



RESULTS FROM AMGEN'S PHASE 2 OBESITY STUDY OF MONTHLY MARITIDE PRESENTED AT THE AMERICAN DIABETES ASSOCIATION 85TH SCIENTIFIC SESSIONS

June 23, 2025

MariTide, the First Monthly or Less Frequently Dosed Obesity Treatment, Demonstrated Up to ~20% Average Weight Loss Without a Weight Loss Plateau, and Delivered Significant Cardiometabolic Improvements at 52 Weeks

In People Living With Obesity With Type 2 Diabetes, MariTide Demonstrated Up to ~17% Average Weight Loss and Robust HbA1c Improvements

Dose Escalation With Lower Starting Doses Substantially Improved Gastrointestinal Tolerability, Without Compromising Efficacy

The MARITIME Phase 3 Chronic Weight Management Studies are Actively Enrolling, and Phase 3 Studies in People Living With Atherosclerotic Cardiovascular Disease, Heart Failure and Obstructive Sleep Apnea Will be Initiated in 2025

THOUSAND OAKS, Calif., June 23, 2025 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced full results from Part 1 of the Phase 2 study of MariTide (maridebart cafraglutide, formerly AMG 133), a long-acting, peptide-antibody conjugate subcutaneously administered monthly or less frequently. In addition to these data, complete results from the primary analysis of the Phase 1 pharmacokinetics low dose initiation (PK-LDI) study evaluating lower starting doses of MariTide were presented as part of an expert-led Symposium at the 85th American Diabetes Association (ADA) Scientific Sessions and simultaneously [published](#) in *The New England Journal of Medicine*.

In the Phase 2 study, MariTide demonstrated up to ~20% average weight loss in people living with obesity without Type 2 diabetes (T2D) compared with 2.6% in the placebo arm, and up to ~17% average weight loss in people living with obesity with T2D, compared with 1.4% in the placebo arm, per the efficacy estimand.¹ Weight loss had not plateaued by 52 weeks, indicating the potential for further weight reduction. In addition to meaningful weight loss, MariTide demonstrated a robust and sustained reduction in hemoglobin A1c (HbA1c) of up to 2.2%¹ in people living with obesity and T2D. Weight loss with MariTide was also accompanied by improvements across pre-specified cardiometabolic measures, including waist circumference, blood pressure, high-sensitivity C-reactive protein (hs-CRP) and select lipid parameters.

"MariTide delivered strong efficacy, including sustained weight loss without a plateau in the 52-week Phase 2 study and meaningful improvements in cardiometabolic risk factors, representing a defining advance for the obesity field," said Jay Bradner, M.D., executive vice president of Research and Development at Amgen. "These results, alongside the Phase 1 Pharmacokinetics Low Dose Initiation data, have shaped our Phase 3 MARITIME program. MariTide's monthly or less frequent dosing has the potential to improve adherence and long-term weight control, providing the opportunity to optimize health outcomes for people living with obesity, Type 2 diabetes and related conditions."

No new safety signals were identified in the Phase 2 study and tolerability was consistent with the GLP-1 class. The most frequently reported adverse events (AEs) were gastrointestinal (GI) related, and most were mild to moderate. The study employed a rigorous daily patient reporting tool known as the MINVR (modified index of nausea/vomiting/retching) to actively solicit the presence of select GI symptoms in addition to standard unsolicited AE reporting. Gastrointestinal events were predominantly limited to initial dosing and less frequent when dose escalation was used without compromising efficacy. Discontinuation rates of MariTide due to GI AEs in the dose escalation arms (up to 7.8%) were lower than non-dose escalation arms.

"In this Phase 2 study, participants living with obesity treated with MariTide had substantial weight reduction at 52 weeks without reaching a weight plateau," said Ania Jastreboff, M.D., Ph.D., professor at Yale School of Medicine and director of the Y-Weight Yale Obesity Research Center. "Additionally, robust improvements in HbA1c were observed in participants who had Type 2 diabetes and obesity. These data demonstrate the potential for once monthly or less frequent dosing and are particularly encouraging as we seek sustainable, long-term treatments for people living with obesity, with and without Type 2 diabetes."

The Phase 1 PK-LDI study assessed PK and also used the MINVR reporting tool to assess different dose escalation schedules of MariTide. The complete primary analysis showed participants that received 21 mg/70 mg/350 mg had an overall incidence of vomiting of 24.4% and participants that received 35 mg/70 mg/350 mg had an overall incidence of vomiting of 22.5%. There were no discontinuations due to GI AEs at any time during the study.

Data from the Phase 2 and Phase 1 PK-LDI MariTide studies informed the Phase 3 MARITIME program. The recently initiated Phase 3, 72-week chronic weight management studies will evaluate the safety, efficacy and tolerability of MariTide in participants living with obesity or overweight with and without Type 2 diabetes. Participants will be randomized to one of three target doses, each with an initial starting dose of 21 mg, followed by 35 mg and then 70 mg, over a further optimized eight-week dose escalation period. Amgen also expects to initiate Phase 3 clinical outcomes studies for atherosclerotic cardiovascular disease (ASCVD) and heart failure (HF), as well as a Phase 3 study for obstructive sleep apnea (OSA) in 2025.

Amgen to Webcast Investor Meeting at ADA 85th Scientific Sessions

Amgen will host a webcast call for the investment community in conjunction with the ADA Scientific Sessions. On Monday, June 23 at 4:30 p.m. CDT, Jay Bradner, M.D., executive vice president of Research and Development at Amgen, along with other members of Amgen's management team, will discuss the MariTide program. 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. Information regarding presentation times, webcast availability and webcast links are noted on Amgen's Investor Relations Events Calendar. The webcast will be archived and available for replay for at least 90 days after the event.

