AMGEN ANNOUNCES CARDIOVASCULAR STUDY TO EVALUATE ASSOCIATION BETWEEN LIPOPROTEIN(a) AND CARDIOVASCULAR RISK IN AFRICAN AMERICANS

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Unique Community-Based Partnership With the Association of Black Cardiologists and Morehouse School of Medicine to Identify Study Sites and Participants

Observational Study to Better Understand Associations Between Lp(a) Levels and Atherosclerotic Cardiovascular Disease (ASCVD) in an Underrepresented Patient Population

THOUSAND OAKS, Calif., Feb. 22, 2023 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the African American Heart Study, in collaboration with the Association of Black Cardiologists (ABC) and the Morehouse School of Medicine (MSM), which will measure the association between Lipoprotein(a), or Lp(a), and atherosclerotic cardiovascular disease (ASCVD) in 5,000 African American individuals across the United States. ASCVD is defined as the buildup of cholesterol plaque in arteries and includes events such as heart attack and stroke.

"The African American Heart Study is a unique collaborative study including community outreach in partnership with trusted organizations to help improve our understanding of the disproportionate higher incidence of Lp(a) and cardiovascular disease progression in African Americans and hopefully provide insights of ways to address barriers in clinical trial access," said Ponda Motsepe-Ditshego, M.D., vice president, global medical and head of Amgen's Representation in Clinical Research team. "At Amgen, our mission is to serve patients, and important to that mission is expanding clinical trial access and diverse representation in the community setting to provide a full picture of how a disease impacts certain groups."

Cardiovascular disease is the number one killer of all Americans, and the cardiovascular risk for African Americans is even higher. According to the U.S. Department of Health and Human Services, African Americans are 30% more likely to die from heart disease than non-Hispanic whites.[1-2]

Lp(a) is a presumed independent risk factor for heart disease; levels are genetically determined and are known to differ by race and ethnicity.[3-6] African American individuals show a higher average Lp(a) concentration than white populations, but Lp(a) research to date has primarily been conducted in individuals of European descent.[7] This leaves the association between Lp(a) levels and incident ASCVD in persons of African American descent uncertain and important to investigate further to understand drivers of cardiovascular risk in African Americans. Amgen has initiated the African American Heart Study to bridge this gap.

"People of all races and ethnicities can have high levels of Lp(a), but it appears to be more common in African Americans. I am excited about the African American Heart Study because we have the opportunity to study up to 5,000 self-identified African Americans, who have been so often underrepresented in studies, in order to gain a better understanding of the genetic underpinnings of Lp(a) and to determine if African American patients are at a higher risk of cardiovascular disease," said Elizabeth Ofili, M.D., M.P.H., FACC, professor of medicine at Morehouse School of Medicine and principal investigator of the study. "The results of this study will potentially provide insights that will help determine which types of patients would benefit most from future therapy."

This prospective case-control study design will enroll 2,500 self-identified African Americans with ASCVD and 2,500 self-identified African Americans without ASCVD from cardiology and primary care practices across the United States. Enrollment is voluntary. ABC and MSM will conduct community outreach, as well as identify sites through the Health 360x Clinical Trial Network and Registry. The Health 360x Network practice sites are trusted providers, crucial to the success of the African American Heart Study. The Health 360x Clinical Trial Network and Registry is funded by the National Institutes of Health to support clinical trials in community-based practices.[9]

Amgen's subsidiary, deCODE genetics, based in Iceland, with its world-class human genetics capabilities, will sequence and analyze DNA, RNA, and protein markers from participants' blood samples. With three years of follow-up planned, the broad omics data analyzed by deCODE will help Amgen broaden the understanding of ASCVD and other diseases that disproportionately affect African Americans. The learnings may also inform future clinical trials and drug development.

"Increasing the diversity in our clinical trials is essential to achieving our ambition of serving all patients. This requires us to think differently than we have in the past about how we design and conduct our trials," said Rob Lenz, M.D., Ph.D., senior vice president, Global Development at Amgen. "To do that, we are educating the community on why this is critical and building trusted relationships with our partners. We also are training external investigators and building new capabilities that will help provide them with the right infrastructures in communities of underserved patient populations to make projects like the African American Heart Study possible."

The African American Heart Study is emblematic of Amgen's unwavering commitment to diversity in clinical trials. In 2020, Amgen launched its Representation in Clinical Research team to accelerate its work in promoting diversity in clinical trials and is focused on improving clinical trial diversity and proportional representation by addressing the systemic issues that deter people from participating in research, especially those who have been historically excluded due to race, ethnicity, sex, age, and other factors.

About the African American Heart Study

The main objective of the study is to determine associations between Lp(a) levels, sequence variants, clinical factors and cardiovascular outcomes in African Americans. Participants will be followed for at least three years leveraging real-world evidence from electronic health records.

About Lp(a)

Lp(a) is genetically determined and presumed to be an independent risk factor for cardiovascular disease (CVD). [4-6] Although an agreed upon threshold for elevated Lp(a) is not firmly established, it has been estimated that approximately 20% of adults have Lp(a) >125 nmol/L (or approximately 50 mg/dL).[3-6] Evidence has emerged from pathophysiological, epidemiologic, and genetic studies on the potential role of elevated Lp(a) in contributing to myocardial infarction, stroke, and peripheral arterial disease.[3-8]

About Amgen
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2022, Amgen was named one of the "World's Best Employers" by Forbes and one of "America's 100 Most Sustainable Companies" by Barron's.

For more information, visit Amgen.com and follow us on Twitter, LinkedIn, Instagram, TikTok and YouTube.

About deCODE genetics
Based in Reykjavik, Iceland, deCODE genetics, is a global leader in analyzing and understanding the human genome. Using its unique expertise and population resources, deCODE has discovered genetic risk factors for dozens of common diseases. The purpose of understanding the genetics of disease is to use that information to create new means of diagnosing, treating and preventing disease. deCODE is a wholly-owned subsidiary of Amgen (NASDAQ:AMGN).

Forward-Looking Statements
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd., Kyowa-Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, the Teneobio, Inc. acquisition, the ChemoCentryx, Inc. acquisition, or the proposed acquisition of Horizon Therapeutics plc, as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social

and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Further, any scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational uses discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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[9] Health 360x Clinical Research Platform for Scalable Access to Clinical Trials is funded by the National Center for Advancing Translational Science, National Institutes of Health, Small Business Innovation Research Award # 5R44TR003832 (PI Chamberlain Obialo, MD, AccuHealth Technologies Inc.) The content of the Press Release is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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