ACC.16 Expo Daily
APRIL 3, 2016 | CHICAGO
SUNDAY
65TH ANNUAL SCIENTIFIC SESSION & EXPO

CONTINUE YOUR **EDUCATIONAL EXPERIENCE** WITH
ACC.16 LEARNING DESTINATIONS

Industry-Expert Theater 1
#24100

Industry-Expert Theater 2
#25078

Innovation Stage
#24046

Interactive Learning Labs
#13016, #17021

Patient Engagement Pavilion
#24035

Sim Center
#24062

SEE THE **FULL SCHEDULE** INSIDE

TODAY'S EXPO HOURS

9:30 a.m. – 4:45 p.m.

TODAY'S EXPO BREAKS

9:30 a.m. – 10:45 a.m.
12:15 p.m. – 2:00 p.m.
3:30 p.m. – 4:45 p.m.

Non-Statin Treatment: The Place of PCSK9 Inhibitors For LDL-C Reduction

Solutions and questions came with the approval of alirocumab and evolocumab, the first two agents in a new class of proprotein convertase subtilisin/kexin 9 (PCSK9) inhibitors, by the U.S. Food and Drug Administration last summer. Approved as adjunctive treatment for persistently elevated levels of LDL-C despite diet and maximally-tolerated statin therapy, these drugs are an important solution for selected patients, including adults with familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease with residual risk.

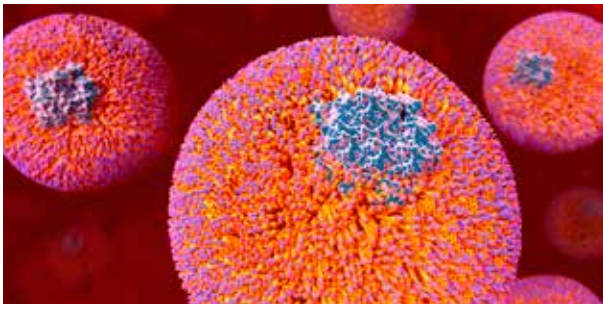
Key among the questions is whether the substantial reduction in LDL-C produced by these drugs will also reduce cardiovascular events and save lives and what is the long-term safety profile, along with the appropriate treatment algorithm and the impact of their cost.

"We are eagerly looking forward to the results of the larger outcomes trials to have a better understanding of the risk-benefit profile of the PCSK9 inhibitors," says **Christie Ballantyne, MD, FACC,** chair and moderator of ACC's LDL: Address the Risk Think Tank, which took place this past September at ACC's Heart House in Washington, DC. The event-driven FOURIER trial with evolocumab is anticipated to be completed in 2017 and the ODYSSEY study with alirocumab in 2018.

The approval studies demonstrated good tolerability and efficacy, with reductions in LDL-C ranging from 47-56 percent with evolocumab and from 39-62 percent with alirocumab, compared with placebo, on top of maximally-tolerated statin therapy and diet.

"Statins remain the mainstay of treatment," says Ballantyne, and have the bulk of the evidence for lowering LDL-C and hard outcomes. The emphasis continues to be matching the intensity of statin treatment to the patient's level of risk, as first recommended by the 2013 ACC/American Heart Association guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular disease (ASCVD) risk, which identified four statin benefit groups.

The PCSK9 inhibitors provide a more potent drug for combination therapy with a statin, providing a greater



reduction in LDL-C than the modest (~20 percent) reduction achieved with ezetimibe added to the moderate-intensity simvastatin in the IMPROVE-IT trial in high-risk patients who had an acute coronary syndromes. This was the first trial to show a benefit with the addition of a non-statin drug and provided further evidence for the LDL hypothesis of clinical benefit with lower levels of LDL-C.

For high-risk patients with clinical atherosclerotic disease and familial hypercholesterolemia, including those with true statin intolerance, "these drugs are a breakthrough that provide the first new treatment for elevated LDL-C in decades," says **Kim Birtcher, MS, PharmD, AACC,** chair of the ACC's LDL: Address the Risk Oversight Workgroup. In the absence of the hard data needed from the randomized, controlled trials with these drugs, there are preliminary data from the approval study with evolocumab suggesting a reduction in cardiovascular events and safety, although the follow-up was only 18 months.

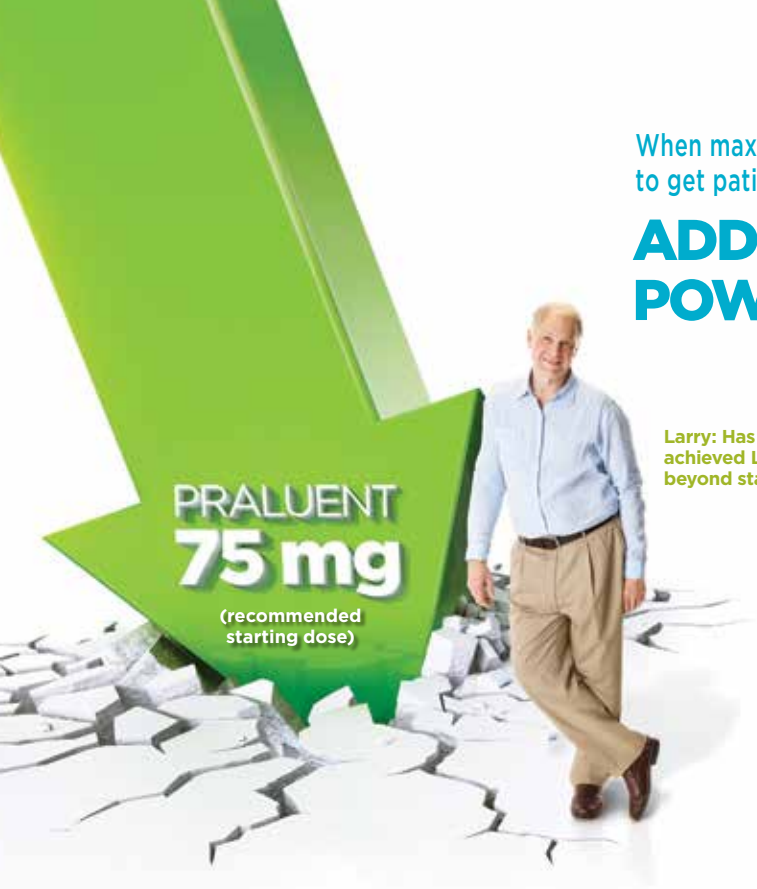
In terms of long-term safety, experts will be looking for signals of possible downsides of lowering LDL-C to much lower levels than previously achieved. There are concerns that if LDL-C is too low there could be negative neurocognitive effects and an increased risk of diabetes and hemorrhagic stroke.

The College has published an Expert Consensus Decision Pathway on the role of non-statin therapies for LDL-C lowering in the management of ASCVD risk to complement the guidelines and bridge the gaps in

continued on page 19

When maximally tolerated statins and diet aren't enough to get patients with clinical ASCVD or HeFH to their LDL-C goal...

ADD PRALUENT® (alirocumab): POWER LIKE NEVER BEFORE...



Larry: Has ASCVD and achieved LDL-C reduction beyond statins[1]*

INDICATIONS AND USAGE

- PRALUENT is a PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) inhibitor antibody indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C
- The effect of PRALUENT on cardiovascular morbidity and mortality has not been determined

IMPORTANT SAFETY INFORMATION

- PRALUENT is contraindicated in patients with a history of a serious hypersensitivity reaction to PRALUENT. Reactions have included hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization
- Hypersensitivity reactions (e.g., pruritus, rash, urticaria), including some serious events (e.g., hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization), have been reported with PRALUENT treatment. If signs or symptoms of serious allergic reactions occur, discontinue treatment with PRALUENT, treat according to the standard of care, and monitor until signs and symptoms resolve
- The most commonly occurring adverse reactions (≥5% of patients treated with PRALUENT and occurring more frequently than with placebo) are nasopharyngitis, injection site reactions, and influenza
- Local injection site reactions including erythema/redness, itching, swelling, and pain/tenderness were reported more frequently in patients treated with PRALUENT (7.2% versus 5.1% for PRALUENT and placebo, respectively). Few patients discontinued treatment because of these reactions (0.2% versus 0.4% for PRALUENT and placebo, respectively), but patients receiving PRALUENT had a greater number of injection site reactions, had more reports of associated symptoms, and had reactions of longer average duration than patients receiving placebo
- Neurocognitive events were reported in 0.8% of patients treated with PRALUENT and 0.7% of patients treated with placebo. Confusion or memory impairment were reported more frequently by those treated with PRALUENT (0.2% for each) than in those treated with placebo (<0.1% for each)

*Not actual patients; individual results may vary.

†Patients started on PRALUENT 75 mg Q2W in addition to existing statin therapy: Up-titration to 150 mg Q2W occurred at week 12 in 17% of patients who did not achieve their predefined target LDL-C at week 8.[1]

LDL-C = low-density lipoprotein cholesterol; **ASCVD =** atherosclerotic cardiovascular disease; **HeFH =** heterozygous familial hypercholesterolemia.

...AND MORE POWER IF YOU NEED IT

Stephanie: Has ASCVD and achieved LDL-C reduction beyond statins[1]*

PRALUENT offers 2 doses with 2 levels of efficacy[1]

In COMBO I

44% LDL-C reduction at 24 weeks on top of statins starting with **PRALUENT 75 mg**†

In the LONG TERM Study

58% LDL-C reduction at 24 weeks on top of statins with **PRALUENT 150 mg**

The recommended starting dose is 75 mg every 2 weeks[1]

CLINICAL STUDIES

COMBO I (Study 2) was a multicenter, double-blind, placebo-controlled trial that compared PRALUENT (n=209) with placebo (n=107). Patients were taking maximally tolerated doses of statins with or without other lipid-modifying therapy, and required additional LDL-C reduction. The mean age was 63 years (range 39-87), 34% were women, 82% were Caucasian, 16% were Black, and 11% were Hispanic/Latino. Mean baseline LDL-C was 102 mg/dL. The primary efficacy endpoint, measured at week 24, was the mean percent change in LDL-C from baseline.[1]

LONG TERM trial (Study 1) was a multicenter, double-blind, placebo-controlled trial that compared PRALUENT 150 mg Q2W (n=1553) with placebo (n=788). The average LDL-C at baseline was 122 mg/dL. The primary efficacy endpoint, measured at week 24, was the mean percent change in LDL-C from baseline.[1]

IMPORTANT SAFETY INFORMATION

- Liver-related disorders (primarily related to abnormalities in liver enzymes) were reported in 2.5% of patients treated with PRALUENT and 1.8% of patients treated with placebo, leading to treatment discontinuation in 0.4% and 0.2% of patients, respectively. Increases in serum transaminases to greater than 3 times the upper limit of normal occurred in 1.7% of patients treated with PRALUENT and 1.4% of patients treated with placebo
- The most common adverse reactions leading to treatment discontinuation in patients treated with PRALUENT were allergic reactions (0.6% versus 0.2% for PRALUENT and placebo, respectively) and elevated liver enzymes (0.3% versus <0.1%)
- PRALUENT is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with PRALUENT

Please see brief summary of Prescribing Information on next page.

