Subject: Competitive Intelligence Update - Amgen Q1 2024 Earnings
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Metsera Reports

May 3, 2024

Competitive Intelligence Update

Amgen Reports Q1 2024 Earnings

Summary and Implications

- Amgen indicates that MariTide is moving into Ph3 for obesity following an interim read-out of Ph2
- Top-line data from MariTide Phase 2 Obesity study will be available by 2024 year-end (no quantitative data were released from the interim read-out)
- Amgen will start separate MariTide Phase 2 T2DM study and pursue T2DM indication
- Amgen was deliberately vague about the form factor used to administer MariTide; management did say an “auto-injector device” will be used (but seems to deliberately avoid the use of the word “pen”)

Context

Amgen is developing Maridebart Cafraglutide (‘MariTide’), a first-in-class antibody peptide conjugate consisting of a GIPr antagonist antibody conjugated with GLP1 peptide analogues. In Q4 2022, Amgen announced positive Phase 1 MAD data in healthy Obese individuals (n = 26). The MAD included 3 separate doses: 140 mg, 240 mg, and 420 mg, dosed monthly for 3 months with no dose titration. The 420 mg arm (n = 8) showed 14.5% weight loss by day 85. This weight loss was maintained for 3-4 months following the last dose. However, all 8 patients in the highest dose arm experienced nausea and 4 of 8 patients discontinued therapy. In Q4 2023 earnings,

management said discontinuations were not AE-driven and occurred late in study.

Amgen is currently conducting a Phase 2 study (n = 592) with 11 arms evaluating MariTide in Obese patients with and without T2DM. This Phase 2 is evaluating both once-monthly and less frequent dose intervals.

Content

MariTide Phase 2 Update

In the Q1 2024 earnings call, Amgen said it is 'very encouraged' by interim Phase 2 analysis and patient drop-out is not an issue – all arms remain active. Phase 2 top-line results will be available before 2024 year-end. Management did not explicitly discuss dose titration in this Phase 2 study.

MariTide Development Update

Amgen is planning a broad Phase 3 development program including Obesity, T2DM, and obesity-related co-morbidities. Amgen is also initiating a dedicated Phase 2 T2DM study and plans to pursue a separate T2DM indication.

MariTide Commercial Update

Amgen initiated manufacturing activities to expand capacity with both clinical and commercial supply in mind. While Amgen said the API would be administered via auto-injector, questions remain about the ability to "fit" the high doses into a pen (and management seems to deliberately avoid the use of the word "pen"). Management brushed off manufacturing complexities of antibody-peptide conjugate and suggested this was "down the middle of the fairway" in terms of technical challenges. Management did not say if they are planning on 5-10M patient supply or 1-2M patient supply.

Other Obesity Products

Amgen discontinued development of AMG-786, a non-incretin small molecule developed for Obesity, based on the emerging profile. Amgen continues to invest in other preclinical obesity programs.

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