AMGEN PRESENTS NEW AMG 133 PHASE 1 CLINICAL DATA AT WCIRDC 2022

December 1, 2022

AMG 133 is a First-in-Class Investigational Bispecific Molecule That Activates GLP-1R and Inhibits GIPR

Phase 1 Results Showed up to 14.5% Reduction in Body Weight at the Highest Dose After 12 Weeks

Initiating Phase 2 Study in Early 2023

THOUSAND OAKS, Calif., Dec. 1, 2022 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced new Phase 1 data from AMG 133, a novel bispecific glucose-dependent insulinotropic polypeptide receptor (GIPR) antagonist and glucagon-like peptide-1 (GLP-1) receptor agonist molecule. This first-in-human study was designed to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic effects of AMG 133 in people with obesity and without diabetes (NCT04478708). These data will be presented as part of an oral presentation on Saturday, Dec. 3 at the 20th World Congress of Insulin Resistance, Diabetes and Cardiovascular Disease (WCIRDC) Hybrid Conference.

"AMG 133 was designed based on preclinical and human genetic data that strongly suggest GIPR inhibition as a strategy for weight loss, especially in combination with GLP-1 agonism," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We are encouraged by these Phase 1 results with once-monthly dosing of AMG 133, specifically, the degree, rate and durability of the weight loss. We look forward to initiating the Phase 2 study early next year."

Participants were randomized (3:1) to receive subcutaneous AMG 133 or placebo either as a single ascending dose (SAD) or multiple ascending doses (MAD). The MAD cohorts showed mean percent changes in body weight (BW), ranging from -7.2% at the lowest dose (140mg Q4W), to -14.5% at the highest dose (420mg Q4W) by day 85. A substantial degree of weight loss was maintained beyond the treatment period, which will be shared as part of the oral presentation. Most treatment emergent adverse events (TEAEs) were mild and transient. The majority of the TEAEs were GI-related with the most common being nausea and vomiting, most events resolved within 48 hours. Based on these data, a Phase 2 trial will be initiated early next year to further study the attributes of this molecule.

Amgen will host a webcast call for the investment community in conjunction with WCIRDC at 8:00 a.m. ET on Monday, Dec. 5, 2022. For more information visit: https://investors.amgen.com/.

About Obesity
Obesity is a serious, chronic disease that affects a significant proportion of the world population. In the US alone, 74% of adults are either obese or overweight[1], including 42% who are obese[2]. The worldwide prevalence of obesity has tripled over the past 40 years and continues to rise in nearly every demographic.[3] Obesity is linked to a marked reduction in quality of life and an array of serious medical complications[4], placing a significant burden on healthcare systems globally.[5] Despite the scale of the disease, the formal recognition of obesity as a chronic disease by the American Medical Association (2013) and the European Health Commission (2021), and medical guidelines recommending pharmacologic treatment in appropriate individuals, only 1-3% of patients globally are prescribed medication.[6,7]

About AMG 133
AMG 133 is a bispecific glucose-dependent insulinotropic polypeptide receptor (GIPR) antagonist and glucagon-like peptide-1 (GLP-1) receptor agonist molecule. AMG 133 mimics the agonist effects of GLP-1 and antagonizes the effects of glucose-dependent insulinotropic polypeptide (GIP). Amgen moved into this Phase 1 study based on human genetic insights and preclinical evidence that suggested synergistic effects with GIP receptor blockade and GLP-1 receptor agonism on weight loss and improvement in other metabolic parameters.

About the Phase 1 Study and Future Development
The randomized, double-blind, placebo-controlled single and multiple ascending dose study of AMG 133 enrolled people with a Body Mass Index (BMI) of ≥30.0 kg/m2 and ≤40.0 kg/m2 without other medical conditions. Participants were randomized (3:1) to receive subcutaneous AMG 133 or placebo either as a single ascending dose (SAD) or multiple ascending doses (MAD). Participants were assigned to six SAD cohorts (n=49; mean age 48 years, BMI 33.4 kg/m2, and BW 99.5 kg) and three MAD cohorts (n=26; mean age 46 years, BMI 33.5 kg/m2, and BW 96.9 kg). Pharmacokinetics and body weight (BW) were measured and safety and tolerability were monitored. Most treatment emergent adverse events (TEAEs) were mild and transient.[8] The majority of the TEAEs were GI-related with the most common being nausea and vomiting, most events resolved within 48 hours.

Amgen plans to initiate Phase 2 testing with a dose-ranging study in early 2023, where long-term effects in an expanded number of patients will be further characterized.

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, the Teneobio, Inc. acquisition, or the recently announced proposed acquisition of ChemoCentryx, Inc., 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.

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