MEDICINES IN DEVELOPMENT / 2018 REPORT

America's Biopharmaceutical Companies

HEART DISEASE AND STROKE

JUST THE FACTS[1]

HEART DISEASE

IS THE LEADING CAUSE OF DEATH IN THE UNITED STATES

ABOUT

92.1 M

AMERICAN ADULTS ARE LIVING WITH SOME FORM OF CARDIOVASCULAR DISEASE

THERE ARE MORE THAN

800,000

CARDIOVASCULAR DISEASE DEATHS IN THE UNITED STATES EACH YEAR

$316 B

— THE COST OF CARDIOVASCULAR DISEASE AND STROKE IN THE UNITED STATES

MEDICINES IN DEVELOPMENT FOR

HEART DISEASE & STROKE

Biopharmaceutical Researchers are Developing **200 Medicines** for Leading Causes of Death in the United States

Cardiovascular disease, which includes heart disease and stroke, are devastating diseases that share many of the same risk factors and can often occur together. The American Heart Association estimates that cardiovascular disease accounts for about one of every three deaths in the United States each year, making it the leading cause of death in the country. Someone in the United States dies from cardiovascular disease every 40 seconds, and more than 92 million Americans are living with at least one form of the disease or the after-effects of stroke.[1]

Despite the high death rate from cardiovascular disease in the United States, we have made progress. Death rates (per 100,000 population) from heart disease have dropped substantially in recent years, from 412 in 1980 to 168 in 2015.[2] In 2013, stroke dropped to the fifth leading cause of death after being the third or fourth leading cause for 75 years.[2] These declines are due to better prevention, diagnosis and treatment.

Changes in behavior have had a significant impact, with fewer people smoking and increased awareness of healthy lifestyle choices, including diet and exercise. Improved heart medicines and procedures are also having a tremendous impact in driving declining death rates from heart disease and stroke.[3]

Two breakthroughs in medicine that have helped to reduce cardiovascular deaths include the use of the anticoagulant warfarin to thin blood and reduce the risk of stroke, and cholesterol lowering statins that help reduce low-density lipoprotein (LDL, or "bad" cholesterol). This progress offers hope for continued advances to meet the remaining unmet need.

Today, biopharmaceutical research companies are developing 200 medicines[4] for cardiovascular diseases. The medicines in development for cardiovascular disease, including heart disease and stroke, include:

- **42 for heart failure**, which affects about 6.5 million American adults.[1] Heart failure occurs when the heart isn't pumping as well as it should be to deliver oxygen- and nutrient-rich blood to the body's cells. Congestive heart failure is a type of heart failure.

- **23 for stroke**, which is the leading cause of serious long-term disability in the United States. Each year, about 795,000 Americans experience a new or recurrent stroke.[1] A stroke occurs when a blood vessel to the brain is blocked by a clot or ruptures, causing the brain to be deprived of blood and oxygen and brain cells to die.

- **20 for peripheral vascular diseases**, including critical limb ischemia, intermittent claudication and peripheral artery disease (PAD). PAD is caused by atherosclerosis that narrows and blocks arteries to critical areas of the body, but most commonly the legs.

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

- **25 for lipid disorders**, including high cholesterol. Lipid disorders affect 94.6 million American adults with total cholesterol levels of more than 200.[1] High cholesterol is one of the major controllable causes of and risk factors for coronary heart disease, heart attack and stroke.

- **14 for hypertension**, or high blood pressure. Hypertension affects more than 85 million adults in the United States.[1] If left untreated, high blood pressure can cause damage to the circulatory system, contributing significantly to heart attack and stroke.

Women and Heart Disease

Although heart disease is the leading cause of death for both men and women, awareness is lower for its impact on women: only a little more than half of women (56 percent)[5] recognize that heart disease is the leading cause of death. Specifically, heart disease is the leading cause of death for all African American and Caucasian women in the United States, accounting for about one in every four female deaths each year.[6] Among Hispanic women, heart disease and cancer cause about the same number of deaths each year. For American Indian or Alaska Native and Asian or Pacific Islander women, heart disease is second only to cancer. While most people are aware of the signs of heart attack as crushing chest pain that radiates to the shoulder or down the arm, women can experience very different symptoms. Additionally, nearly two thirds of women who die suddenly of coronary heart disease did not have any previous symptoms.[6] According to the U.S. Centers for Disease Control and Prevention (CDC), while some women have no symptoms, others may experience sharp chest pain, pain in the neck, jaw, and throat; or pain in the upper abdomen or back. These symptoms can occur during both periods of rest or physical activity, or be triggered by mental stress. Women are also more likely to describe chest pain that is sharp and burning as opposed to the pressure-like pain that is thought to be "classic" for heart attack.

