Nearly 200 Medicines in Development for Heart Disease, Stroke and Other Cardiovascular Diseases

According to the American Heart Association, someone in the United States dies from cardiovascular disease every 40 seconds, and more than 85 million Americans have at least one form of the disease. Heart disease has been the leading cause of death in the United States since 1921, but these numbers are declining.2

Age-adjusted death rates (per 100,000 population) from diseases of the heart have dropped from 412 in 1980 to 191 in 2012.2 In 2013, stroke dropped to the fifth leading cause of death after being the third or fourth leading cause for more than 50 years.2 While changes in behavior and lifestyle have had a significant impact, declining death rates from heart disease and stroke are largely thought to be a result of new medicines.

The future is promising: today, biopharmaceutical research companies are developing 190 medicines3 for two of the nation’s leading causes of death—heart disease and stroke—all of which are in clinical trials or undergoing regulatory review by the U.S. Food and Drug Administration.

Therapies in the pipeline today hold promise to build on the progress made by existing treatments. Recent therapeutic advances in cardiovascular disease include:

- New therapies for pulmonary arterial hypertension that slow disease progression and reduce the risk of serious heart events associated with the disease.
- A first-in-class medicine to reduce cardiovascular events in patients with a history of heart attacks or peripheral arterial disease.
Innovative Medicines in the Pipeline

Many of the medicines in the pipeline today use novel approaches to treat cardiovascular disease. Among the 190 medicines in development are potential treatments for:

ACUTE CORONARY SYNDROME

Acute coronary syndrome (ACS) refers to cardiovascular events, including heart attack, where there is an abrupt reduction of blood flow to the heart through the coronary arteries. An anti-inflammatory medicine in development for the syndrome inhibits the activity of p38 mitogen activated protein (MAP) kinase, an enzyme associated with the acute inflammation that occurs in the blood vessels during and immediately following an acute coronary syndrome event.

HEART FAILURE

A medicine in development to treat ischemic heart failure is a non-viral gene therapy that targets a tissue repair and regeneration pathway in the body. This pathway promotes cardiac function, cell survival and the repair of injured heart tissue.

CARDIOMYOPATHY

An investigational therapeutic using RNAi (RNA interference) is targeting the protein transthyretin (TTR) for the treatment of familial amyloid cardiomyopathy (FAC). FAC is associated with mutations in the TTR gene that cause the TTR protein to fold or assemble incorrectly, resulting in an accumulation of amyloid fibril deposits in vital organs, such as the heart. RNAi is a biological process that can be used to silence a gene and, in turn, prevent production of the protein it encodes.

The medicines in the development pipeline today are continuing the already remarkable progress against heart disease and stroke, and promise longer, healthier lives for patients suffering from these diseases.

Some medicines are listed in more than one category. For a complete list of the 190 medicines in development, please visit http://phrma.org/sites/default/files/pdf/cardiovascular-drug-list-2015.pdf.

33 for heart failure, which affects about 5.7 million American adults.¹

29 for lipid disorders, including high cholesterol, which affects 30.9 million American adults with total cholesterol levels of more than 240.¹

21 for stroke, which affects 6.6 million American adults.¹

18 for peripheral vascular diseases, including critical limb ischemia and intermittent claudication.

12 for hypertension, or high blood pressure, which affects 80 million adults in the United States.¹

12 for thrombosis, a condition characterized by coagulation or clotting of the blood in the veins or arteries (circulatory system).

The 190 medicines in development for cardiovascular disease, including heart disease and stroke, include:

• The first medicines in a new class of cholesterol-lowering medicines that target LDL-C (low-density lipoprotein cholesterol), or “bad” cholesterol.

• The first in a new class of treatments for heart failure that eases the strain on the failing heart, reducing repeat hospitalizations and death.
Diversity in Clinical Trials:
ABC Clinical Trials Network

The Association of Black Cardiologists (ABC) is a nonprofit organization with an international membership of 1,500 health professionals, lay members of the community (Community Health Advocates), corporate members and institutional members, dedicated to achieving health equity and eliminating disparities related to cardiovascular disease in all people of color.