Learn more at PraluentHCP.com

Praluent®
(alirocumab) Injection 75mg/mL 150mg/mL

Redefining Possible

PRALUENT® **Rx Only**
(alirocumab) injection, for subcutaneous use
Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

1.1 Primary Hyperlipidemia

PRALUENT® is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C.

1.2 Limitations of Use

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

4 CONTRAINDICATIONS

PRALUENT is contraindicated in patients with a history of a serious hypersensitivity reaction to PRALUENT. Reactions have included hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization. [*See Warnings and Precautions (5.1)*]

5 WARNINGS AND PRECAUTIONS

5.1 Allergic Reactions

Hypersensitivity reactions (e.g., pruritus, rash, urticaria), including some serious events (e.g., hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization), have been reported with PRALUENT treatment. If signs or symptoms of serious allergic reactions occur, discontinue treatment with PRALUENT, treat according to the standard of care, and monitor until signs and symptoms resolve [*see Contraindications (4)*].

6 ADVERSE REACTIONS

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

- 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 practice.

The safety of PRALUENT was evaluated in 9 placebo-controlled trials that included 2476 patients treated with PRALUENT, including 2135 exposed for 6 months and 1999 exposed for more than 1 year (median treatment duration of 65 weeks). The mean age of the population was 59 years, 40% of the population were women, 90% were Caucasians, 4% were Black or African American, and 3% were Asians. At baseline, 37% of patients had a diagnosis of heterozygous familial hypercholesterolemia and 66% had clinical atherosclerotic cardiovascular disease.

Adverse reactions reported in at least 2% of PRALUENT-treated patients, and more frequently than in placebo-treated patients, are shown in Table 1.

Table 1 Adverse Reactions Occurring in Greater Than or Equal to 2% of PRALUENT-Treated Patients and More Frequently Than with Placebo

Adverse Reactions	Placebo (N=1276)	PRALUENT* (N=2476)
Nasopharyngitis	11.1%	11.3%
Injection site reactions†	5.1%	7.2%
Influenza	4.6%	5.7%
Urinary tract infection	4.6%	4.8%
Diarrhea	4.4%	4.7%
Bronchitis	3.8%	4.3%
Myalgia	3.4%	4.2%
Muscle spasms	2.4%	3.1%
Sinusitis	2.7%	3.0%
Cough	2.3%	2.5%
Contusion	1.3%	2.1%
Musculoskeletal pain	1.6%	2.1%

*75 mg every 2 weeks and 150 mg every 2 weeks combined
†includes erythema/redness, itching, swelling, pain/tenderness

Adverse reactions led to discontinuation of treatment in 5.3% of patients treated with PRALUENT and 5.1% of patients treated with placebo. The most common adverse reactions leading to treatment discontinuation in patients treated with PRALUENT were allergic reactions (0.6% versus 0.2% for PRALUENT and placebo, respectively) and elevated liver enzymes (0.3% versus <0.1%).

Local Injection Site Reactions

Local injection site reactions including erythema/redness, itching, swelling, and pain/tenderness were reported more frequently in patients treated with PRALUENT (7.2% versus 5.1% for PRALUENT and placebo, respectively). Few patients discontinued treatment because of these reactions (0.2% versus 0.4% for PRALUENT and placebo, respectively), but patients receiving PRALUENT had a greater number of injection site reactions, had more reports of associated symptoms, and had reactions of longer average duration than patients receiving placebo.

Allergic Reactions

Allergic reactions were reported more frequently in patients treated with PRALUENT than in those treated with placebo (8.6% versus 7.8%). The proportion of patients who discontinued treatment due to allergic reactions was higher among those treated with PRALUENT (0.6% versus 0.2%). Serious allergic reactions, such as hypersensitivity, nummular eczema, and hypersensitivity vasculitis were reported in patients using PRALUENT in controlled clinical trials [*see Warnings and Precautions (5.1)*].

Neurocognitive Events

Neurocognitive events were reported in 0.8% of patients treated with PRALUENT and 0.7% of patients treated with placebo. Confusion or memory impairment were reported more frequently by those treated with PRALUENT (0.2% for each) than in those treated with placebo (<0.1% for each).

Liver Enzyme Abnormalities

Liver-related disorders (primarily related to abnormalities in liver enzymes) were reported in 2.5% of patients treated with PRALUENT and 1.8% of patients treated with placebo, leading to treatment discontinuation in 0.4% and 0.2% of patients, respectively. Increases in serum transaminases to greater than 3 times the upper limit of normal occurred in 1.7% of patients treated with PRALUENT and 1.4% of patients treated with placebo.

Low LDL-C Values

In a pool of both placebo- and active-controlled clinical trials, 796 PRALUENT-treated patients had two consecutive calculated LDL-C values <25 mg/dL, and 288 had two consecutive calculated LDL-C values <15 mg/dL. Changes to background lipid-altering therapy (e.g., maximally tolerated statins) were not made in response to low LDL-C values, and PRALUENT 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 PRALUENT are unknown.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity with PRALUENT. In a pool of ten placebo- and active-controlled trials, 4.8% of patients treated with PRALUENT had anti-drug antibodies (ADA) newly detected after initiating treatment as compared with 0.6% of patients treated with control.

Patients who developed ADA had a higher incidence of injection site reactions compared with patients who did not develop ADA (10.2% vs 5.9%).

A total of 1.2% of patients treated with PRALUENT developed neutralizing antibodies (NAb) on at least one occasion as compared with no patients treated with control, and 0.3% of patients both tested positive for NAb and exhibited transient or prolonged loss of efficacy. The long-term consequences of continuing PRALUENT treatment in the presence of persistent NAb are unknown.

Immunogenicity data are highly dependent on the sensitivity and specificity of the assay as well as other factors. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors, including sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to PRALUENT with the incidence of antibodies to other products may be misleading.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary: There are no available data on use of PRALUENT in pregnant women to inform a drug-associated risk. In animal reproduction studies, there were no effects on embryo-fetal development when rats were subcutaneously administered alirocumab during organogenesis at dose exposures up to 12-fold the exposure at the maximum recommended human dose of 150 mg every two weeks. In monkeys, suppression of the humoral immune response was observed in infant monkeys when alirocumab was dosed during organogenesis to parturition at dose exposures 13-fold the exposure at the maximum recommended human dose of 150 mg every two weeks. No additional effects on pregnancy or neonatal/infant development were observed at dose exposures up to 81-fold the maximum recommended human dose of 150 mg every two weeks. Measurable alirocumab serum concentrations were observed in the infant monkeys at birth at comparable levels to maternal serum, indicating that alirocumab, 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 PRALUENT and possible risks to the fetus before prescribing PRALUENT 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 Sprague Dawley rats, no effects on embryo-fetal development were observed when alirocumab was dosed at up to 75 mg/kg/dose by the subcutaneous route on gestation days 6 and 12 at exposures 12-fold the maximum recommended human dose of 150 mg every two weeks, based on serum AUC.

In cynomolgus monkeys, suppression of the humoral immune response to keyhole limpet hemocyanin (KLH) antigen was observed in infant monkeys at 4 to 6 months of age when alirocumab was dosed during organogenesis to parturition at 15 mg/kg/week and 75 mg/kg/week by the subcutaneous route, corresponding to 13- and 81-fold the human exposure at the maximum recommended human dose of 150 mg every two weeks, based on serum AUC. The lowest dose tested in the monkey resulted in humoral immune suppression; therefore it is unknown if this effect would be observed at clinical exposure. No study designed to challenge the immune system of infant monkeys was conducted. No additional embryo-fetal, prenatal or postnatal effects were observed in infant monkeys, and no maternal effects were observed, when alirocumab was dosed at up to 75 mg/kg/week by the subcutaneous route, corresponding to maternal exposure of 81-fold the exposure at the maximum recommended human dose of 150 mg every two weeks, based on serum AUC.

8.2 Lactation

Risk Summary: There is no information regarding the presence of alirocumab 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 PRALUENT and any potential adverse effects on the breastfed infant from PRALUENT or from the underlying maternal condition. Human IgG is present in human milk, but published data suggest that breastmilk IgG antibodies do not enter the neonatal and infant circulation in substantial amounts.

8.4 Pediatric Use

Safety and efficacy in pediatric patients have not been established.

8.5 Geriatric Use

In controlled studies, 1158 patients treated with PRALUENT were ≥65 years of age and 241 patients treated with PRALUENT were ≥75 years of age. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, 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 for patients with mild or moderately impaired renal function. No data are available in patients with severe renal impairment. [*See Clinical Pharmacology (12.3) in the full prescribing information.*]

8.7 Hepatic Impairment

No dose adjustment is needed for patients with mild or moderate hepatic impairment. No data are available in patients with severe hepatic impairment. [*See Clinical Pharmacology (12.3) in the full prescribing information.*]

Manufactured by:
sanofi-aventis U.S. LLC
Bridgewater, NJ 08807
A SANOFI COMPANY
U.S. License # 1752
Marketed by sanofi-aventis U.S. LLC (Bridgewater, NJ 08807)
and Regeneron Pharmaceuticals, Inc. (Tarrytown, NY 10591)

Revised: October 2015
ALI-BPLR-SA-OCT15

SANOFI REGENERON

01/2016 US-PRB-1513 US.ALI.16.01.008

Reference: 1. PRALUENT® (alirocumab) Prescribing Information. Sanofi/Regeneron Pharmaceuticals, 2015.

INDUSTRY-EXPERT THEATER 1

Expo Hall, #24100

9:45 a.m. – 10:45 a.m.

Treating HFrEF: Focus on Pathophysiology and Mechanism of Action of a Novel Therapy

Evidence has shown that even patients with "stable" heart failure (HF) with reduced ejection fraction (HFrEF) receiving standard-of-care therapy have a risk of cardiovascular death or HF hospitalization. Heart failure progression is the result of the sustained activation of certain neurohormonal systems, including the sympathetic nervous system (SNS) and renin-angiotensin-aldosterone system (RAAS) that become deleterious over time. Please join us as we review the pathophysiology of HFrEF and the mechanism of action of a novel therapy.

1/16 T-HFS-1327274

Gregg Fonarow, MD, FACC
Professor of Medicine, UCLA Division of Cardiology; Director, Ahmanson-UCLA Cardiomyopathy Center; Co-Chief, UCLA Division of Cardiology

Barry Greenberg, MD, FACC
Director, Advanced Heart Failure Treatment Program; Professor of Medicine, UC San Diego School of Medicine

Sponsored by Novartis Pharmaceuticals Corporation

12:45 p.m. – 1:45 p.m.

Thrombosis: AFib & DVT/PE — An Exploration in Risk Reduction

This lecture will discuss treatment options for patients with deep vein thrombosis and pulmonary embolism, and how they can reduce the risk of recurrent thrombotic events. It will also present options for reducing the risk of stroke in patients with nonvalvular atrial fibrillation.

Marc Cohen, MD, FACC, FACP, FAHA, FSCAI
Chief, Division of Cardiology, Newark Beth Israel Medical Center; Professor of Medicine Rutgers - New Jersey Medical School; Professor of Medicine, Icahn School of Medicine at Mt Sinai

Sponsored by Janssen Pharmaceuticals, Inc.

