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NEWS RELEASE

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CLEVELAND CLINIC PARTNERING WITH PROCTER & GAMBLE AND CLEVELAND HEARTLAB TO ADVANCE DISCOVERY IN HEART DISEASE

*The Partners Will Build Upon Research That Offers New Insight into Connections Between Diet
and Cardiovascular Disease*

August XX, 2015, CLEVELAND: Cleveland Clinic is collaborating with Cleveland HeartLab and Procter & Gamble (NYSE: PG) to develop and commercialize a diagnostic and management solution for a heart disease biomarker recently discovered by researchers in Cleveland Clinic's Lerner Research and Heart & Vascular Institutes.

As part of the collaboration, Cleveland HeartLab will develop a diagnostic test to measure blood levels of TMAO, or Trimethylamine-N-oxide, a substance produced by gut bacteria and that is linked to heart disease. Meanwhile, Cleveland Clinic researchers will work with Cincinnati-based P&G to develop an over-the-counter product that can help people manage their TMAO levels.

In 2011, a research team led by Dr. Stanley Hazen, vice chair of translational research at the Lerner Research Institute, discovered that elevated blood levels of TMAO are linked to enhanced risk of heart attack, stroke and death. Their studies also showed that TMAO directly contributes to the narrowing of artery walls through atherosclerotic plaque build-up. TMAO gets formed when a dietary nutrient called lecithin, which is most abundant in animal products rich in fat and cholesterol, gets metabolized by the natural bacterial flora in the gastrointestinal tract.

The initial findings were published in 2011 in *Nature*. Follow-up clinical studies were published in 2013 in the *New England Journal of Medicine* and *Nature Medicine*, leading to new insight into the connection between diet, gut bacteria and health. Findings help explain why, for some people, diets rich in foods like red meat, egg yolks and high-fat dairy products are more associated with increased cardiovascular risk. Numerous clinical studies now indicate that

measuring TMAO levels can reveal heightened cardiovascular risks that standard tests, such as cholesterol and inflammation testing, tend to miss.

“The notion that the natural bacteria of the gut would make a substance that becomes a circulating factor related to the risk of heart disease was not on anyone’s radar when Dr. Hazen’s pioneering study was published,” said Dr. Edward A. Fisher, director of the Center for the Prevention of Cardiovascular Disease at NYU School of Medicine. “This research is truly remarkable and has revealed a whole new level for researchers and industry to explore.”

Since the discovery, Cleveland Clinic Innovations – the commercialization arm of Cleveland Clinic – has been working to license the biomarker as a clinical diagnostic test and to develop a solution for managing elevated TMAO levels.

“We knew early on that this discovery was of profound importance and could impact the lives of patients everywhere for the better,” said Dr. Thomas Graham, the Chief Innovation Officer of Cleveland Clinic. “All stakeholders sought to find the right partnership to help realize the potential advancements in health and wellness promised by this discovery.”

Partnering with P&G is a logical strategy, Graham added, because the company has developed and distributed a number of health and wellness brands, including a new “Meta” line of wellness products that offer consumers an array of simple wellness solutions that can be easily incorporated into their lives.

Cleveland Clinic and P&G have entered into a Joint Development Agreement to develop an over-the-counter product that will help manage TMAO levels.

Meanwhile, Cleveland HeartLab has licensed the biomarker in order to offer TMAO testing. The company, a Cleveland Clinic spinoff, will validate the test in its CLIA-certified and CAP-accredited clinical laboratory. It intends to add the new test to its menu of advanced cardiovascular disease tests by the end of the year.

“This collaborative effort between nationally recognized leaders further illustrates Cleveland HeartLab’s commitment to bring cutting-edge discoveries to clinicians who are eagerly looking for better tools to manage heart disease, the number one killer of men and women in the US.” said Jake Orville, President and CEO of Cleveland HeartLab. “We have a strong history of innovation and are very pleased to collaborate with two global giants in healthcare—the Cleveland Clinic and Procter & Gamble—on this promising project.”

TMAO has received widespread scientific and public attention since its discovery. In 2013, the American Heart Association and the American Stroke Association selected the discovery of the connection between gut flora, TMAO and cardiovascular disease risk as “a Top 10 advance in heart disease and stroke science.”

About Cleveland Clinic Innovations

Cleveland Clinic Innovations is responsible for company creation, business development and commercialization of all medical technology throughout Cleveland Clinic and its Global Healthcare

Innovations Alliance partners. Since it was founded in 2000, Cleveland Clinic Innovations has executed over 450 licenses and created 75 spin-off companies that have raised over \$1 billion in equity investment and commercialization grants. These efforts have resulted in the creation of over 1,200 jobs. Visit us at www.clevelandclinic.org/innovations.

About Procter & Gamble

P&G serves nearly five billion people around the world with its brands. The Company has one of the strongest portfolios of trusted, quality, leadership brands, including Always®, Ambi Pur®, Ariel®, Bounty®, Charmin®, Crest®, Dawn®, Downy®, Fairy®, Febreze®, Gain®, Gillette®, Head & Shoulders®, Lenor®, Olay®, Oral-B®, Pampers®, Pantene®, SK-II®, Tide®, Vicks® and Whisper®. The P&G community includes operations in approximately 70 countries worldwide. Please visit <http://www.pg.com> for the latest news and in-depth information about P&G and its brands.

About Cleveland HeartLab

Cleveland HeartLab Inc. is the premier cardiovascular disease (CVD) Management Company with a comprehensive array of propriety tests focused on improving the early identification of those with CVD risk. In addition to its industry leading approach to inflammation testing, CHL manages a robust R&D program to accelerate the clinical use of scientifically proven and medically relevant biomarkers. CHL's biomarkers have been validated in more than 100 peer-review studies published in leading medical and scientific journals. Formed in 2009 as a spin-off from the Cleveland Clinic, CHL offers its testing to thousands of leading clinicians focused on health and wellness as well as corporate wellness plans through its CAP-accredited and CLIA-certified clinical lab. Half of all patients who suffer from heart attack have normal cholesterol. With the goal of improving CVD risk assessment, CHL's unique testing provides a more complete picture of CVD risk allowing clinicians to deploy personalized medical programs and interventions to reduce the overall risk of CVD, with a specific focus on reducing the risks of inflammation. In a 2015 *Journal of Medical Economics* study on the economic impact of CHL's core inflammation tests, CHL's CVD management protocol demonstrated the potential to avoid nearly 10% of heart attacks and strokes for patients of average health. The cost of care averted was estimated to exceed \$187 million. CHL holds over 20 issued and 30 pending global patents and has been recognized for its innovation with the prestigious Nortech Innovation Award, The Ohio Venture of the Year Award and the Edison Crystal Award for Excellence. CHL was also named an "Inc. 5,000" company in recognition of its innovation and growth. For more information about CHL visit us at www.clevelandheartlab.com. For more information on CVD visit www.knowyourrisk.com.