About the Phase 2 MariTide Study (NCT05669599)

The trial enrolled 592 adults into two Cohorts. Cohort A enrolled participants living with obesity or overweight without Type 2 diabetes and Cohort B enrolled participants living with obesity or overweight with Type 2 diabetes. In Part 1, participants in Cohort A (n=465) were assigned to one of four monthly fixed dose arms (placebo, 140 mg, 280 mg, or 420 mg) or an 8-week, 420 mg dose arm. There were also two dose escalation arms, with a

starting dose of 70 mg and a target dose of 420 mg, given over a 4-week or 12-week dose escalation period. Adults in Cohort B (n=127) were assigned to one of four monthly fixed dose arms (placebo, 140 mg, 280 mg, and 420 mg).

In Cohort A, the mean percent change in weight loss from baseline to Week 52 per the treatment policy estimand² ranged from 12.3% to 16.2% with MariTide, compared to 2.5% with the placebo arm, and per the efficacy estimand¹, ranged from 16.3% to 19.9% with MariTide, compared to 2.6% with the placebo arm. In Cohort B, the mean percent change in weight loss per the treatment policy estimand ranged from 8.4% to 12.3% with MariTide, compared to 1.7% with the placebo arm, and per the efficacy estimand, ranged from 12.1% to 17.0% with MariTide, compared to 1.4% with the placebo arm.

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, which is investigating MariTide beyond 52 weeks. In part 2, participants 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 or 420 mg, or 420 mg dose every 12 weeks. Part 2 evaluates further weight loss with continued treatment, durable weight loss after discontinuation of MariTide and weight maintenance through less frequent or lower dosing in participants that met the eligibility criteria.

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

To learn more about MARITIME, a Phase 3 program in obesity and obesity-related conditions, visit www.maritimestudy.com.

About Phase 2 Efficacy Estimand and Treatment Policy Estimand (Intent-to-Treat Analysis)

The efficacy estimand represents the efficacy as if treated participants had adhered to MariTide for the entire 52-week study period. The efficacy estimand includes endpoint data so long as study drug is taken. Where endpoint data is missing with early discontinuation, the endpoint results for the patient are estimated using individual patient response and predicted performance after drug discontinuation.

The treatment policy estimand, i.e., intent-to-treat analysis, represents the efficacy of treated participants regardless of adherence to MariTide for the entire 52-week study period and conforms to regulatory guidance for clinical trials. The treatment policy estimand includes all endpoint data, irrespective of whether study drug is taken or not. Where endpoint data is missing with early discontinuation, this approach assumes the endpoint for the study patient approximates that of placebo.

The difference between the results generated by the efficacy estimand and the treatment policy estimand was driven by early discontinuations and a conservatively defined treatment estimand used in the Phase 2 study.

About Phase 1 PK-LDI Study (NCT06976372)

The Phase 1 pharmacokinetics low dose initiation (PK-LDI) study was a Phase 1, randomized, double-blind, multiple-dose, parallel-group study to investigate the PK, safety, and tolerability of multiple dose escalation schemes of MariTide administered subcutaneously (SC) in patients living with obesity or overweight. On Day 1, participants were randomized to receive one of three dosing regimens, either 21 mg, 35 mg, or 70 mg of MariTide SC, followed by a dose of 70 mg on Day 15, followed by a dose of 350 mg on Day 29. The primary endpoints were pharmacokinetics of MariTide including maximum observed concentration (C_{max}) and area under the concentration time-curve (AUC). Secondary endpoints included incidence of treatment-emergent adverse events and serious adverse events, and incidence of anti-MariTide antibodies. In addition to standard reporting, GI (AEs) were also ascertained directly from patients with MINVR. The primary analysis included all data for participants through the Day 43 visit. Overall, 121 participants were enrolled and included in the safety population, defined as participants who received at least one dose of MariTide and at least one post-dose safety assessment.

For more detailed information about the study, please visit <https://clinicaltrials.gov/study/NCT06976372>.

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. In the U.S., more than two in five adults (42.5%) are living with obesity. In 2022, 890 million adults (18 years and older) globally were living with obesity, and 2.5 billion adults were living with overweight.

Obesity is linked to a marked reduction in quality of life and an array of serious medical complications and conditions. 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.

For more information about Amgen's approach to addressing obesity and related conditions, visit <https://www.amgen.com/obesity>.

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 peptide-antibody conjugate molecule with a long half-life and dual mechanism of action, MariTide may allow for greater durability or reduce the likelihood of weight regain after treatment stops. Amgen used its genetic expertise to identify GIP receptor inhibition as a key factor in reducing body mass, an insight that led to MariTide's development. 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.

A primary clinical goal for people living with obesity or overweight is to achieve weight loss, and avoid weight regain 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 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](https://www.amgen.com) and follow Amgen on [X](#), [LinkedIn](#), [Instagram](#), [YouTube](#) and [Threads](#).

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 BeOne Medicines Ltd. or Kyowa Kirin Co., Ltd.), the performance of Otezla[®] (apremilast), our acquisitions of ChemoCentryx, Inc. or Horizon Therapeutics plc (including the prospective performance and outlook of Horizon's business, performance and opportunities, and any potential strategic benefits, synergies or opportunities expected as a result of such 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 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, including those resulting from geopolitical relations and government actions. 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. 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, 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 sustainability 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 The efficacy estimand represents the efficacy as if treated participants had adhered to MariTide for the entire 52-week study period. The efficacy estimand includes endpoint data so long as study drug is taken. Where endpoint data is missing with early discontinuation, the endpoint results for the patient are estimated using individual patient response and predicted performance after drug discontinuation.

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