3:45 p.m. – 4:45 p.m.

The Myth of the Clinically Stable Patient with Heart Failure: Exploring Clinical Trajectories and the Threat of Sudden Cardiac Death

Recent CDC findings report that heart failure (HF)-related mortality in the United States has steadily increased in recent years. There are 3 common clinical trajectories for patients diagnosed with HF with reduced ejection fraction (HFrEF). While myocardial recovery is rare, but possible, for certain HF syndromes, the vast majority of patients will either experience stabilization of the inexorable progression of HF or acceleration to end-stage HF or death. For all 3 scenarios, sudden cardiac death (SCD) can occur at any time. It is impossible to predict the clinical course and risk of SCD for an individual patient with HF. Even patients exhibiting mild symptoms are at high risk for the next HF-related event, which could be death. This program will review current understanding of the mechanisms underlying different clinical trajectories and the constant threat of SCD for patients with HF.

Javed Butler, MD, MPH, FACC, FAHA, MBA
Professor of Medicine, Professor of Physiology & Biophysics, Director, Division of Cardiovascular Medicine; Co-Director, Heart Institute; Stony Brook University

Sponsored by Novartis Pharmaceuticals Corporation

INDUSTRY-EXPERT THEATER 2

Expo Hall, #25078

9:45 a.m. – 10:45 a.m.

The Evolving Cholesterol Landscape

This presentation will provide a historical review of the evolving understanding of cholesterol physiology and guidelines.

Peter P. Toth, MD, PhD, FACC
Director of Preventative Cardiology, CGH Medical Center; Professor of Clinical Family and Community Medicine, University of Illinois College of Medicine; Professor of Clinical Medicine, Michigan State University College of Osteopathic Medicine

Sponsored by Amgen

12:45 p.m. – 1:45 p.m.

Repatha® (evolocumab): Product Overview

Seth J. Baum, MD, FACC, FACPM, FAHA, FNLA
North Ridge Heart Associates

Sponsored by Amgen

3:45 p.m. – 4:45 p.m.

Understanding the Ongoing Risk of Atherothrombosis Beyond the Culprit Lesion

This session will:

- Review the pathophysiology and burden of acute coronary syndrome (ACS)
- Examine the current evidence for persistent risk for recurrent cardiovascular (CV) events in patients with prior myocardial infarction (MI)
- Identify and assess risk factors that influence the recurrence of CV events
- Discuss American College of Cardiology (ACC) goals for improving CV Health

Gary Schaer, MD, FACC
Professor of Medicine and Director of Cardiology Research and Strategic Development, Rush University Medical Center

Sponsored by AstraZeneca Pharmaceuticals

INTERACTIVE LEARNING LABS

Interactive Learning Lab #17021

HeartWare

Changing the Treatment of Heart Failure
Discover how VAD therapy is becoming an essential part of heart failure programs around the world.

Who should attend: Cardiologists who manage advanced heart failure patients.

9:30 a.m. – 10:15 a.m.

Advanced Heart Failure and VAD Therapy: The Right Patient. The Right Time. The Right Device.

Identify high-risk patients early and develop your treatment strategy.

Jonathan Rich, MD, FACC
Northwestern Memorial Hospital

3:30 p.m. – 4:15 p.m.

Tools for Real-Time Patient Management
Learn about a unique user-friendly system that provides real-time information about VAD function to help optimize device performance and improve patient management.

Jeffrey Teuteberg, MD
University of Pittsburgh Medical Center

MORE LEARNING DESTINATIONS ON PAGE 7

Now FDA approved

Visit Booth **#8070** to learn about

www.UPTRAVI.com

ACTELION

UPTRAVI tablet strengths:
200, 400, 600, 800, 1000, 1200, 1400, and 1600 mcg

SIM CENTER

Expo Hall #24062

10:00 a.m. – 10:30 a.m.

Stroke in the Hypertensive Patient Simulation Training

Learning objectives:

- Identify stroke and perform the right procedures to stabilize the patient
- Determine the appropriate target blood pressure, including consideration of a history of chronic untreated hypertension
- Establish which antihypertensive agents are appropriate for use in the acute setting
- Understand blood pressure management after acute ischemic stroke and a wider definition of hypertension that also takes into account the absolute risk of cardiovascular events and associated metabolic factors or early disease markers

1:00 p.m. – 1:30 p.m.

Acute Heart Failure Simulation Training

Learning objectives:

- Prompt recognition of acute decompensated heart failure
- Identify the acute triggers for the decompensation as well as non invasive characterization of cardiac filling pressures and output
- Understand novel treatments that may change the landscape of management of acute decompensated heart failure

4:00 p.m. – 4:30 p.m.

ST Elevation Myocardial Infarction Simulation Training

Learning objectives:

- Rapid assessment of myocardial infarction and management of priorities
- Determine immediate measures to salvage threatened myocardium to increase survival after myocardial infarction
- Understand primary angioplasty and long-term survival advantages

PATIENT ENGAGEMENT PAVILION

Expo Hall, #24035

9:45 a.m. – 10:15 a.m.

Every Minute Matters — Improving Patient Outcomes Starts with Community Education on What to do When Someone Displays the Symptoms of a Heart Attack

One of the key components to improving outcomes is educating the public before they become patients. SCPC offers the Early Heart Attack Care curriculum for hospitals to use as community education. The audience will learn how process improvement — starting with an educated public — reduces mortality, decreases length of stay, and improves patient outcomes.

Beth Stokes
Accreditation Conformance Research Manager, Society of Cardiovascular Patient Care (SCPC)

10:25 a.m. – 10:55 a.m.

Why Should the Public Care About Public Reporting?

Details on the importance of public reporting and the ACC/NCDR's new public reporting program, Find Your Heart a Home.

Gregory J. Dehmer, MD, MACC, MSCAI, FAHA, FACP
Baylor Scott & White Health

11:05 a.m. – 11:35 a.m.

Introducing the Heart Valve Ambassador Program: Connecting Patients with Support

Learn how the American Heart Association is providing online patient support through the Support Network. The Support Network helps patients reach treatment goals and achieve healthier outcomes.

Kimberly Goodloe
AHA Heart Valve Ambassador

11:45 a.m. – 12:15 p.m.

Basic Education of Hypertriglyceridemia

Basic education on the assessment and treatment of hypertriglyceridemia.

Harold Bays, MD, FACC, FACE, FNLA, FTOS
Medical Director, L-MARC Research Center

12:30 p.m. – 1:00 p.m.

FDA Patient Liaison Program: The Patient Voice

The communication tools and activities developed by the FDA's Office of Health and Constituent Affairs program focus on supporting and encouraging patients and patient advocates in FDA decision-making and policy formation.

Helene D. Clayton-Jeter, O.D.
Food and Drug Administration (FDA)

1:10 p.m. – 1:40 p.m.

Melding Innovation with Infrastructure: How the Stronger Hearts Helpline is Improving the Lives of Heart Failure Patients

The National Forum for Heart Disease & Stroke Prevention partnered with national and local community-based and clinical organizations to pilot the Stronger Hearts Helpline – a free, bilingual heart failure support service available to patients and their caregivers 24 hours a day, 7 days a week in San Bernardino County, CA.

John Clymer
Executive Director, National Forum for Heart Disease & Stroke Prevention

1:50 p.m. – 2:20 p.m.

The Patient & You: Aligning Interests to Increase Medication Adherence

Jon Michaeli
EVP Marketing & Business Development, Medisafe

2:30 p.m. – 3:00 p.m.

Patient Empowerment through Education: The Role of Nursing

A review of PCNA standards for patient-facing materials and a demonstration of interactive print tools designed to empower the patient to participate as a full partner in his/her care.

Lynne Braun, PhD, CNP, CLS, FAHA, FPCNA, FAAN
Board of Directors, Preventive Cardiovascular Nurses Association

3:10 p.m. – 3:40 p.m.

Heart Failure Nurses: Leading the Way to Success in Heart Failure Outcomes

This discussion will focus on the important role that heart failure nurses and disease management play in ensuring optimal outcomes for today's medically complex patient population.

Marilyn A. Prasun, PhD, CCNS, CNL, CHFN, FAHA
President, American Association of Heart Failure Nurses

3:50 p.m. – 4:20 p.m.

Team-Based Cardiovascular Care: A Unified Vision to Improve Patient Care

A panel discussion on the roles and contributions of physicians, advanced practice registered nurses, pharmacists, and physician assistants in caring for patients with cardiovascular disease.

Dave Dixon, PharmD
Virginia Commonwealth University School of Pharmacy

Linda Tavares, DNP
Cardiovascular Associates of Virginia, PC

John Brush, MD
Sentara Cardiology Specialists

Sondra DePalma, PA
Penn State Hershey Heart & Vascular Institute

MORE LEARNING DESTINATIONS ON PAGE 9

ACC IS YOUR PROFESSIONAL HOME

FOR PURPOSEFUL EDUCATION

Stop by ACC Central, Booth #14033 to save 15% on your purchase of ACC products and live courses.

AMERICAN COLLEGE *of* CARDIOLOGY

INNOVATION STAGE

Expo Hall, #24046

9:45 a.m. – 10:15 a.m.

Praluent® (alirocumab) Injection: Efficacy and Safety with Two Different Dosing Regimens

A review of the mechanism of action, efficacy and safety data of two dosing regimens of a PCSK9 inhibitor in treating hypercholesterolemia in patients with clinical atherosclerotic cardiovascular disease (ASCVD) and heterozygous familial hypercholesterolemia (HeFH). Clinical data will be presented on two dosing regimens.

Paul Davis Thompson, MD, FACC
Chief, Division of Cardiology, Hartford Hospital

Sponsored by Sanofi-Regeneron

12:30 p.m. – 1:00 p.m.

Role and Clinical Application of an Oral Prostacyclin Class Therapy in the Early Treatment of Pulmonary Arterial Hypertension

With prostacyclin class therapy being recommended for treatment of PAH for more than a decade, this session will focus on the use of an oral prostacyclin class therapy in the early treatment of PAH. Discussion will review the clinical data and practical applications for initiating an oral prostacyclin class therapy in prostacyclin naïve or stable parenteral patients.

Sponsored by United Therapeutics

1:30 p.m. – 2:00 p.m.

The Complex Patient with Chronic Exertional Dyspnea: Narrowing the Differential Diagnosis

Idiopathic Pulmonary Fibrosis (IPF) commonly presents with a chronic dry, nonproductive cough and unexplained chronic exertional dyspnea. Because IPF occurs in older individuals, it is not uncommon for comorbid cardiac conditions such as coronary artery disease or congestive heart failure to also be present. Pulmonary hypertension, either due to chronic hypoxia or as a result of interstitial lung disease may also be present. Thus, patients are often referred to cardiologists for work up. It is imperative that they consider interstitial lung diseases, including IPF, in the differential diagnosis. This will facilitate earlier referral to pulmonologists for a definitive diagnosis and initiation of effective treatment for IPF, if present.

Imre Noth, MD
Professor of Medicine, Section of Pulmonary and Critical Care Medicine; Director, Interstitial Lung Disease Program; The University of Chicago

Sponsored by Boehringer Ingelheim Pharmaceuticals Inc.

3:45 p.m. – 4:15 p.m.

