BIOBUSINESS BRIEFS

MARKET WATCH

Upcoming market catalysts in Q1 2018

Potential market catalysts in the first quarter of 2018 include important top-line clinical trial results for rigerimod (developed by ImmuPharma and SymBio) for systemic lupus erythematosus (SLE); ofranergene obadenovec (developed by VBL Therapeutics and NanoCarrier) for recurrent glioblastoma (rGBM); and azeliragon (developed by vTv Therapeutics) for mild Alzheimer disease (AD).

ImmuPharma expects top-line results from a pivotal 52-week phase III trial of rigerimod in patients with SLE to be reported in the first quarter of 2018. Rigerimod, a polypeptide that is thought to act by modulating $CD4^+$ signalling, has received fast-track designation from the FDA. Its development is being conducted under an FDA special protocol assessment (SPA), and the number of patients (~200) in the placebo-controlled phase III trial of a 200 µg dose of rigerimod plus standard of care is lower than typical. Positive trial results would position rigerimod for regulatory submission and also mark an important milestone for ImmuPharma, as it is the company's only late-stage clinical asset.

Results of a phase III study of VBL's ofranergene obadenovec (VB-111) in patients with rGBM are also expected in the first quarter of 2018. VB-111 is a viral vector engineered to express a pro-apoptotic Fas-chimera transgene only in angiogenic blood vessels. Patients with GBM have a poor prognosis, with only 3–5% of patients surviving for more than 3 years. In a phase I/II study in patients with rGBM, the combination of VB-111 with bevacizumab following disease progression doubled survival times observed with bevacizumab alone historically. VB-111 has received orphan drug designation in the United States and Europe and was granted fast-track designation by the FDA on the basis of the promising survival results observed. The company is proceeding with a pivotal phase III trial in combination with bevacizumab under an SPA, and pending positive results, the company should be able to file for approval on the basis of this study given the high unmet medical need in rGBM.

In late March 2018, vTv Therapeutics is expected to announce data from the first part of a phase III trial known as STEADFAST that is investigating azeliragon in patients with mild AD. Azeliragon is an inhibitor of the receptor for advanced glycation end products (RAGE), which has been implicated in amyloid-β aggregation, tau fibril formation and chronic inflammation. Azeliragon was being developed by Pfizer, but was dropped by the company in 2011 following a phase IIb trial in which safety issues led to study of a 20 mg per day dose being halted. However, a post-hoc subgroup analysis of this trial suggested that 18-month treatment with a 5 mg per day dose of azeliragon added to an acetylcholinesterase inhibitor and/or memantine slowed the rate of cognitive decline in patients with mild AD. The 5 mg daily dose is being studied in the STEADFAST trial, which is being conducted under an SPA, and azeliragon has received FDA fast-track designation. Positive data from the initial phase III read-out could be an exceptional event given the long history of failed late-stage trials of AD drug candidates.

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The author declares no competing interests.