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MARKET WATCH

Upcoming market catalysts in Q2 2014

Important catalysts expected in the second quarter of 2014 include three major US Food and Drug Administration (FDA) approval decisions for drugs with established mechanisms of action: the anti-angiogenic agent ramucirumab (developed by Eli Lilly), the immunomodulatory agent peginterferon beta-1a (developed by Biogen Idec) and the antibiotic tedizolid phosphate (developed by Cubist). The sponsors for ramucirumab and peginterferon beta-1a have also submitted marketing applications for centralized European Union approval, and Cubist expects to follow suit by the middle of the year.

Lilly is seeking approval for ramucirumab, a monoclonal antibody against vascular endothelial growth factor receptor 2 (VEGFR2) as a second-line monotherapy treatment for advanced gastric cancer. Although VEGFR2 is a popular target for less specific, small-molecule multi-kinase inhibitors, ramucirumab is poised to become the first VEGFR2-specific antibody approved in the United States. The FDA decision on the biologics license application (BLA) for ramucirumab is expected by 3 June following Priority Review. The application is supported by results from the Phase III REGARD trial, which met its primary end point of improved median overall survival and key secondary end point of improved median progression-free survival for patients receiving ramucirumab compared to best supportive care alone. In other ongoing Phase III trials,

ramucirumab provided positive interim results in combination with docetaxel for non-small-cell lung cancer but failed to demonstrate efficacy in breast cancer — perhaps not surprising considering the mixed outcomes for other anti-angiogenic drugs in this indication. Given its complementary mechanism of action, ramucirumab could eventually be used in patients with cancer who fail to benefit from treatment with the widely used VEGF-specific antibody bevacizumab (Avastin; Genentech/Roche).

Biogen Idec hopes to expand its multiple sclerosis treatment franchise with a pegylated version of its marketed interferon beta-1a (Avonex). If approved by the Prescription Drug User Fee Act (PDUFA) date of 21 May, it would be the first peginterferon product approved for multiple sclerosis in the United States. In the Phase III ADVANCE study, patients receiving the treatment every 2–4 weeks exhibited statistically significant reductions in exacerbation rate and disability progression versus placebo; the magnitude of effect was similar to historical data from unconjugated interferons, which are administered one to three times weekly. Although this long-acting interferon may not offer improved disease control, patients' quality of life may benefit from less frequent dosing.

In an effort to stimulate research on new agents to combat antibiotic resistance, the FDA has granted Qualified Infectious Disease

Product (QIDP) designation — which provides additional marketing exclusivity following approval — to tedizolid phosphate and other antibiotics in development. The PDUFA date for tedizolid phosphate's new drug application (NDA) for acute bacterial skin and skin-structure infections (ABSSSIs) is 20 June. The FDA scheduled an advisory committee meeting to discuss the ABSSSI applications for tedizolid phosphate and Durata's dalbavancin on 31 March. Tedizolid is a second-generation oxazolidinone that inhibits protein synthesis in Gram-positive bacteria, including pathogens that are resistant to the first-generation oxazolidinone linezolid. In the Phase III ESTABLISH programme, tedizolid phosphate demonstrated non-inferiority to linezolid in ABSSSI clinical cure rate despite a shorter course of treatment (10 days versus 6 days) and fewer drug-related side effects. The high bioavailability of oxazolidinones allows for intravenous or oral dosing, which may reduce hospitalization times compared to patients who receive intravenous-only 'antibiotics of last resort', such as glycopeptides and lipopeptides.

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The author declares no competing interests.