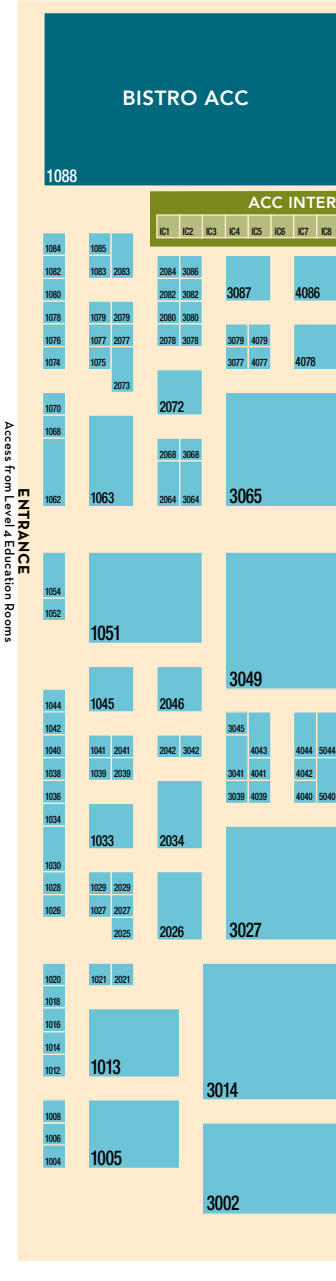
A Focused Look at Unmet Need in Hyperlipidemia

Paul Davis Thompson, MD, FACC
Chief, Division of Cardiology, Hartford Hospital

Sponsored by Amgen

MORE LEARNING DESTINATIONS ON PAGE 17

ACC.16 EXHIBITORS
In Alphabetical Order



Northwestern Medicine	17018
Novartis Pharmaceuticals Corporation	3049
nVoq Incorporated	20062

O

Objective Medical Systems, LLC	20092
Oxford University Press	22052

P

Pfizer	6003
Philippine Heart Association	IC 13
Philips	6054
Pie Medical Imaging, B.V	22071
Portola Pharmaceuticals, Inc.	11102
Preventice Solutions	2072
PreventionGenetics	20112
Preventive Cardiovascular Nurses Association	PEP 9
Prothia LLC	19025
Providence Health & Services	19110
Pulmonary Hypertension Association	1080
Pulse Medical	19019
Pulse Systems, Inc.	22092

Q

QGenda, Inc.	22082
Quten Research Institute, LLC	2078

R

Radcliffe Cardiology	22094
Relypsa	8062, 10099
ResMed	21089
Rijuven	13021
Russian Society of Cardiology	IC 14

S

SA Heart	23040
Sanofi Regeneron	3027, 4040
SCAD Alliance	1021
Schiller AG	1063
SciImage, Inc.	20076
ScottCare Cardiovascular Solutions	4043
ScribeAmerica, LLC	3086, 22033
Sensogram Technologies, Inc.	17108
Siemens Healthcare	2026, 3014
SIUI American, Inc.	2077
SmartBrief, Inc.	22045
Society for Cardiovascular Angiography and Interventions Foundation	1076
Society of Cardiovascular Patient Care	PEP 7
Southwest Medical Resources	22031
Spacelabs Healthcare	22039
Spartan Bioscience	20025
Spectranetics	21034
Springer	22042
St. Jude Medical	10004
Staff Care, Inc.	1082
StopAfib.org	PEP 4

T

TandemLife	19032
Taylor & Francis	22060
TeraRecon, Inc.	4078
Terumo Interventional Systems	18032
The Doctors Company	22034
The FH Foundation	22098, PEP 6
The Heart Hospital Baylor Plano	6087
The Interventionist Back Saver	20034
The JAMA Network	22059
The Medicines Company	19035
The National Death Index	2042
theheart.org/Medscape Cardiology	1013
Thinklabs Medical	1018
TIMI Study Group, Brigham & Women's Hospital	4044
TOMTEC IMAGING SYSTEMS GMBH	7051
Toshiba Medical Systems	7061
Transgenomic, Inc.	2068
Transradial Solutions LLC - Cardio-TRAP	20021

U

Unfors RaySafe	19026
United Biologics, Inc.	19024
United Therapeutics Corp.	9089
University of Tennessee Physician Executive MBA Program	1012

V

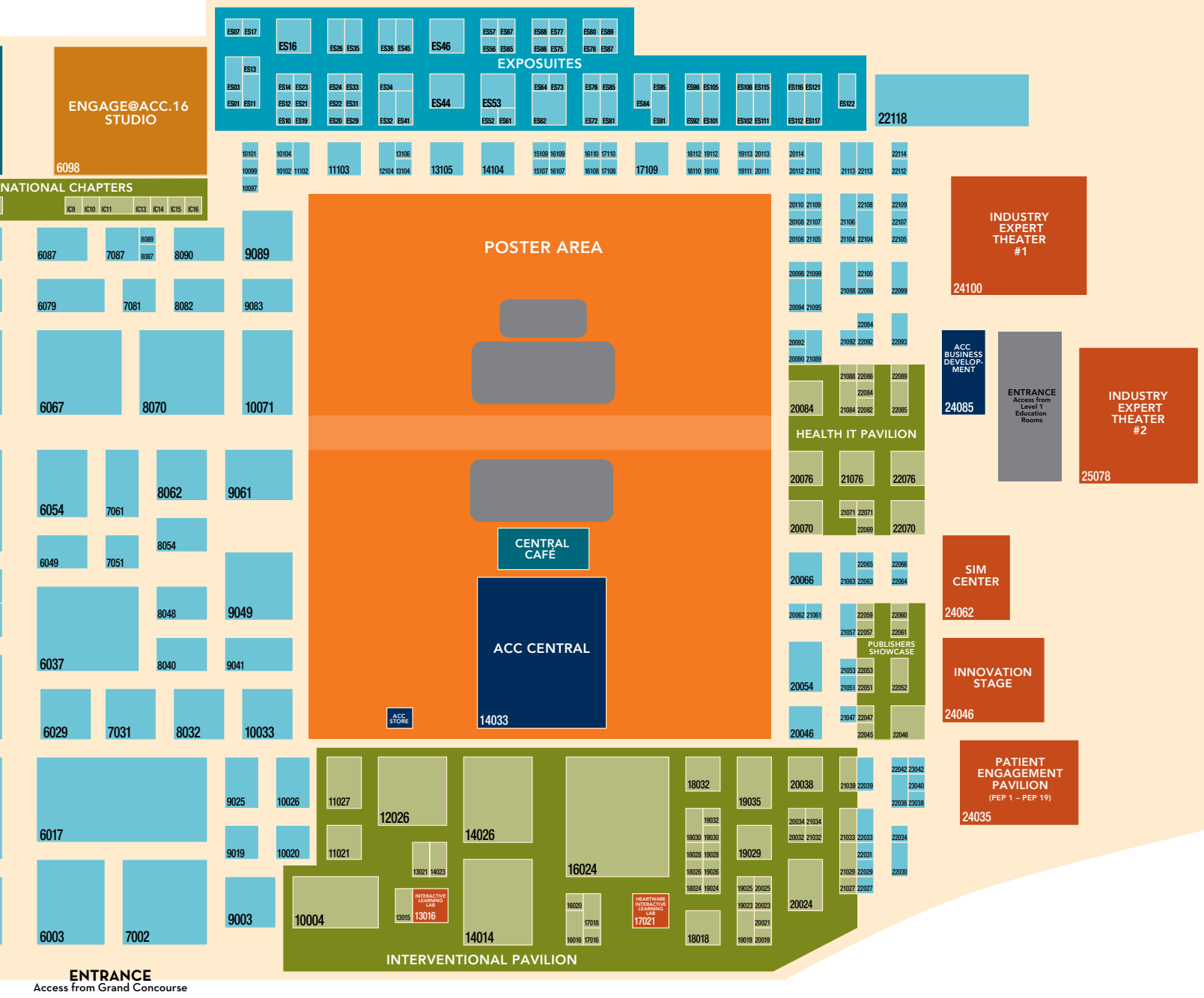
Vales & Hills Biomedical Tech. Ltd.	3080
Vasomedical, Inc	21112
VectraCor, Inc.	1054

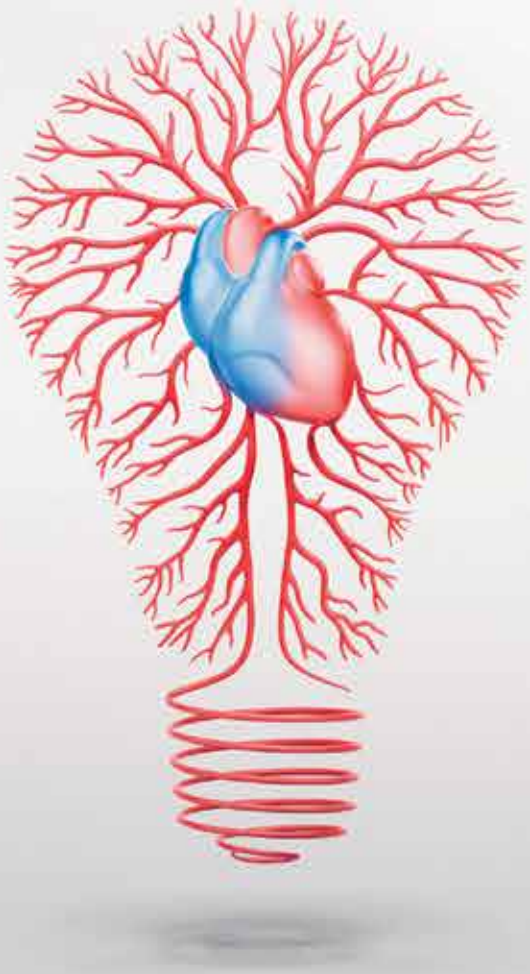
W

W.A. Baum Company	3045
WCPCCS 2017	2084
WMCHealth	21099
Wolters Kluwer	22046
WomenHeart: The National Coalition for Women with Heart Disease	PEP 5
World Heart Federation	3082

Z

Zeus Scientific	4039
ZOLL Medical Corporation	11027
ZS Pharma	20054





For your patients with a history of MI or with PAD

Think differently about your approach to reducing thrombotic CV events

- ZONTIVITY is indicated for the reduction of thrombotic cardiovascular (CV) events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). ZONTIVITY has been shown to reduce the rate of a combined endpoint of CV death, MI, stroke, and urgent coronary revascularization (UCR)

