AMGEN PRESENTS NEW PHASE 2 DATA THAT SHOW OLPASIRAN DELIVERS SIGNIFICANT REDUCTION IN LIPOPROTEIN(A) LEVELS

November 6, 2022

Olpasiran Reduced Lipoprotein(a) Levels by More Than 95% in Patients With Established ASCVD

Amgen is Initiating a Phase 3 Cardiovascular Outcomes Trial Based on These Results

Data Simultaneously Published in the New England Journal of Medicine

THOUSAND OAKS, Calif. , Nov. 6, 2022 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today presented end-of-treatment data from its Phase 2 OCEAN(a)-DOSE study of investigational olpasiran (formerly AMG 890) in adults with elevated lipoprotein(a) [Lp(a)] levels (>150 nmol/L) and a history of atherosclerotic cardiovascular disease (ASCVD). The study was designed to assess safety, tolerability and optimal dose of olpasiran in adults with established ASCVD to reduce Lp(a).[1] These data were presented during the Nov. 6 Late-Breaking Science Session of the American Heart Association (AHA) Scientific Sessions 2022 in Chicago, Illinois, and simultaneously published in the New England Journal of Medicine.

OCEAN(a)-DOSE is a multicenter, randomized, double-blind, placebo-controlled dose-finding study of olpasiran in 281 patients with established ASCVD and Lp(a) levels >150 nmol/L. Patients were randomized to one of four doses of olpasiran (10 mg Q12 weeks, 75 mg Q12 weeks, 225 mg Q12 weeks or 225 mg Q24 weeks) or placebo, given subcutaneously.[2] Across cohorts, the median baseline Lp(a) concentration was 260.3 nmol/L. Patients who received 75 mg or higher every 12 weeks had a 95% or greater reduction in Lp(a) compared to placebo at week 36. At these doses (75 mg or higher), more than 98% of patients achieved an Lp(a) level of 125 nmol/L or less at week 36.[2] Overall, the rates of adverse events were similar in the olpasiran and placebo arms. The most common treatment-related adverse events were injection site reactions, primarily pain.[2]

"Epidemiological research has shown us that Lp(a) is an independent risk factor and is primarily genetically determined. It has been estimated that up to 20% of people worldwide are living with elevated levels, which are linked to a higher risk for heart disease, stroke and the potential significant burden on patients with cardiovascular disease,"[5] said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Our Phase 2 data for olpasiran presented at AHA continue to demonstrate a significant reduction in Lp(a) and provide strong evidence supporting its potential for patients with ASCVD. We look forward to studying this treatment further in Phase 3 clinical trials, which we expect to begin enrolling in December 2022."

At week 36, Lp(a) increased by a mean of 3.6% in the placebo arm, whereas there were substantial reductions of Lp(a) levels in all of the olpasiran arms. Placebo-adjusted mean percent reductions were 70.5% for 10 mg every 12 weeks, 97.4% for 75 mg every 12 weeks, 101.1% for 225 mg every 12 weeks and 100.5% for 225 mg every 24 weeks .[2]

"Currently, there are no approved medicines that can consistently achieve marked or sustained reductions in Lp(a) concentration," said Michelle L. O'Donoghue M.D., MPH, Senior Investigator, TIMI Study Group at Brigham and Women's Hospital and OCEAN(a)-DOSE trial Global Principal Investigator. "RNA interference with olpasiran is a promising treatment approach that led to a profound and sustained reduction in Lp(a) concentration in this Phase 2 study."

About Lp(a)

Lp(a) is genetically determined[3-5] and a presumed independent risk factor for cardiovascular disease (CVD). Although an agreed upon threshold for elevated Lp(a) is not firmly established, approximately 20% of adults have Lp(a) >125 nmol/L (or approximately 50 mg/dL).[3] 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.[5]

About OCEAN(a)

The OCEAN(a) (Olpasiran Trials of Cardiovascular Events And LipoproteiN(a) Reduction) clinical program for Amgen's investigational olpasiran is designed to treat patients with atherosclerotic cardiovascular disease (ASCVD) and elevated Lp(a) levels to reduce the risk of cardiovascular events.

The OCEAN(a)-DOSE trial is a multicenter, randomized, double-blind, placebo-controlled dose-finding Phase 2 study in 281 patients with ASCVD and Lp(a) >150 nmol/L. Patients were randomly assigned to one of four active subcutaneous doses of olpasiran (10 mg Q12 weeks, 75 mg Q12 weeks, 225 mg Q12 weeks or 225 mg Q24 weeks) or placebo. The primary endpoint is percent change from baseline in Lp(a) at 36 weeks. A secondary endpoint is percent change from baseline in Lp(a) at 48 weeks.

A prespecified exploratory endpoint was the percent change in Lp(a) from baseline at each scheduled visit for the 225 mg Q24 week dose group.

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.

Amgen 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, or the Teneobio, Inc. acquisition, or the ChemoCentryx, Inc. acquisition, 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 use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

References

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