AMGEN ANNOUNCES ROBUST WEIGHT LOSS WITH MARITIDE IN PEOPLE LIVING WITH OBESITY OR OVERWEIGHT AT 52 WEEKS IN A PHASE 2 STUDY

November 26, 2024

MariTide Demonstrated up to ~20% Average Weight Loss at 52 Weeks Without a Weight Loss Plateau in People Living With Obesity or Overweight

MariTide is the First Obesity Treatment With Monthly or Less Frequent Dosing to Demonstrate Safe and Effective Weight Loss in a Phase 2 Study

In People With Type 2 Diabetes Living With Obesity or Overweight MariTide Demonstrated up to ~17% Average Weight Loss Without a Weight Loss Plateau and Lowered Average HbA1c by up to 2.2 Percentage Points at 52 Weeks

MariTide Delivered Substantial Improvements Across Cardiometabolic Parameters

Amgen Announces "MARITIME," a Phase 3 Clinical Development Program in Obesity and Obesity-Related Conditions

THOUSAND OAKS, Calif., Nov. 26, 2024 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced positive data at 52 weeks in a double-blind, dose-ranging Phase 2 study with MariTide (maridebart cafraglutide, formerly AMG 133), an investigational antibody peptide conjugate subcutaneously administered monthly or less frequently. In people living with obesity or overweight without Type 2 diabetes, MariTide demonstrated up to ~20% average weight loss at week 52 without a weight loss plateau, indicating the potential for further weight loss beyond 52 weeks.[1] The study also showed people living with obesity or overweight and Type 2 diabetes, who typically lose less weight on GLP-1 therapies, achieved up to ~17% average weight loss, also without a weight loss plateau, and lowered their average hemoglobin A1C (HbA1c) by up to 2.2 percentage points at week 52.[1] In summary, in both study populations, a weight loss plateau was not observed, again indicating the potential for further weight loss beyond 52 weeks.

MariTide also demonstrated robust and clinically meaningful improvements in cardiometabolic parameters, including blood pressure, triglycerides and high-sensitivity C-reactive protein (hs-CRP) across doses. There were no significant increases in free fatty acids.

There was no association between the administration of MariTide and bone mineral density changes.

The most common adverse events (AEs) in the Phase 2 study were gastrointestinal (GI) related, including nausea, vomiting and constipation. Nausea and vomiting were predominately mild, transient and primarily associated with the first dose. The incidence of nausea and vomiting was substantially reduced with dose escalation. In the dose escalation arms, for those with symptoms, nausea and vomiting were episodic; generally resolving within a median window of six days for nausea and one to two days for vomiting. The discontinuation rate in the dose escalation arms due to any AE was ~11% and less than 8% for GI-related events. No additional safety signals were identified. In a separate ongoing Phase 1 pharmacokinetic study, additional dosing regimens have been evaluated in a planned preliminary analysis.

"We are very excited by MariTide's differentiated profile, with clinically meaningful attributes of substantial and progressive weight loss, monthly or less frequent dosing, significant improvements in cardiometabolic parameters and strong reduction of HbA1C," said Jay Bradner, M.D., executive vice president of Research and Development and chief scientific officer at Amgen. "These results provide us confidence to initiate MARITIME, a Phase 3 program across obesity and a number of related conditions, providing a unique potential new treatment option for patients."

Data from this Phase 2 study will be presented at a future medical congress and submitted for publication.

The ongoing Part 2 of the Phase 2 study is investigating MariTide beyond 52 weeks to evaluate further weight loss with continued treatment, weight maintenance through less frequent or lower dosing and durability of weight loss after discontinuation of MariTide. More than 90% of eligible patients chose to continue to participate in Part 2 of the study.

MariTide is expected to be delivered as a single dose in a convenient, handheld, patient-friendly, autoinjector device with a monthly or less frequent single-injection administration. MariTide is produced in Amgen's industry-leading manufacturing network.

Amgen is also advancing its obesity pipeline, which includes both oral and injectable approaches, composed of both incretin and non-incretin mechanisms.

The company announced that it is hosting a webcasted call for the investment community at 5 a.m. PT on Tuesday, Nov. 26, 2024, to provide a MariTide update. The webcast, as with other selected presentations regarding developments in Amgen's business given by management at certain investor and medical conferences, can be found on Amgen's website, www.amgen.com, under Investors.