ZONTIVITY®
(vorapaxar) tablets 2.08 mg*

*equivalent to 2.5 mg vorapaxar sulfate

Add ZONTIVITY to aspirin and/or clopidogrel to further reduce CV risk

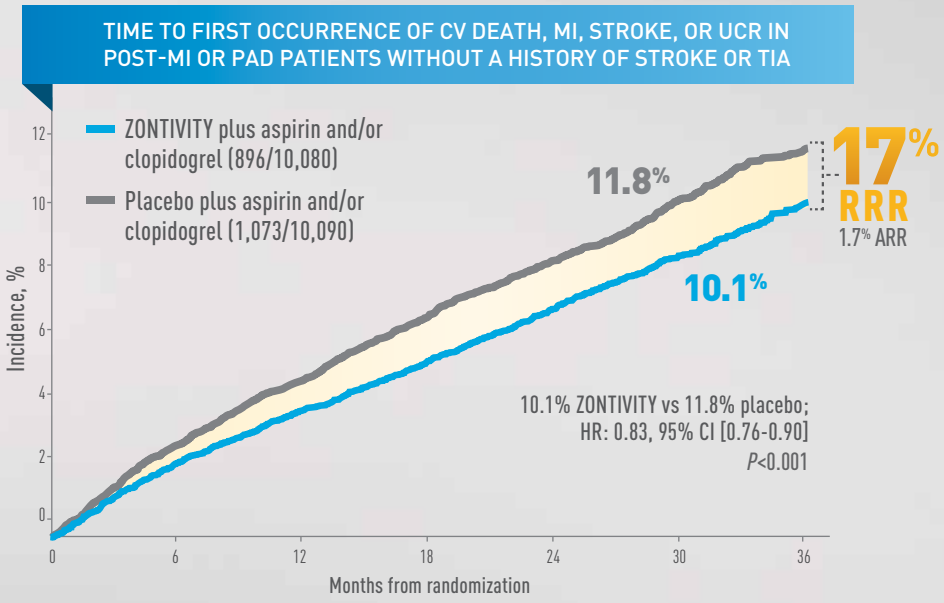
- ZONTIVITY, taken as one 2.08-mg tablet daily, was studied only as an addition to aspirin and/or clopidogrel and should be used with aspirin and/or clopidogrel according to their indications or standard of care. There is no experience with use of ZONTIVITY as monotherapy

Selected Safety Information

- **Warning: Bleeding Risk**
  - **—Do not use ZONTIVITY in patients with a history of stroke, transient ischemic attack (TIA), or intracranial hemorrhage (ICH), or with active pathological bleeding (eg, ICH or peptic ulcer)**
  - **—Antiplatelet agents, including ZONTIVITY, increase the risk of bleeding, including ICH and fatal bleeding**
- Discontinue ZONTIVITY in patients who experience a stroke, TIA, or ICH
- ZONTIVITY increases the risk of bleeding (which may include ICH and fatal bleeding) in proportion to the patient's underlying bleeding risk. Consider the underlying risk of bleeding before initiating ZONTIVITY
- Withholding ZONTIVITY for a brief period will not be useful in managing an acute bleeding event due to its long half-life. There is no known treatment to reverse the antiplatelet effect of ZONTIVITY

In a landmark secondary prevention trial over 3 years, among more than 20,000 post-MI or PAD patients without a history of stroke or TIA

ZONTIVITY delivered significant and sustained reduction of thrombotic CV events on top of aspirin and/or clopidogrel



Study Design: Multicenter, double-blind, placebo-controlled study in 26,449 patients with a history of spontaneous MI within the prior 2 weeks to 12 months, ischemic stroke, or documented PAD. Patients were randomized to receive daily treatment with ZONTIVITY or placebo in addition to standard of care that included aspirin and/or a thienopyridine (principally clopidogrel), and were followed for up to 4 years (median 2.5 years). In the overall study population, ZONTIVITY plus standard of care was superior to standard of care alone on the primary composite endpoint of CV death, MI, stroke, and UCR, and on the key secondary composite endpoint of CV death, MI, and stroke. Because patients in the overall study population with a history of stroke or TIA showed an increased risk of ICH, the approved use of ZONTIVITY is based on the study population with a history of MI or with PAD and without a history of stroke or TIA (n=10,080 randomized to ZONTIVITY, n=10,090 randomized to placebo).

Patients who had experienced a prior MI were eligible for the trial if at least 2 weeks post-MI at enrollment.

Selected Safety Information

- Use of certain concomitant medications (eg, anticoagulants, fibrinolytic therapy, chronic nonsteroidal anti-inflammatory drugs, selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors) also increases the risk of bleeding
- Avoid concomitant use of warfarin or other anticoagulants due to the risk of bleeding. Avoid concomitant use of strong CYP3A inhibitors or inducers due to their effect on ZONTIVITY exposure
- ZONTIVITY is not recommended in patients with severe hepatic impairment
- Bleeding, including life-threatening and fatal bleeding, is the most commonly reported adverse reaction with ZONTIVITY. Among post-MI or PAD patients with no history of stroke or TIA, three-year bleeding rates (shown with hazard ratios and 95% confidence intervals) in patients who added ZONTIVITY or placebo, respectively, to aspirin and/or clopidogrel were:
  - —GUSTO moderate or severe bleeding,[a] 3.7% vs 2.4%, HR 1.55 (1.30–1.86)
  - —GUSTO severe bleeding,[a] 1.3% vs 1.0%, HR 1.24 (0.92–1.66)
  - —Any GUSTO bleeding (severe/moderate/mild),[a] 27.7% vs 19.8%, HR 1.52 (1.43–1.61)
  - —ICH, 0.6% vs 0.4%, HR 1.46 (0.92–2.31)
  - —Fatal bleeding, 0.2% vs 0.2%, HR 1.15 (0.56–2.36)
  - —Clinically significant bleeding,[b] 15.5% vs 10.9%, HR 1.47 (1.35–1.60)

Please see the adjacent Brief Summary of the Prescribing Information, including the Boxed Warning about bleeding risk.

[a]Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Arteries (GUSTO) severe bleeding: fatal, intracranial, or bleeding with hemodynamic compromise requiring intervention; GUSTO moderate bleeding: bleeding requiring transfusion of whole blood or packed red blood cells without hemodynamic compromise.

[b]Clinically significant bleeding: bleeding requiring medical attention including ICH, or clinically significant overt signs of hemorrhage with a drop in Hgb ≥3 g/dL (or, when Hgb is not available, an absolute drop in Hct ≥9%).

RRR=relative risk reduction; ARR=absolute risk reduction; HR=hazard ratio; CI=confidence interval.

MERCK

CARD-1154460-0000 07/15 **zontivity.com**

Brief Summary of Prescribing Information

ZONTIVITY® (vorapaxar) Tablets 2.08 mg*, for oral use
***Equivalent to 2.5 mg vorapaxar sulfate**

WARNING: BLEEDING RISK

- **Do not use ZONTIVITY in patients with a history of stroke, transient ischemic attack (TIA), or intracranial hemorrhage (ICH); or active pathological bleeding *[see Contraindications]*.**
- **Antiplatelet agents, including ZONTIVITY, increase the risk of bleeding, including ICH and fatal bleeding *[see Warnings and Precautions]*.**

INDICATIONS AND USAGE

Patients with History of Myocardial Infarction (MI) or with Peripheral Arterial Disease (PAD). ZONTIVITY® is indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). ZONTIVITY has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization (UCR).

DOSAGE AND ADMINISTRATION

General Dosing Information. Take one tablet of ZONTIVITY 2.08 mg orally once daily, with or without food.

Coadministration with Other Antiplatelet Drugs. There is no experience with use of ZONTIVITY alone as the only administered antiplatelet agent. ZONTIVITY has been studied only as an addition to aspirin and/or clopidogrel. Use ZONTIVITY with aspirin and/or clopidogrel according to their indications or standard of care. There is limited clinical experience with other antiplatelet drugs.

CONTRAINDICATIONS

History of Stroke, TIA, or ICH. ZONTIVITY is contraindicated in patients with a history of stroke, TIA, or ICH because of an increased risk of ICH in this population *[see Adverse Reactions]*.

Discontinue ZONTIVITY in patients who experience a stroke, TIA, or ICH *[see Adverse Reactions]*.

Active Pathologic Bleeding. ZONTIVITY is contraindicated in patients with active pathological bleeding such as ICH or peptic ulcer *[see Warnings and Precautions and Adverse Reactions]*.

WARNINGS AND PRECAUTIONS

General Risk of Bleeding. Antiplatelet agents, including ZONTIVITY, increase the risk of bleeding, including ICH and fatal bleeding *[see Adverse Reactions]*.

ZONTIVITY increases the risk of bleeding in proportion to the patient's underlying bleeding risk. Consider the underlying risk of bleeding before initiating ZONTIVITY. General risk factors for bleeding include older age, low body weight, reduced renal or hepatic function, history of bleeding disorders, and use of certain concomitant medications (e.g., anticoagulants, fibrinolytic therapy, chronic nonsteroidal anti-inflammatory drugs [NSAIDS], selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors) increases the risk of bleeding *[see Use in Specific Populations]*. Avoid concomitant use of warfarin or other anticoagulants.

Suspect bleeding in any patient who is hypotensive and has recently undergone coronary angiography, percutaneous coronary intervention (PCI), coronary artery bypass graft surgery (CABG), or other surgical procedures.

Withholding ZONTIVITY for a brief period will not be useful in managing an acute bleeding event because of its long half-life. There is no known treatment to reverse the antiplatelet effect of ZONTIVITY. Significant inhibition of platelet aggregation remains 4 weeks after discontinuation *[see Overdosage]*.

Strong CYP3A Inhibitors or Inducers. Strong CYP3A inhibitors increase and inducers decrease ZONTIVITY exposure. Avoid concomitant use of ZONTIVITY with strong CYP3A inhibitors or inducers *[see Drug Interactions]*.

ADVERSE REACTIONS

The following serious adverse reaction is also discussed elsewhere in the labeling:

- Bleeding *[see Boxed Warning and Warnings and Precautions]*.

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.

ZONTIVITY was evaluated for safety in 13,186 patients, including 2,187 patients treated for more than 3 years, in the Phase 3 study TRA 2°P TIMI 50 (Thrombin Receptor Antagonist in Secondary Prevention of Atherothrombotic Ischemic Events). The overall study population, patients who had evidence or a history of atherosclerosis involving the coronary (post-MI), cerebral (ischemic stroke), or peripheral vascular (documented history of PAD) systems, was treated once a day with ZONTIVITY (n=13,186) or placebo (n=13,166). Patients randomized to ZONTIVITY received treatment for a median of 2.3 years.

The adverse events in the ZONTIVITY-treated (n=10,059) and placebo-treated (n=10,049) post-MI or PAD patients with no history of stroke or TIA are shown below *[see Contraindications]*.

Bleeding. GUSTO severe bleeding was defined as fatal, intracranial, or bleeding with hemodynamic compromise requiring intervention; GUSTO moderate bleeding was defined as bleeding requiring transfusion of whole blood or packed red blood cells without hemodynamic compromise. (GUSTO: Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Arteries.)

The results for the bleeding endpoints in the post-MI or PAD patients without a history of stroke or TIA are shown in Table 1. ZONTIVITY increased GUSTO moderate or severe bleeding by 55%.