High cholesterol, high blood pressure (hypertension) and diabetes are all risk factors for heart disease, stroke, and other cardiovascular diseases. In addition, smoking, lack of physical activity, being overweight, and a high fat diet all contribute to high cholesterol, high blood pressure, diabetes, and ultimately, heart disease and stroke. Medicines in development for lipid disorders and hypertension are included in this report. You can find information on diabetes medicines in development **here.**

Innovative Medicines in the Pipeline

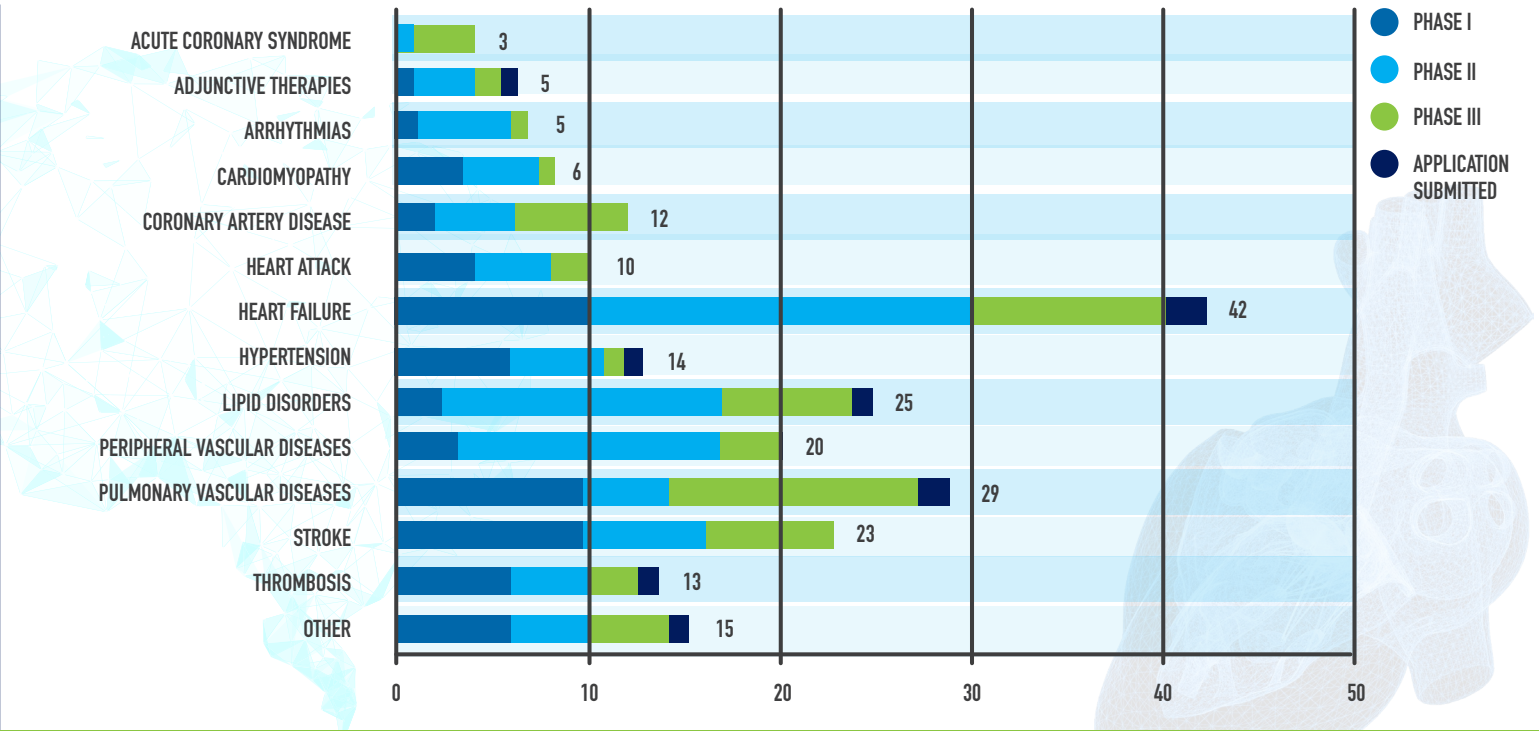
Therapies in the development pipeline today aim to build on the progress made by existing treatments with many using novel approaches to treat cardiovascular disease. Among the 200 medicines in development are potential treatments for:

