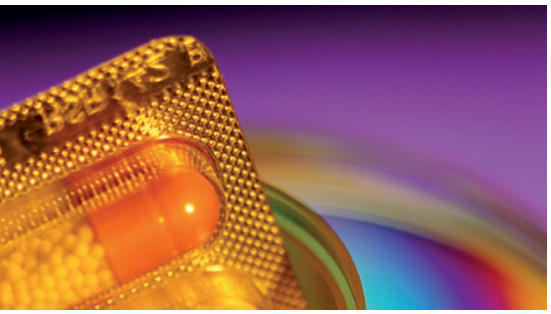
MARKET WATCH

Upcoming market catalysts in Q3 2011



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Highlights in the third quarter include approval decisions in the United States on brentuximab vedotin for the treatment of relapsed/refractory Hodgkin's lymphoma and relapsed/refractory systemic anaplastic large cell lymphoma (ALCL), and on rivaroxaban for the prevention of deep vein thrombosis and pulmonary embolism in hip or knee replacement surgery. Initial Phase III data on low-concentration bromfenac ophthalmic solution for dry eye disease are also expected.

A US Food and Drug Administration (FDA) advisory committee meeting to discuss Seattle Genetics' brentuximab vedotin, an antibody–drug conjugate that is composed of a monoclonal antibody that is specific for the CD30 receptor coupled to a cytotoxic agent, is scheduled for 14 July 2011, and an accelerated approval decision is expected by 30 August 2011. Brentuximab vedotin is being developed for the treatment of patients with relapsed/refractory Hodgkin's lymphoma and ALCL, for which there are limited treatment options beyond autologous stem cell transplants and chemotherapy.

In two pivotal Phase II studies — SG035-0003 in Hodgkin's lymphoma and SG035-0004 in ALCL — brentuximab vedotin showed an objective response rate of 75% and 86%, and a complete remission rate of 34% and 53%, respectively. Although both studies were uncontrolled, it seems likely that the FDA will grant approval for brentuximab vedotin, owing to the positive efficacy data, a tolerable safety profile and the need for treatments in these severely ill patients. However, the accelerated approval process has recently come under scrutiny — for example, in the debate about the potential removal of the metastatic breast cancer indication from the label of bevacizumab (Avastin; Roche) — and so the FDA might require an additional study prior to approving brentuximab vedotin.

A second Prescription Drug User Fee Act (PDUFA) date for the oral anticoagulant rivaroxaban, a factor Xa inhibitor developed by Bayer, is scheduled for 5 July 2011. In May 2009, the FDA issued a complete response letter requesting additional data from completed and ongoing studies, data from sites in the pivotal Phase III RECORD studies, as well as market surveillance from countries where the drug was available. Despite a positive 15–2 vote at its March 2009 advisory committee meeting, the complete response letter was not completely unexpected, as long-term safety was a significant concern for members of the panel. The main issues were related to bleeding, cardiovascular events and liver toxicity, owing to the potential for off-label usage in more chronic conditions such as acute venous thromboembolism (VTE) and atrial fibrillation. As results from the EINSTEIN-DVT (acute treatment of VTE) and ROCKET-AF (prevention of stroke in atrial fibrillation) studies did not show increases in liver toxicity or bleeding with longer treatment and at higher doses, approval seems to be more likely the second time around.

The first Phase III efficacy results from Ista Pharmaceutical's twice-daily, low-concentration version of bromfenac ophthalmic solution, which is in development to alleviate the signs and symptoms of dry eye disease, are also anticipated this quarter. Bromfenac, which is currently approved as a 0.09% once- or twice-daily solution for the treatment of ocular inflammation and pain following cataract surgery, is part of the non-steroidal anti-inflammatory drug class and primarily inhibits cyclooxygenases. In a Phase II study, low-dose bromfenac met all of the primary and secondary end points and no serious ocular or systemic adverse events were reported. The results that are due soon from the first Phase III efficacy study will provide a key indicator for the likely success of the remainder of the programme, which consists of two efficacy studies and two safety studies.

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