Research & Development

XP21279

Program/ Potential Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3	NDA Filed
XP21279					
Parkinson's Disease			■		

Discovered by XenoPort, XP21279 is a patented, oral product candidate that utilizes naturally-occurring, high-capacity nutrient transporters in the gastrointestinal tract to generate active, efficient absorption into the body. Once absorbed, XP21279 is rapidly converted into levodopa, a drug that acts to replace dopamine in the brain. XenoPort currently holds all rights to this product candidate.

XenoPort is evaluating XP21279 for further development as a potential treatment of patients with advanced idiopathic Parkinson's disease. In 2011, we completed a Phase 2 clinical trial of patient-optimized doses of a bi-layer tablet of XP21279/carbidopa compared to patient-optimized doses of Sinemet (levodopa/carbidopa) in patients with Parkinson's disease who experience motor fluctuations. Results of the pharmacokinetic analysis from the trial showed that subjects had significantly higher variation in levodopa blood levels over a 16-hour time period while taking Sinemet as compared to XP21279/carbidopa. Results of the study indicated that XP21279/carbidopa dosed three times per day reduced mean daily "off time" by 46% compared to baseline when the patients were taking their pre-trial Sinemet dosing regimen. However, in the primary analysis of the trial, the improvement with XP21279/carbidopa dosed three times per day was not statistically better than the improvement seen with optimized Sinemet dosed four or five times per day during the double-blind phase of the trial. We have discussed the results of this trial with key experts in Parkinson's disease and with regulatory authorities. As a result, we plan to continue development of XP21279 to the extent our resources permit or we enter into a collaboration with a third party.

Parkinson's Disease

Parkinson's disease is a motor system disorder that results from the loss of dopamine-producing nerve cells in the brain. Dopamine is a chemical that is naturally produced by the body. It is responsible for smooth, coordinated function of the body's muscles and movement. When approximately 80% of dopamine-producing cells are damaged, the symptoms of Parkinson's disease appear. The primary symptoms of Parkinson's disease are tremor or shaking, slowness of movement, rigidity or stiffness and difficulty with balance. Levodopa is an immediate precursor of dopamine that, unlike dopamine, readily crosses the blood brain barrier. When administered in conjunction with carbidopa (and, in some cases, with benzerazide or carbidopa and entacapone), levodopa is protected from rapid degradation by enzymes that are outside of the brain and is able to be converted to dopamine at its desired site of action in the brain. Levodopa is widely viewed as one of the most effective treatments of Parkinson's disease, and virtually all patients with Parkinson's disease ultimately require it. However, levodopa has many undesirable pharmacokinetic characteristics, including its rapid breakdown by gastric and other peripheral enzymes, a short duration in blood after oral dosing that leads to the fluctuation of drug plasma concentrations upon frequent dosing and a narrow absorption window within the gastrointestinal tract. The poor colonic absorption of levodopa has precluded the development of a satisfactory sustained-release formulation of levodopa that would prolong absorption beyond the small intestine. The pharmacokinetic profile of levodopa in the blood after administration of XP21279 shows more constant exposure to levodopa and

Research & Development Home
XenoPort Pipeline
XP23829
Arbaclofen Placarbil
XP21279
Our Technology

Clinical Trial Information

The U.S. National Institutes of Health provides a Web site of many current and past clinical trials. To view information about XenoPort's clinical trials, please go to www.clinicaltrials.gov.

This icon indicates a link to an external site.

less severe peaks and troughs of drug blood levels than orally administered levodopa. As such, we believe the use of XP21279 for the treatment of Parkinson's disease could provide more continuous exposure to levodopa and thereby potentially offer better treatment benefit.