The ABC Clinical Trials Network (ABC CTN) provides investigators from multiple specialties with unparalleled access to clinical studies of interest while offering industry “one-stop” access to multiple investigators that ascribe to the same standard of clinical trial conduct.

Comprised of investigators from a variety of therapeutic areas, the ABC CTN was developed to serve as a central “wheel hub” of sorts to identify and vet clinical trial opportunities, match investigators to trials of interest, and provide some of the infrastructure support that some physicians have said they would find to be beneficial. More information for investigators and industry can be found here: www.abcardio.org/memberservices_research.php.

ABC believes this is a win-win for investigators to create or increase their flow of research studies while reducing some of the administrative burden and associated costs. Patients will also have access to a portal that offers a wealth of educational resources as well as information about clinical studies of interest.

ABC CTN members will enjoy a number of benefits, such as, clinical trial training and certification, referral to scientific leadership opportunities, contract and budget negotiation services, patient recruitment and retention support, the strength of ABC’s combined marketing and research development to identify trials of interest, periodic training on clinical research topics of interest, access to therapeutic area mentors and industry leading diversity engagement updates.

Immediate Past President and ABC Research Committee Chair Dr. Ola Akinboboye said, “We are excited about the unlimited potential of the ABC Clinical Trials Network for many reasons, but especially because of the opportunity to positively impact ethnic diversity in clinical trials, which is central to ABC’s mission.”

ABC membership is not required nor is there a fee to join the clinical trials network. To join, please take a few minutes to complete the ABC CTN survey. The purpose of this survey is to gather information regarding clinical research interests and capacity.

TO COMPLETE THE ABC CTN SURVEY QUESTIONS, PLEASE VISIT: WWW.SURVEYMONKEY.COM/S/ABCCLINICALTRIALSNETWORK
“FACTORS CONTRIBUTING TO THE DECLINE IN HEART DISEASE AND STROKE MORTALITY INCLUDE BETTER CONTROL OF RISK FACTORS, IMPROVED ACCESS TO EARLY DETECTION, AND BETTER TREATMENT AND CARE, INCLUDING NEW DRUGS AND EXPANDED USES FOR EXISTING DRUGS.” - CDC

Spotlight: Heart Failure

ADHERENCE AND ECONOMIC VALUE

As the prevalence and cost of heart failure increases, a recent study\(^1\), supported by PhRMA, found that improved adherence to medication, following the expansion of drug coverage under Medicare Part D, led to nearly $2.3 billion in savings in Medicare expenditures annually among beneficiaries with congestive heart failure. Despite the improvements in adherence following Part D, medication use remains sub-optimal. The study also found that improving adherence to recommended levels could save Medicare another $1.9 billion annually, leading to $22.4 billion saved over 10 years.

BIOMARKERS AND PERSONALIZED MEDICINE

Molecular biomarkers (i.e., characteristics that can guide treatment and diagnosis) are integral to personalized medicine and have the potential to expedite drug development, increase patient safety and help to optimize clinical response. Findings from a recent survey\(^2\) of the biopharmaceutical industry conducted by PhRMA and the Biotechnology Industry Organization (BIO) suggest that congestive heart failure is one of the top categories where qualified biomarkers may be the most useful in drug development. Currently, industry, regulators, academia, patient groups and others are working on solutions to increase the number of qualified biomarkers so they can be used to improve the efficiency of drug development.

THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS

From drug discovery through FDA approval, developing a new medicine takes at least 10 years on average and costs an average of $2.6 billion.\(^3\) Less than 12% of the candidate medicines that make it into Phase I clinical trials will be approved by the FDA.

Footnotes:
1. American Heart Association
2. Centers for Disease Control and Prevention, National Center for Health Statistics
3. Number of medicines obtained through public, government and industry sources, and the Adis “R&D Insight” database, Current as of November 6, 2015.
4. Age-adjusted death rates per 100,000 based on Year 2000 US Standard Population. 1980-1998 causes of death are classified by the Ninth Revision International Classification of Diseases (ICD-9). Beginning in 1999, causes of death are classified by the Tenth Revision International Classification of Diseases (ICD-10)