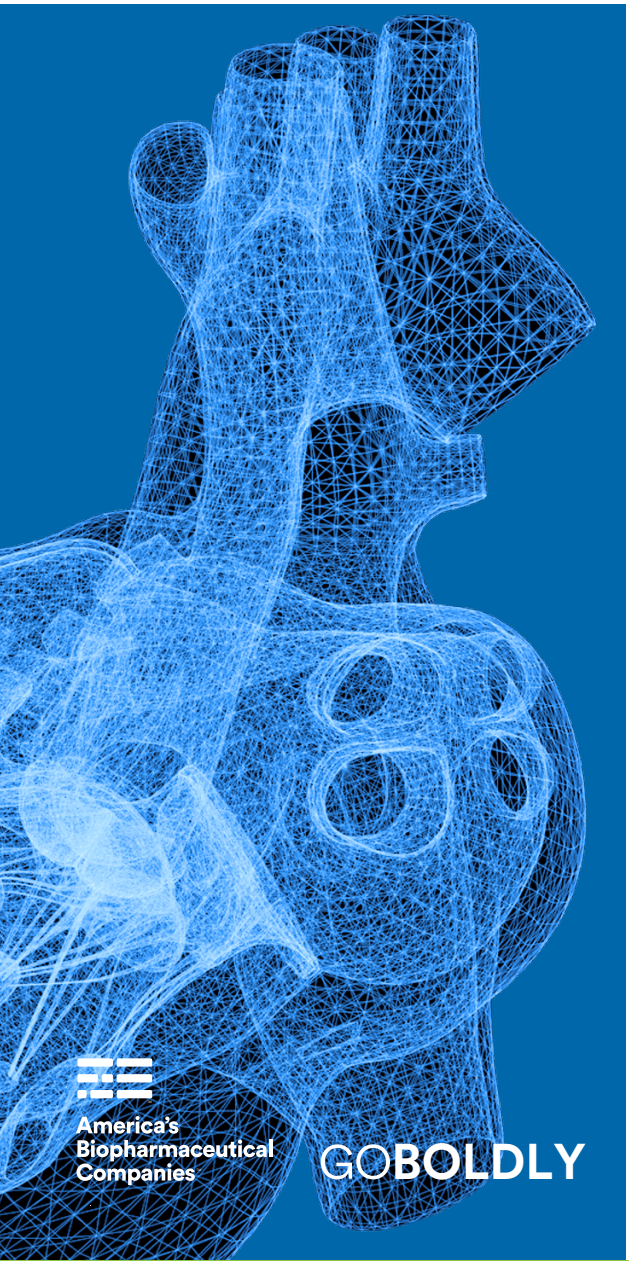
Coronary Artery Disease
A medicine is in clinical trials to potentially reduce major adverse cardiac events, such as heart attack or stroke, in patients with coronary artery disease, type 2 diabetes and low levels of high-density lipoprotein (HDL, or "good" cholesterol). The medicine is an inhibitor of the BET (bromodomain and extra-terminal) protein. It is thought that the inhibition of BET can produce specific biological effects that can provide health benefits to these patients and reduce the incidence of adverse cardiac events.

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.

Stroke
A novel treatment is being tested for the potential to reverse brain damage suffered from a stroke – often referred to as a heart attack of the brain. The treatment, a combination of a human activated protein C (a protein that plays a role in regulating anticoagulation) and human stem cells, is administered to patients within a few hours of having had an ischemic stroke. The transplanted combination stem cells mature into brain cells, helping to reverse brain damage from the stroke. Ischemic strokes account for 87 percent of all strokes.[1]

Medicines in Development by Phase





GOING BOLDLY: MY JOURNEY THROUGH HEART DISEASE AND BACK

In 2006, Roxanne thought she had pulled a muscle in her back, experiencing a dull, but constant pain. The constant pain was annoying enough for her to go to the hospital, where she found out that the twinge in her back was actually a silent heart attack.

She survived the attack, but after numerous tests, doctor visits and medications, she was told she would need a heart transplant – her heart was failing. On July 16, 2010, she received the news that a heart match had been found. It was the heart of a 23-year-old U.S. Coast Guard fireman, who had checked the organ donor box on his military ID, saving the lives of five people, all from different backgrounds and ethnicities. As Roxanne likes to say, "we all match on the inside."

Leaving the hospital nine days after her transplant surgery, Roxanne is living a full life. New medical breakthroughs are helping patients like Roxanne live longer lives. She takes two different anti-rejection medications every day, as well as a variety of blood pressure medications. These new medications, including the ones that keep her healthy, are allowing transplant recipients to live 20-25 years longer than they used to.

Roxanne had committed to use every one of her years to sign up as many new organ donors as possible. It's how she can honor her donor and his family for the gift of his heart. Today, Roxanne has signed up more than 10,000 Americans for the organ donor registry.

More than 120,000 people are on the waiting list for an organ in the United States. Out of that group, 22 people will die each day waiting for a donated organ. But just one donor can save as many as eight lives.

Sources:

1. *Heart Disease and Stroke Statistics* – 2017 Update, American Heart Association.
2. Centers for Disease Control and Prevention (CDC), National Center for Health Statistics.
3. *Heart disease death rate continues to drop*, American Heart Association News, 12/9/2015.
4. Number of vaccines obtained through public, government and industry sources, and the Springer "Adis Insight" database. Current as of January 24, 2018. The medicines are either in clinical trials or undergoing regulatory review at the U.S. Food and Drug Administration.
5. *Women's Heart Disease Awareness Study (2012)*, GO Red for Women, American Heart Association.
6. Women and Heart Disease Fact Sheet, CDC.