Table 1: Non-CABG-Related Bleeds in Post-MI or PAD Patients without a History of Stroke or TIA (First Dose to Last Dose + 30 Days) in the TRA 2°P Study

	Placebo (n=10,049)		ZONTIVITY (n=10,059)		
Endpoints	Patients with events (%)	K-M %*	Patients with events (%)	K-M %*	Hazard Ratio†,‡ (95% CI)
GUSTO Bleeding Categories					
Severe	82 (0.8%)	1.0%	100 (1.0%)	1.3%	1.24 (0.92-1.66)
Moderate or Severe	199 (2.0%)	2.4%	303 (3.0%)	3.7%	1.55 (1.30-1.86)
Any GUSTO Bleeding (Severe/ Moderate/Mild)	1769 (17.6%)	19.8%	2518 (25.0%)	27.7%	1.52 (1.43-1.61)
Fatal Bleeding	14 (0.1%)	0.2%	16 (0.2%)	0.2%	1.15 (0.56-2.36)
Intracranial Hemorrhage (ICH)	31 (0.3%)	0.4%	45 (0.4%)	0.6%	1.46 (0.92-2.31)
Clinically Significant Bleeding†	950 (9.5%)	10.9%	1349 (13.4%)	15.5%	1.47 (1.35-1.60)
Gastrointestinal Bleeding	297 (3.0%)	3.5%	400 (4.0%)	4.7%	1.37 (1.18-1.59)

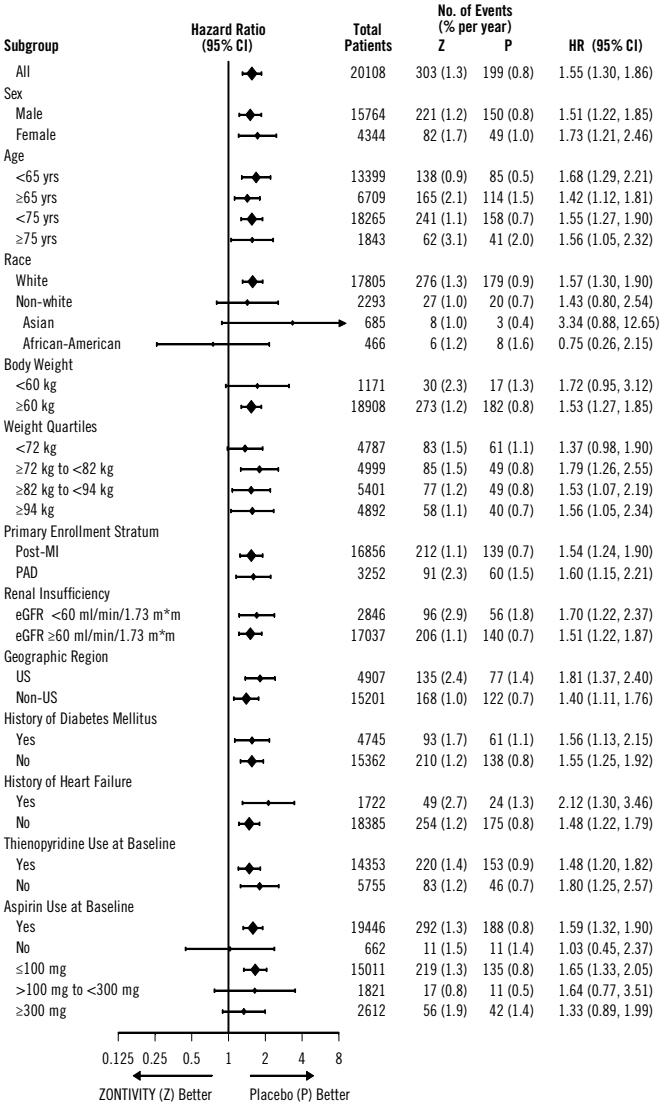
*K-M estimate at 1,080 days.

†Clinically significant bleeding includes any bleeding requiring medical attention including ICH, or clinically significant overt signs of hemorrhage associated with a drop in hemoglobin (Hgb) of ≥3 g/dL (or, when Hgb is not available, an absolute drop in hematocrit (Hct) of ≥9%).

‡Hazard ratio is ZONTIVITY group vs. placebo group.

The effects of ZONTIVITY on bleeding were examined in a number of subsets based on demographic and other baseline characteristics. Many of these are shown in Figure 1. Such analyses must be interpreted cautiously, as differences can reflect the play of chance among a large number of analyses.

Figure 1: Subgroup Analyses (GUSTO Moderate or Severe Bleeding) in Post-MI or PAD Patients without a History of Stroke or TIA in the TRA 2°P Study (First Dose to Last Dose + 30 Days)



In TRA 2°P, 367 post-MI or PAD patients without a history of stroke or TIA underwent CABG surgery. Study investigators were encouraged not to discontinue treatment with study drug (i.e., ZONTIVITY® (vorapaxar) or placebo) prior to surgery. Approximately 12.3% of patients discontinued ZONTIVITY more than 30 days prior to CABG. The relative risk for GUSTO moderate or severe bleeding was approximately 1.2 on ZONTIVITY vs. placebo.

Bleeding events that occurred on ZONTIVITY were treated in the same manner as for other antiplatelet agents.

Use in Patients with History of Stroke, TIA, or ICH. In the TRA 2°P study, patients with a history of ischemic stroke had a higher rate for ICH on ZONTIVITY than on placebo. ZONTIVITY is contraindicated in patients with a history of stroke, TIA, or ICH *[see Contraindications]*.

Other Adverse Reactions. Adverse reactions other than bleeding were evaluated in 19,632 patients treated with ZONTIVITY [13,186 patients in the TRA 2°P study and 6,446 patients in the TRA•CER (Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome) study]. Adverse events other than bleeding that occurred at a rate that was at least 2% in the ZONTIVITY group and also 10% greater than the rate in the placebo group are shown in Table 2.

Table 2: TRA 2°P / TRA•CER - Percentage of Patients Reporting Non-hemorrhagic Adverse Reactions at a Rate at Least 2% in the ZONTIVITY Group and at Least 10% Greater than Placebo

	ZONTIVITY (N=19,632)	Placebo (N=19,607)
	n (%)	n (%)
Anemia	982 (5.0)	783 (4.0)
Depression	477 (2.4)	405 (2.1)
Rashes, Eruptions, and Exanthemas	439 (2.2)	395 (2.0)

The following adverse reactions occurred at a rate less than 2% in the ZONTIVITY group but at least 40% greater than placebo. In descending order of rate in the ZONTIVITY group: iron deficiency, retinopathy or retinal disorder, and diplopia/oculomotor disturbances.

An increased rate of diplopia and related oculomotor disturbances was observed with ZONTIVITY treatment (30 subjects, 0.2%) vs. placebo (10 subjects, 0.06%). While some cases resolved during continued treatment, information on resolution of symptoms was not available for some cases.

DRUG INTERACTIONS

Effects of Other Drugs on ZONTIVITY. Vorapaxar is eliminated primarily by metabolism, with contributions from CYP3A4 and CYP2J2.

Strong CYP3A Inhibitors. Avoid concomitant use of ZONTIVITY with strong inhibitors of CYP3A (e.g., ketoconazole, itraconazole, posaconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, boceprevir, telaprevir, telithromycin and conivaptan) *[see Warnings and Precautions]*.

Strong CYP3A Inducers. Avoid concomitant use of ZONTIVITY with strong inducers of CYP3A (e.g., rifampin, carbamazepine, St. John's Wort and phenytoin) *[see Warnings and Precautions]*.

USE IN SPECIFIC POPULATIONS

Pregnancy. *Pregnancy Category B*. There are no adequate and well-controlled studies of ZONTIVITY use in pregnant women.

Risk Summary. Based on data in rats and rabbits, ZONTIVITY is predicted to have a low probability of increasing the risk of adverse developmental outcomes above background. No embryo/fetal toxicities, malformations or maternal toxicities were observed in rats exposed during gestation to 56 times the human systemic exposure at the recommended human dose (RHD). No embryo/fetal toxicities, malformations or maternal toxicities were observed in rabbits exposed during gestation to 26 times the human systemic exposure at the RHD. The No Adverse Effect Level (NOAEL) for decreased perinatal survival and body weight in offspring exposed *in utero* and during lactation was 31 times the human systemic exposure at the RHD. Both male and female pups displayed transient effects on sensory function and neurobehavioral development at weaning at 67 times the human exposure at the RHD, whereas female pups displayed decreased memory at 31 times the human exposure at the RHD. However, animal studies are not always predictive of a human response. ZONTIVITY should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Animal Data. In the rat embryo/fetal developmental toxicity study, pregnant rats received daily oral doses of vorapaxar at 0, 5, 25, and 75 mg/kg from implantation to closure of the fetal hard palate (6th to 17th day of gestation). Maternal systemic exposures were approximately 0, 7, 56, and 285 times greater than exposures in women treated at the RHD based on AUC. No embryo/fetal toxicities, malformations, or maternal toxicities were observed in rats receiving exposures up to 56 times the human systemic exposure at the RHD.

In the rabbit embryo/fetal developmental toxicity study, pregnant rabbits received daily oral doses of vorapaxar at 0, 2, 10, or 20 mg/kg from implantation to closure of the fetal hard palate (7th to 19th day of gestation). The NOAEL for maternal and fetal toxicity was equal to or above the highest dose tested. However, an overall increase in the number of litters with any malformation was observed at the highest dose, where systemic exposures were 89-fold higher than the human exposure at RHD.

The effects of vorapaxar on prenatal and postnatal development were assessed in pregnant rats dosed at 0, 5, 25, or 50 mg/kg/day from implantation through the end of lactation. Rat pups had decreased survival and body weight gain from birth to postnatal day 4 and decreased body weight gain for the overall pre-weaning period at exposures 67 times the human exposure at the RHD. Both male and female pups displayed effects on sensory function (acoustic startle) and neurobehavioral (locomotor assay) development on post-natal day (PND) 20 and 21, but not later (PND 60, 61) in development, whereas decreased memory was observed in female pups on PND 27 at 31 times the human exposure at the RHD. *In utero* and lactational exposure did not affect fertility or reproductive behavior of offspring at exposures up to 67 times the RHD.

Nursing Mothers. It is unknown whether vorapaxar or its metabolites are excreted in human milk, but it is actively secreted in milk of rats. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from ZONTIVITY, discontinue nursing or discontinue ZONTIVITY.

Pediatric Use. The safety and effectiveness of ZONTIVITY in pediatric patients have not been established.

Geriatric Use. In TRA 2°P, in post-MI or PAD patients without a history of stroke or TIA, 33% of patients were ≥65 years of age and 9% were ≥75 years of age. The relative risk of bleeding (ZONTIVITY compared with placebo) was similar across age groups. No overall differences in safety or effectiveness were observed between these patients and younger patients. ZONTIVITY increases the risk of bleeding in proportion to a patient's underlying risk. Because older patients are generally at a higher risk of bleeding, consider patient age before initiating ZONTIVITY *[see Adverse Reactions]*.

Renal Impairment. No dose adjustment is required in patients with renal impairment.

Hepatic Impairment. No dose adjustment is required in patients with mild and moderate hepatic impairment. Based on the increased inherent risk of bleeding in patients with severe hepatic impairment, ZONTIVITY is not recommended in such patients *[see Warnings and Precautions]*.

OVERDOSAGE

There is no known treatment to reverse the antiplatelet effect of ZONTIVITY, and neither dialysis nor platelet transfusion can be expected to be beneficial if bleeding occurs after overdose. Inhibition of platelet aggregation can be expected for weeks after discontinuation of normal dosing. There is no standard test available to assess the risk of bleeding in an overdose situation.

