Optum Rx®

Drug Pipeline Insights Report

Pill

Roluperidone: Brand name TBD
Expected FDA decision: Feb. 26, 2024

Roluperidone would be the first drug FDA approved specifically to treat the negative symptoms of schizophrenia.

Unlike other antipsychotics, roluperidone does not block dopamine, which can cause adverse effects like weight gain. Instead, it blocks a specific type of serotonin receptor to minimize symptoms of schizophrenia.

Trial results for roluperidone were mixed, with modest efficacy results. Also, there were several limitations in the pivotal trials that could limit its use in practice.

For reference, the WAC for Caplyta® (lumateperone), a commonly used antipsychotic, is approximately $19,000 per year.

Injectible

Sotatercept: Brand name TBD
Expected FDA decision: March 26, 2024

Sotatercept is under review for the treatment of adult patients with pulmonary arterial hypertension, a rare, progressive disease causing high blood pressure in the arteries of the lungs.

In pulmonary arterial hypertension, excessive cell growth coupled with not enough cells dying at the end of their natural life cycle. This causes narrower blood vessels, thicker artery walls, and coagulating blood in the lung system.

Sotatercept works by restoring the proper balance between normal cell growth or encouraging natural cell death, as required.

Trial results for sotatercept appear promising, although its use will be limited to the population studied (i.e., treatment-experienced patients). Also, long-term efficacy is still unknown.

For reference, the WAC for a competitor drug, Uptravi® (selexipag), is approximately $260,000 per year.

Pill

Resmetirom: Brand name TBD
Expected FDA decision: March 14, 2024.

Resmetirom is a novel treatment under review for the treatment of nonalcoholic steatohepatitis (NASH). There are currently no approved treatments for NASH. NASH affects approximately 2 million persons in the U.S., although the total including those not diagnosed may be much higher.

Resmetirom works by activating increased levels of a hormone in the liver. This helps to reduce excess liver fat and lipids linked to the formation of fatty plaques in the arteries.

In trials, resmetirom met both of its primary efficacy goals. While the data is promising, the outcomes are considered **surrogate.** That is, they are a substitute for a direct measure of how a patient feels, functions, or survives. A long-term trial is ongoing to evaluate actual clinical outcomes.

Optum Rx continuously monitors and evaluates the drug development pipeline. Join us as we regularly share our insights about upcoming drug approvals.

Please refer here for additional technical background and supplemental sources.

Optum