FDA Approves Stiolto™ Respimat® for Treating Chronic Obstructive Pulmonary Disease

Boehringer Ingelheim announced that the U.S. Food and Drug Administration approved once-daily Stiolto™ Respimat® (tiotropium bromide and olodaterol) inhalation spray as a long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Stiolto Respimat is not indicated to treat asthma or acute deterioration of COPD.

Pivotal trials for Stiolto Respimat evaluated more than 5,000 patients with COPD and showed statistically significant improvements in lung function at 24 weeks versus tiotropium and olodaterol alone.

First Patient Dosing of VX-745 for Alzheimer’s Disease Announced

EIP Pharma announced that patient dosing in phase 2 clinical development of VX-745 in Alzheimer’s disease is underway. VX-745 is an oral brain penetrant and highly selective and potent inhibitor of the alpha isoform of the protein enzyme p38 mitogen activated protein kinase (p38 MAPK alpha).

In the brain, p38 MAPK alpha regulates inflammation through effects on microglia, the major immune cell in the central nervous system (CNS). p38 MAPK alpha is also expressed in neurons, where it is involved in memory formation and synaptic plasticity. In addition, it is increasingly recognized as a highly promising therapeutic target for a broad range of CNS disorders, with animal data indicating that p38 MAPK alpha antagonists have the potential to rapidly improve cognitive function.

VX-745 readily enters the brain, with brain concentrations in pre-clinical studies being approximately two-fold higher than in peripheral blood. VX-745 was discovered by Vertex Pharmaceuticals, Inc., and previously had been clinically evaluated in non-CNS disorders.

These 52-week, phase 3 Tonado™ 1 and 2 trials were randomized, double-blind, active-controlled trials that compared Stiolto Respimat to tiotropium Respimat 5 mcg and olodaterol Respimat 5 mcg. Stiolto Respimat showed a safety profile similar to tiotropium or olodaterol alone.