NONCLINICAL TOXICOLOGY

Animal Pharmacology

Vorapaxar did not increase bleeding time in non-human primates when administered alone. Bleeding time was prolonged slightly with administration of aspirin or aspirin plus vorapaxar. The combination of aspirin, vorapaxar, and clopidogrel produced significant prolongation of bleeding time. Transfusion of human platelet rich plasma normalized bleeding times with partial recovery of *ex vivo* platelet aggregation induced with arachidonic acid, but not induced with ADP or TRAP. Platelet poor plasma had no effect on bleeding times or platelet aggregation *[see Warnings and Precautions]*.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved Patient Labeling (Medication Guide).

Benefits and Risks

- Summarize the benefits and potential side effects of ZONTIVITY.
- Tell patients to take ZONTIVITY exactly as prescribed.
- Inform patients not to discontinue ZONTIVITY without discussing it with the prescribing physician.
- Tell patients to read the Medication Guide.

Bleeding

Inform patients that they:

- May bleed and bruise more easily.
- Should report any unanticipated, prolonged or excessive bleeding, or blood in their stool or urine.

Invasive Procedures

Instruct patients to:

- Inform physicians and dentists that they are taking ZONTIVITY before any surgery or dental procedure.
- Tell the doctor performing any surgery or dental procedure to talk to the prescribing physician before stopping ZONTIVITY.

Concomitant Medications

Tell patients to list all prescription medications, over-the-counter medications, or dietary supplements they are taking or plan to take so that the physician knows about other treatments that may affect bleeding risk.

For more detailed information, please read the Prescribing Information.

uspi-mk5348-t-1504r001

Revised: 04/2015

CARD-1154460-0000 07/15

MERCK

iScience

The ACC.16 *Meeting on Demand*™ Program

ORDER TODAY AND SAVE $1,000 OR MORE*

The easiest way to watch the session you can't attend during the meeting.

Special offer ends April 4, 2016

List Price	Members	Non-Members	FIT/CV Team Members	Allied Health/ Resident Non-Members
~~$1,499~~	$399 **Save $1,100**	$499 **Save $1,000**	$199 **Save $1,300**	$249 **Save $1,250**

Hard drive available for additional $50.

Features of iScience include:

- 400 hours of sessions available within 24 hours of the live presentation
- Online access from any computer or mobile device
- Advanced Search: Find any word on any slide
- Recently Viewed: Revisit presentations and pick up where you left off
- Downloadable MP3 audio files (listen to presentations on-the-go)
- Printable PDFs of presentations (for easier note taking and review)
- CME available
- Portable hard drive for offline access (available for additional $50 fee)

ORDER TODAY

Onsite Sales Booths:
North Hall B1 or
ACC Central, Booth #14033

Online:
iScience.acc.org/Chicago

Phone:
800-501-2303 (U.S. only)
or 818-844-3299
Monday – Friday, 6:00 a.m. – 5:00 p.m. PST

ACC.16 LEARNING DESTINATIONS

Schedule for
Sunday, April 3
Hall A1

Learning Destinations and Prime Time Events are not part of ACC.16, as planned by its Program Committee, and do not qualify for continuing medical education (CME), continuing nursing education (CNE) or continuing education (CE) credit.

PRIME TIME EVENTS

6:30 p.m. – 8:30 p.m.
Chicago Marriott Downtown Magnificent Mile, Grand Ballroom

Introducing a New Treatment Option for PAH: A Case-based Discussion

The science behind pulmonary arterial hypertension (PAH) continues to evolve. This interactive, case-based symposium will feature a panel of experts who will introduce a new option for the treatment of patients with PAH.

Dinner will be provided. Dinner will not be provided to physicians and other healthcare professionals licensed in Vermont or other states where gifts and meals are prohibited.

Ronald Oudiz, MD, FACC
Program Chair, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center

Myung Park, MD, FACC
Houston Methodist Hospital

Victor Tapson, MD
Cedars-Sinai Medical Center

Sponsored by Actelion Pharmaceuticals US, Inc.

6:30 p.m. – 8:00 p.m.
Palmer House, Grand Ballroom

Managing Stroke Risk in NVAF Patients: The Role of Left Atrial Appendage Closure

An expert panel discusses Left Atrial Appendage Closure including the supporting clinical data, their experience with LAAC, and appropriate patient selection.

Moderated by:

Vivek Reddy, MD
Mount Sinai Medical Center

Speakers:

William O'Neill, MD, FACC
Henry Ford Hospital

Megan Coylewright, MD, MPH
Heart & Vascular Center, Dartmouth-Hitchcock Medical Center

As space is limited, please register for this event at *watchmandevice.com/ACC16*

Sponsored by Boston Scientific Corporation

* Information is current as of March 23, 2016 and is subject to change. For the most up-to-date information, download the ACC.16 App, or visit *accscientificsession.org*.

ACC.16 EXHIBITORS
By Booth Number

ACC International Chapters

IC 1 ACC Chapter in Egypt
IC 2 Interamerican Society of Cardiology
IC 3 Hellenic Cardiological Society
IC 4 Cardiology Societies of Serbia and Republic of Srpska Society of Cardiology
IC 5 ACC Italy Chapter
IC 6 ACC International Regional Conferences
IC 7 ACC China Chapter
IC 8 Mexico Chapter of the American College of Cardiology
IC 9 Chinese Society of Cardiology
IC 10 Israel Heart Society
IC 11 British Cardiovascular Society
IC 11 Irish Cardiac Society & Irish Board for Training in Cardiovascular Medicine
IC 13 Philippine Heart Association
IC 14 Russian Society of Cardiology
IC 15 ACC Caribbean Chapter – Caribbean Cardiac Society
IC 16 Canadian Cardiovascular Society

Patient Engagement Pavilion

PEP 1 GUARDaHeart
PEP 2 Association of Black Cardiologists
PEP 3 American Association of Cardiovascular and Pulmonary Rehabilitation
PEP 4 StopAfib.org
PEP 5 WomenHeart: The National Coalition for Women with Heart Disease
PEP 6 The FH Foundation
PEP 7 Society of Cardiovascular Patient Care
PEP 8 Health Media Network
PEP 9 Preventive Cardiovascular Nurses Association
PEP 10 Hypertrophic Cardiomyopathy Association
PEP 11 American Association of Heart Failure Nurses
PEP 12 National Forum Heart Disease & Stroke Prevention
PEP 13 Mended Hearts, Inc.
PEP 14 Mended Little Hearts
PEP 15 Medisafe

1000

1004 Israel 2017 Acute Cardiac Care Conference
1005 ACIST Medical Systems
1006 Munson Healthcare
1008 Daxor Corporation
1012 University of Tennessee Physician Executive MBA Program
1013 theheart.org/Medscape Cardiology
1014 All Star Recruiting
1016 Gore & Associates
1018 Thinklabs Medical
1020 Auburn University Physicians Executive MBA Program
1021 SCAD Alliance
1026 Cardiology Today and Healio.com by SLACK Incorporated
1027 DiaDexus Inc.
1028 3D Systems, Healthcare
1029 Cardionics
1030 Lifeline Sciences
1033 Mayo Clinic
1034 Johns Hopkins Aramco Healthcare
1036 eNNOVEA LLC
1038 Nasiff Associates, Inc.
1039 Mayo Clinic Self Study Tutorials in Cardiology
1040 American College of Lifestyle Medicine
1041 Cardio Renal Society of America
1042 Chison Medical Imaging Co., Ltd.
1044 HCPLive
1045 Mindray North America
1051 Daiichi Sankyo
1052 Ambu Inc.
1054 VectraCor, Inc.
1062 Harvard Clinical Research Institute
1063 Schiller AG
1068 New Haven Pharmaceuticals, Inc.
1070 Edan Instruments, Inc.
1074 Hospital Corporation of America
1075 Community Health Systems
1076 Society for Cardiovascular Angiography and Interventions Foundation
1077 CoverMyMeds LLC
1079 AltaThera Pharmaceuticals
1080 Pulmonary Hypertension Association
1082 Staff Care, Inc.
1083 Konsyl Pharmaceuticals
1084 Gamma Systems Services, Inc
1085 Mespere Lifesciences Inc.

2000

2021 Amery Medical Academy
2025 Diagnostic and Interventional Cardiology
2026 Siemens Healthcare
2027 Jaypee Brothers Medical Publishers
2029 D.E. Hokanson
2034 BioTelemetry Healthcare, CardioNet/Mednet
2039 CardioVillage/University of Virginia
2041 EncaptureMD Flexible Informatics
2042 The National Death Index
2046 Intermountain Heart Institute
2064 Cardiorentis
2068 Transgenomic, Inc.
2072 Preventice Solutions
2073 Medicomp, Inc.
2077 SIUI American, Inc.
2078 Quten Research Institute, LLC
2079 Labtech Ltd
2080 CardioAlex 2016
2083 HealthCare International, Inc.
2084 WCPCCS 2017

3000

3002 Medtronic
3014 Siemens Healthcare
3027 Sanofi Regeneron
3039 Accriva Diagnostics
3041 AtCor Medical, Inc. (USA)
3042 Cook Medical Incorporated
3045 W.A. Baum Company
3049 Novartis Pharmaceuticals Corporation
3064 Janssen Pharmaceuticals, Inc.
3065 Janssen Pharmaceuticals, Inc.
3068 Cardiology News
3077 HealthLevel, Inc.
3078 Glenmark Pharmaceuticals
3079 Concierge Choice Physicians
3080 Vales & Hills Biomedical Tech. Ltd.
3082 World Heart Federation
3086 ScribeAmerica, LLC
3087 ContextMedia:Health

4000

4039 Zeus Scientific
4040 Sanofi-Regeneron
4041 Conavi Medical
4042 Healthways
4043 ScottCare Cardiovascular Solutions
4044 TIMI Study Group, Brigham & Women's Hospital
4077 American Society Of Nuclear Cardiology

4078 TeraRecon, Inc.
4079 Alaska Native Medical Center
4086 Norav Medical

5000

5040 CellAegis Devices, Inc.
5044 IEM

6000

6003 Pfizer
6017 Amgen
6029 Amarin Pharma Inc.
6037 AstraZeneca
6049 Elsevier
6054 Philips
6067 Boehringer Ingelheim Pharmaceuticals, Inc.
6079 American Heart Association
6087 The Heart Hospital Baylor Plano

7000

7002 Merck & Co., Inc.
7031 GE Healthcare
7051 TOMTEC IMAGING SYSTEMS GMBH
7061 Toshiba Medical Systems
7081 Cytokinetics, Inc.
7087 European Society of Cardiology

8000

8032 Bayer Healthcare Pharmaceuticals Inc.
8040 AstraZeneca
8054 Mortara Instrument, Inc.
8062 Relypsa
8070 Actelion Pharmaceuticals US, Inc.
8082 Aralez
8087 DOTmed.com
8089 Clementine Live Answering Service
8090 Denka Seiken Co., Ltd.

9000

9003 Medstreaming
9019 MedAxiom
9025 Inova Heart and Vascular Institute
9041 Duke Clinical Research Institute
9049 Gilead Sciences, Inc.
9061 McKesson Corporation
9083 Boehringer Ingelheim Pharmaceuticals, Inc.
9089 United Therapeutics Corp.