About Obesity

Obesity is a complex biological disease that increases the risk of many other serious diseases and conditions, including Type 2 diabetes, heart failure, kidney disease, sleep apnea, atherosclerotic cardiovascular disease and metabolic dysfunction-associated steatohepatitis. The worldwide prevalence of obesity more than doubled between 1990 and 2022.[2] In the U.S., more than two in five adults (42.5%) are living with obesity.[3] In 2022, 890 million adults (18 years and older) globally were living with obesity, and 2.5 billion adults were living with overweight.[2]

Obesity is linked to a marked reduction in quality of life and an array of serious medical complications and conditions.[4,5] Despite the breadth 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 eligible adults in the U.S. are prescribed medication for chronic weight management.[6-8]

About MariTide
MariTide is a bispecific glucagon-like peptide 1 (GLP-1) receptor agonist and glucose-dependent insulinotropic polypeptide receptor (GIPR) antagonist being investigated for the treatment of obesity and Type 2 diabetes mellitus. As a pioneering antibody-peptide conjugate molecule with a long half-life and dual mechanism of action, MariTide may allow for greater durability or reduce the likelihood of weight rebound after treatment stops. Pre-clinical studies have demonstrated that simultaneously activating GLP-1 and inhibiting GIP pathways had a stronger effect on weight loss than targeting either GLP-1 or GIP receptors alone. Amgen utilized its strong capabilities of human genetics to confirm the benefits of GIPR inhibition.

The clinical goal for people living with obesity or overweight is to achieve weight loss, and to maintain weight thereby improving health. Given the heterogeneity of obesity and the number of people impacted, a variety of approaches will be needed. In addition to MariTide, Amgen is also advancing an obesity pipeline, which includes both oral and injectable approaches, composed of both incretin and non-incretin mechanisms.

About the Phase 2 Study (NCT05669599)
The trial enrolled 592 adults included two Cohorts of people living with obesity or overweight. Cohort A enrolled participants without a diagnosis of Type 2 diabetes, Cohort B participants had Type 2 diabetes. In Part 1, participants in Cohort A (n=465), without Type 2 diabetes, were assigned to one of four monthly fixed dose arms (placebo, 140 mg, 280 mg, 420 mg) or an 8-week 420 mg dose arm. There were also two dose escalation arms with either 4-week or 12-week dose escalation periods to a target dose of 420 mg. Adults in Cohort B (n=127), with type 2 diabetes, were assigned to one of four monthly fixed dose arms (placebo, 140 mg, 280 mg and 420 mg). At the end of Part 1, participants who met eligibility criteria (at least 15% weight loss at week 52 and still taking investigational product) had the option to enter Part 2 of the study.

Part 2 of this Phase 2 study is investigating MariTide beyond 52 weeks. In Part 2, Cohorts from Part 1 were pooled, then re-randomized based on their Part 1 doses to receive either placebo or a fixed monthly dose of 70 mg, 140 mg, 420 mg or a 12-week 420 mg dose. The purpose of Part 2 is to evaluate further weight loss with continued treatment, durable weight loss after discontinuation of MariTide and weight maintenance through less frequent or lower dosing.

For more detailed information about the study, please visit https://clinicaltrials.gov/study/NCT05669599.

We will initiate "MARITIME," a Phase 3 program in obesity and obesity-related conditions. For more information about participating in our clinical studies, please visit www.maritimestudy.com.

About Amgen
Amgen discovers, develops, manufactures and delivers innovative medicines to help millions of patients in their fight against some of the world's toughest diseases. More than 40 years ago, Amgen helped to establish the biotechnology industry and remains on the cutting-edge of innovation, using technology and human genetic data to push beyond what's known today. Amgen is advancing a broad and deep pipeline that builds on its existing portfolio of medicines to treat cancer, heart disease, osteoporosis, inflammatory diseases and rare diseases.

In 2024, Amgen was named one of the "World's Most Innovative Companies" by Fast Company and one of "America's Best Large Employers" by Forbes, among other external recognitions. Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average®, and it is also part of the Nasdaq-100 Index®, which includes the largest and most innovative non-financial companies listed on the Nasdaq Stock Market based on market capitalization.

For more information, visit Amgen.com and follow Amgen on X, LinkedIn, Instagram, TikTok, YouTube and Threads.

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. or Kyowa Kirin Co., Ltd.), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), our acquisitions of Teneobio, Inc., ChemoCentryx, Inc., or Horizon Therapeutics plc (including the prospective performance and outlook of Horizon's business, performance and opportunities, any potential strategic benefits, synergies or opportunities expected as a result of such acquisition, and any projected impacts from the Horizon acquisition on our acquisition-related expenses going forward), 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 on our business, outcomes, progress, 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. There can be no guarantee that we will be able to realize any of the strategic benefits, synergies or opportunities arising from the Horizon acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. We may not be able to successfully integrate Horizon, and such integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach of our information technology systems 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.

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References

[1] These reported efficacy data are based on a standard analytical measure commonly used for obesity medicines, the efficacy estimand, per Amgen's investor presentation on November 26, 2024.

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