MARKET WATCH

Upcoming market catalysts in Q1 2017

Potentially important market catalysts in the first quarter of 2017 include top-line phase IIb/III trial results for PRO 140 (developed by CytoDyn, Progenics Pharmaceuticals and PDL BioPharma) in highly treatment-experienced patients with HIV and top-line phase II/III trial results for CR845 (developed by Cara Therapeutics, Maruishi Pharmaceutical, Unigene Laboratories and Chong Kun Dang Pharmaceutical) in dialysis patients with uraemic pruritus. In addition, an FDA decision is expected on the possible approval of safinamide (developed by Newron Pharmaceuticals, US WorldMeds, Meiji Seika Pharma and Zambon) for Parkinson disease.

CytoDyn anticipates primary end point results from the pivotal phase IIb/III trial of PRO 140, a humanized immunoglobulin (Ig) G4 monoclonal antibody to CC-chemokine receptor 5 (CCR5), in combination with current standard-of-care antiretroviral therapy in highly treatment-experienced patients with HIV. In October 2016, CytoDyn announced that the FDA had accepted protocol modifications to the trial that lowered both the number of patients to be enrolled from 150 to 30 and the primary end point for viral load reduction from 0.7log to 0.5log. PRO 140 inhibits the entry of the predominant HIV (R5) subtype into T cells by binding to the required co-receptor, CCR5. In August 2016, CytoDyn announced that the first of 11 HIV patients receiving weekly subcutaneous PRO 140 as a single agent in a phase IIb extension trial had reached 2 years of complete virological suppression and that 9 additional patients were expected to reach the 2-year milestone in the next 2 months. If the trial is successful, PRO 140 could become the first FDA-approved monoclonal antibody therapeutic for HIV.

Cara Therapeutics expects top-line data from part A of the adaptive phase II/III trial of intravenous CR845 in dialysis patients with moderate-to-severe uraemic pruritus. CR845 is a κ-opioid receptor agonist designed and selected for its inability to enter the central nervous system. Results from a phase II trial demonstrated that CR845 significantly improved itching intensity and quality of life in haemodialysis patients with moderate to severe uraemic pruritus. There are no FDA-approved drugs for this condition.

The FDA is expected to make a decision regarding the new drug application (NDA) for safinamide, a small molecule that inhibits dopamine uptake, monoamine oxidase B and glutamate release, by the Prescription Drug User Fee Act (PDUFA) action date of 21 March 2017. Results from phase III studies demonstrated that daily oral safinamide significantly improved motor function in patients with early-stage Parkinson disease on a single dopamine agonist and significantly improved motor fluctuations without any worsening in troublesome dyskinesia in patients with mid-to-late-stage Parkinson disease on levodopa and other drugs. This positive effect may be related to the novel dual mechanism of safinamide, acting on both the dopaminergic and glutamatergic pathways. Based on these studies, safinamide was approved as add-on therapy to levodopa alone or in combination with other Parkinson disease drugs in patients with mid-to-late-stage Parkinson disease in the European Union in February 2015. The NDA for safinamide as an add-on therapy to a single dopamine agonist in patients with early Parkinson disease, and as an add-on therapy to levodopa alone or in combination with other Parkinson disease drugs in patients with mid-to-late-stage Parkinson disease, was originally accepted for submission by the FDA in March 2015. However, Newron Pharmaceuticals reported that the FDA issued a complete response letter in March 2016, requesting further information on the potential effect of safinamide on behaviours relating to abuse liability and dependence/withdrawal effects. After working to address these issues, Newron Pharmaceuticals recently announced that the FDA considered their resubmission of the NDA in September 2016 to be a complete, class 2 response and had determined the 21 March 2017 PDUFA date.

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