10000

10004 St. Jude Medical
10020 Lundbeck, Inc.
10026 Corindus Vascular Robotics
10033 Cordis, A Cardinal Health Company
10071 BMS/Pfizer
10097 Corazon, Inc
10099 Relypsa
10101 Nationwide Childrens Hospital
10102 GeneDx, Inc.
10104 Leonhard Lang USA

11000

11021 3M Littmann Stethoscopes
11027 ZOLL Medical Corporation
11102 Portola Pharmaceuticals, Inc.
11103 Digisonics, Inc.

12000

12026 Boston Scientific
12104 Children's Hospital of Wisconsin

13000

13015 Bracco Diagnostics, Inc.
13021 Rijuven
13104 Fruit Street Health
13105 LifeWatch Inc.
13106 Centers for Disease Control and Prevention – Office on Smoking and Health

14000

14014 ABIOMED, Inc.
14023 Medicure
14026 Abbott
14033 ACC Central
14104 ACS Diagnostics, Inc.

15000

15107 MNG Laboratories
15109 Cardiovascular Business

16000

16016 Advocate Children's Hospital
16020 EKOS Corporation, a BTG International group company
16024 Edwards Lifesciences
16107 Mazankowski Alberta Heart Institute
16108 dms-service llc

17000

17016 Best Vascular/Novoste
17018 Northwestern Medicine
17108 Sensogram Technologies, Inc.

18000

18018 HeartWare
18024 Endovascular Today
18026 CBSET, Inc.
18028 AtriCure, Inc.
18030 Itamar Medical
18032 Terumo Interventional Systems
18110 Houston Methodist DeBakey Heart & Vascular Center

19000

19019 Pulse Medical
19023 MAQUET Medical Systems
19024 United Biologics, Inc.
19025 Prothia LLC
19026 Unfors RaySafe
19028 Koven Technology, Inc.
19029 Cardiovascular Research Foundation
19030 Greater Hudson Valley Health System
19032 TandemLife
19035 The Medicines Company
19110 Providence Health & Services
19111 Admera Health

20000

20019 Mount Sinai Heart
20021 Transradial Solutions LLC - Cardio-TRAP
20023 Beijing Demax Medical Technology Co.,Ltd
20024 Arbor Pharmaceuticals
20025 Spartan Bioscience
20032 Astellas
20034 The Interventionist Back Saver
20038 Hitachi Aloka Medical
20046 Merge Healthcare, an IBM Company
20054 ZS Pharma
20062 nVoq Incorporated
20066 Cerner Corporation
20070 Epiphany Healthcare
20076 SciImage, Inc.
20084 iRhythm Technologies, Inc
20092 Objective Medical Systems, LLC
20094 NextGen Healthcare
20098 MD Anderson Cancer Center, Cardiology
20106 Banyan
20108 Captive Risk Planners
20110 Health Net Connect, Inc.
20111 Lohman Technologies
20112 PreventionGenetics
20114 HRA Healthcare Research & Analytics

21000

21027 Cyfuse Biomedical
21029 Ambry Genetics
21032 DICOM Grid
21033 HMP Communications
21034 Spectranetics
21039 Millar, Inc.
21047 Epsilon Imaging
21051 Alliance for Physician Certification and Advancement (APCA)
21053 CBNC/CBCCT
21057 NEJM Group
21061 IU Kelley School Business of Medicine Physician MBA
21063 American Society of Echocardiography
21071 Circle Cardiovascular Imaging Inc
21076 FUJIFILM Medical Systems USA, Inc.
21084 Agfa HealthCare Corp.
21088 Medis Medical Imaging Systems
21089 ResMed
21092 Core Sound Imaging
21095 IntegriTech
21098 ASCEND HiT
21099 WMCHealth
21104 ISCTR
21105 Jackson & Coker
21106 NorthEast Monitoring, Inc.
21109 Integrated Systems Management Inc. (Omnimd)
21112 Vasomedical, Inc

22000

22027 GSK
22029 Lifeline Vascular Access
22030 Cleveland Clinic C5Research
22031 Southwest Medical Resources
22033 ScribeAmerica, LLC
22034 The Doctors Company
22038 athenahealth, Inc.
22039 Spacelabs Healthcare
22042 Springer
22045 SmartBrief, Inc.
22046 Wolters Kluwer
22047 American College of Physicians/Annals of Internal Medicine
22051 John Wiley & Sons, Inc.
22052 Oxford University Press
22053 Cardiotext
22057 McGraw-Hill Education
22059 The JAMA Network
22060 Taylor & Francis
22061 CRC Press / Taylor & Francis Group LLC
22063 American Board of Internal Medicine
22064 Cardiostim 2016 – REED Expositions France
22065 Blueprint Genetics
22066 Eizo, Inc.
22069 Aprima Medical Software, Inc.
22070 Infinitt North America
22071 Pie Medical Imaging, B.V
22076 LUMEDX
22082 QGenda, Inc.
22084 Laitek Inc.
22085 Greenway Health
22086 1Comm Medical
22089 Logan Solutions
22092 Pulse Systems, Inc.
22093 AliveCor, Inc.
22094 Radcliffe Cardiology
22098 The FH Foundation
22100 National Board of Physicians and Surgeons
22105 Amyloidosis Foundation
22107 BCM/John Welsh Cardiovascular Diagnostic Laboratory
22108 HealthWatch TeleDiagnostics Pvt., Ltd.
22118 ABIOMED, Inc.

23000

23038 American College of Radiology
23040 SA Heart
23042 Cardiovascular Credentialing International (CCI)

Non-Statin Treatment

continued from page 1

clinical guidance. The document provides treatment algorithms and details the patient groups for which it is reasonable to consider a PSCK9 inhibitor and other non-statin therapies.

Before adding other treatment approaches to a statin, there should be a thorough assessment of adherence and intolerance to statin and reinforcement of all healthy lifestyle habits. In most cases, ezetimibe should be the first choice for an additional drug, and exhaustive efforts made to optimize and maximize statin therapy before considering adding a PCSK9 inhibitor. ACC's Statin Intolerance App, which launched in 2015, is a useful tool for physicians and patients.

The nearly $15,000 annual price tag for these drugs is an issue, "particularly because of the lack of data showing a clinical gain," says **Joseph Alpert, MD,** who co-chaired a scientific session yesterday that discussed the economic implications of PCSK9 inhibitors. However, he notes their cost is "not out of control" for an engineered molecule and in line with those used in hematology and oncology. The willingness of patients to contribute to the cost of these drugs is another question.

Today's Innovation Stage presentation "Praluent® (alirocumab) Injection: Efficacy and Safety with Two Different Dosing Regimens," given by **Paul Davis Thompson, MD, FACC,** chief of the Division of Cardiology, Hartford Hospital, will review the mechanism of action, efficacy and safety data of two dosing regimens. The presentation will take place from 9:45 to 10:15 a.m. and is sponsored by Sanofi-Regeneron.

Later today, **Seth J. Baum, MD, FACC,** of

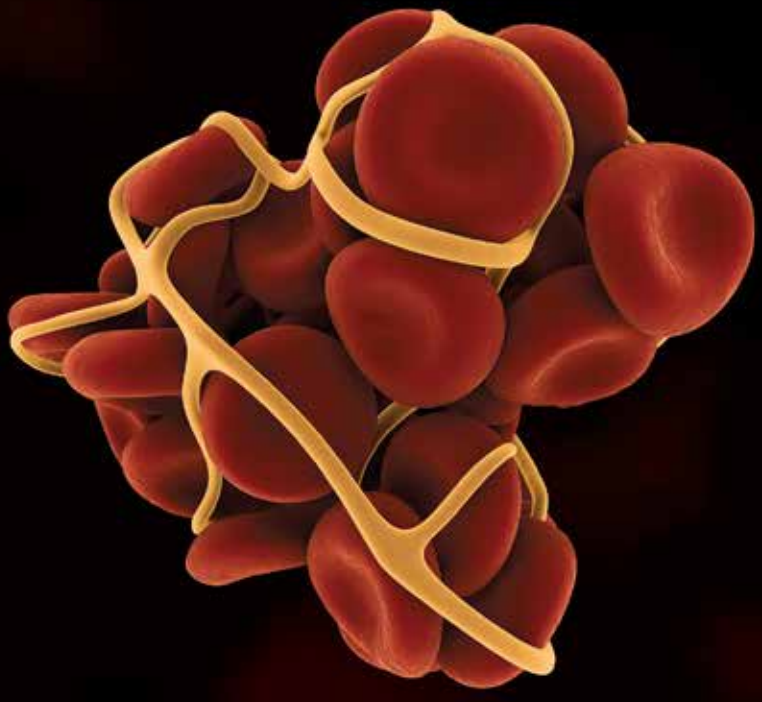
North Ridge Heart Associates, will be giving a product overview of Repatha® (evolocumab) in Industry-Expert Theater 2. The presentation will take place from 12:45 to 1:45 p.m. and is sponsored by Amgen.

Thompson will also be giving a separate presentation sponsored by Amgen later today in the Innovation Stage from 3:45 to 4:15 p.m. on "A Focused Look at Unmet Need in Hyperlipidemia."

You are invited to a Lunch Industry-Expert Theater Presentation at **ACC.16**

THROMBOSIS: AFib & DVT/PE

AN EXPLORATION IN RISK REDUCTION



SUNDAY, APRIL 3, 2016

12:45 PM – 1:45 PM

McCormick Place
Industry-Expert Theater 1
Expo Hall, #24100
Chicago, Illinois

Marc Cohen MD, FACC, FACP, FSCAI, FAHA
Chief, Division of Cardiology
Newark Beth Israel Medical Center
Newark, New Jersey
Professor of Medicine
Rutgers - New Jersey Medical School
New Brunswick, New Jersey
Professor of Medicine
Icahn School of Medicine at Mount Sinai
New York, New York

PROGRAM DESCRIPTION

This lecture will discuss treatment options for patients with deep vein thrombosis and pulmonary embolism and how they can reduce the risk of recurrent thrombotic events. It will also present options for reducing the risk of stroke in patients with nonvalvular atrial fibrillation.

In adherence with PhRMA guidelines, spouses or other guests are not permitted to attend company-sponsored programs.

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

Please note that the company prohibits the offering of gifts, gratuities, or meals to federal government employees/officials. Thank you for your cooperation.

This promotional educational activity is not accredited. The program content is developed by Janssen Pharmaceuticals, Inc. Speakers present on behalf of the company and are required to present information in compliance with FDA requirements for communications about its medicines.

The personal information you provide may be used to contact you about your request to attend the Janssen Pharmaceuticals, Inc., educational program using your preferred method of communication as indicated by you. This information may be shared with Janssen Pharmaceuticals, Inc., its affiliates, and a third party for the sole purpose of completing your registration for this program and as required by law.

This event is not part of ACC.16, as planned by its Program Committee, and does not qualify for continuing medical education (CME), continuing nursing education (CNE) or continuing education (CE) credit.

Supported by Janssen Pharmaceuticals, Inc.

janssen | PHARMACEUTICAL COMPANIES OF Johnson&Johnson

February 2016

046619-160202