hepatitis is the highest dose of systemic exposures up to 38- and 15-fold the recommended human exposures of 140 mg every 2 weeks and 420 mg once monthly, respectively, based on plasma AUC. The most commonly observed effect was decreased body weight. 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 development toxicology study in hamsters when evinacumab was subcutaneously administered at 10, 30, and 100 mg/kg (e.g., the maximum exposures of 44 and 440 mg every 2 weeks or 1,100 mg every 4 weeks, respectively). In addition, there were no evinacumab-related effects on estrus cycle length. Reproductive organ histopathology, menstrual cycling, or sperm parameters in these studies was not evaluated.

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Indications

- **Prevention of Cardiovascular Events:** In adults with established cardiovascular disease, Repatha® is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization.

- **Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia):** Repatha® is indicated as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C).

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 in Primary Hyperlipidemia, Including HeFH:** The most common adverse reactions (>5% of Repatha®-treated patients and occurring more frequently than placebo) in clinical trials in primary hyperlipidemia (including HeFH) 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).

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 0.3%, respectively.

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

- **Adverse Reactions in the Cardiovascular Outcomes Trial:** The safety profile of Repatha® in this trial was generally consistent with the safety profile described above in the 12- and 52-week controlled trials involving patients with primary hyperlipidemia (including HeFH). Serious adverse events occurred in 24.8% and 27.4% of Repatha®-treated and placebo-treated patients, respectively. Adverse events led to discontinuation of study treatment in 4.4% of patients assigned to Repatha® and 4.2% assigned to placebo. Common adverse reactions (>5% of patients treated with Repatha® and occurring more frequently than placebo) included diabetes mellitus (8.8% Repatha®, 8.2% placebo), nasopharyngitis (7.8% Repatha®, 7.4% placebo), and upper respiratory tract infection (5.1% Repatha®, 4.8% placebo).

Among the 16,676 patients without diabetes mellitus at baseline, the incidence of new-onset diabetes mellitus during the trial was 8.1% in patients assigned to Repatha® compared with 7.7% in those assigned to placebo.

- **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 previous page.

References: