BIOBUSINESS BRIEFS

MARKET WATCH

Upcoming market catalysts in Q4 2015

Potential market catalysts in the fourth quarter of 2015 include a decision on the US approval of Merrimack's MM-398 for the treatment of pancreatic cancer, and the announcement of clinical trial data for Roche's ocrelizumab for the treatment of multiple sclerosis and AstraZeneca's mavrilimumab for the treatment of rheumatoid arthritis.

MM-398 is the most clinically advanced drug in Merrimack's pipeline, and has a Prescription Drug User Fee Act (PDUFA) action date of 24 October on its new drug application. MM-398 is a nanoliposomal encapsulation of the cytotoxic drug irinotecan that is designed to reduce the toxicity of irinotecan to normal tissues while increasing its antitumour efficacy. In May 2014, Merrimack released positive results of a Phase III study (NAPOLI-1) of MM-398 alone or in combination with 5-fluorouracil (5-FU) and leucovorin in patients with metastatic pancreatic cancer who previously received gemcitabine-based therapy. Although the monotherapy results were lacklustre, the combination therapy arm had a median overall survival of 6.1 months compared with 4.2 months with 5-FU plus leucovorin alone, providing encouragement that the drug might soon become the company's first approved therapy.

Roche has announced plans to report updated and top-line results from their Phase III programme of ocrelizumab at the 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis in early October. Promising top-line results for ocrelizumab, a monoclonal antibody that targets CD20 on B cells, have previously been reported in patients with relapsing multiple sclerosis from two pivotal studies (OPERA I and OPERA II) comparing ocrelizumab with interferon beta-1a (Rebif; EMD Serono). Although Roche has announced that the studies met their primary end point by demonstrating a significant reduction in the annualized relapse rate over a 2-year period, the expected updated results will be the first numerical data from the Phase III programme. Additionally, Roche expects to release top-line results from the Phase III ORATORIO study of ocrelizumab in primary progressive multiple sclerosis (PPMS). So, the data read-outs will not only elucidate how ocrelizumab performs compared with approved therapies in relapsed and refractory multiple sclerosis, but also its potential efficacy in PPMS, for which there are no approved therapies.

Finally, AstraZeneca plans to announce top-line results from their Phase II EARTH Explorer 2 study of mavrilimumab for the treatment of rheumatoid arthritis at the American College of Rheumatology Annual Meeting in November. The company has already reported positive top-line results for mavrilimumab, a monoclonal antibody that targets the alpha subunit of the granulocyte–macrophage colony stimulating factor receptor, from the Phase IIb EARTH Explorer 1 study. This study met its primary end points of Disease Activity Score 28–C-reactive protein test (DAS28-CRP) and the American College of Rheumatology 20 score (ACR20) response rates as compared with placebo, with an impressive 73.4% ACR20 response for the highest dose of mavrilimumab. These numbers compare favourably with those for the currently available tofacitinib (Xeljanz; Pfizer), for which a 52.6% ACR20 response at 6 months was reported in a similar study population. Although these data are promising, the competitive advantage of mavrilimumab is questionable, because its route of administration is intravenous, whereas tofacitinib is an oral drug. As such, results from the EARTH Explorer 2 study comparing mavrilimumab with the approved injectable tumour necrosis factor (TNF)-targeting drug golimumab (Simponi; Johnson & Johnson) will be of particular importance because they will further reveal mavrilimumab's therapeutic profile and marketability in the already competitive market for intravenously administered therapies for rheumatoid arthritis.

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