BIOBUSINESS BRIEFS

MARKET WATCH

Key clinical and regulatory events in Q2 2010

Promising news on several therapies for severe and unmet medical needs is anticipated in the second quarter of 2010. A US FDA decision on the possible approval of potentially the first therapeutic cancer vaccine — sipuleucel-T (Provenge; developed by Dendreon) for castration-resistant metastatic prostate cancer — is expected by 1 May. Another first could be the approval of the oral disease-modifying multiple sclerosis drug, fingolimod (Gilenia; developed by Novartis), with an expected first cycle FDA review in June. Last, the first set of data from a Phase III trial of telaprevir (developed by Vertex and Johnson & Johnson) for the treatment of hepatitis C virus (HCV) infection will be reported.

Sipuleucel-T, a cell-based vaccine that is designed to stimulate an immune response against prostate cancer cells, will again have one of the most highly followed PDUFA (Prescription Drug User Fee Act) dates. Since an FDA advisory panel meeting in March 2007 that recommended approval, followed by a complete response letter in May 2007, Dendreon has completed the IMPACT study, which showed that the vaccine significantly improved overall survival compared with placebo, as required by the FDA for approval. The company also raised more than US$630 million in 2009, resubmitted the biologic licence application and awaits a 1 May PDUFA date. Although a further advisory panel meeting is unlikely, a discussion over why the vaccine did not receive accelerated approval in 2007, despite an overwhelmingly positive committee vote on both efficacy and safety, would be an interesting one to observe.

Fingolimod, an immunomodulatory agent that affects lymphocyte trafficking by acting as an agonist of several members of the sphingosine-1-phosphate receptor family, could become the first oral disease-modifying treatment for relapsing-remitting multiple sclerosis (RRMS). It has a priority review PDUFA date in June, and Novartis expects an FDA advisory panel meeting prior to the decision (at the time of going to press, no panel had been announced). Fingolimod has been shown to be more efficacious than the main current treatments for RRMS — β-interferons and glatiramer acetate (Copaxone; Teva Pharmaceuticals) — and nearly as effective as natalizumab (Tysabri; Elan, Biogen Idec), but it is associated with immunosuppressive and cardiac adverse effects. Given the number of cases of progressive multifocal leukoencephalopathy that have been reported for natalizumab, the risk–benefit balance of fingolimod is likely to be a focus of discussion.

Telaprevir, an HCV protease inhibitor, is currently being investigated in three large Phase III studies, with data expected from a trial known as ADVANCE in the second quarter of 2010, and from the other two trials, known as ILLUMINATE and REALIZE, in the third quarter. The current standard HCV treatment regimen, interferon and ribavirin, has historically produced cure rates lower than 50%, and treatment-experienced patients have a very low chance of being cured if treated again. It is hoped that telaprevir and another HCV protease inhibitor, boceprevir (developed by Merck), could become the first drugs in a new generation of HCV therapies that vastly improve the cure rates for HCV infection. The ADVANCE trial is evaluating telaprevir in combination with PEGylated interferon and ribavirin in previously untreated patients with HCV infection. ILLUMINATE will also examine treatment-naive patients, and assess the differences of 24 or 48 weeks of treatment in patients with a rapid response to telaprevir. The third trial, REALIZE, is being conducted in patients considered to be HCV infection relapsers or non-responders to standard treatment. Owing to the low cure rate of current treatments, there are hundreds of thousands of patients considered to be treatment-experienced, and success in this trial could allow telaprevir to achieve rapid uptake in this population.

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