Research

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Maxim Achkasov

Zogenix

The company

Zogenix, Inc. is pharmaceutical company focusing on developing treatments for orphan indications for a child's central nervous system (CNS). The company's lead product, FINTEPLA (low-dose fenfluramine) succeeded in two phase III studies in Dravet Syndrome, a serious and rare genetic form of epilepsy. The drug is also being assessed as a treatment for Lennox-Gastaut Syndrome (another rare epilepsy) in a phase III study. The drug's tolerability and safety profile have been favorable to date.

FINTEPLA was launched in the US in July 2020. As of March 31, 2021, about 570 healthcare prescribers have completed the Risk Evaluation and Mitigation Strategy (REMS) certification process, up from the YE20 level of about 490. Zogenix received European Commission (EC) approval of FINTEPLA on December 21, 2020. The company plans a staged country-by-country launch as reimbursement negotiations are completed. FINTEPLA was made commercially available in Germany on February 1, 2021. The drug received temporary authorization in France where the company is currently onboarding patients. The company continues to advance in reimbursement and pricing discussions in the UK, Italy, France, and other EU countries. While we anticipate the EU rollout will be somewhat slow due to reimbursement negotiations and the COVID-19 pandemic, we believe the contribution from sales in the EU will be material in 2022 and beyond. The company also anticipates submission of a Japan-NDA (new drug application) in 2H21.

In addition, Zogenix is completing the data package for a supplemental new drug application (sNDA) submission for Lennox-Gastaut syndrome (LGS) and anticipates filing in the 3Q21 period.

The market

Given the lack of treatment options and refractory nature of the disease, there is high unmet demand for innovative drugs in the epilepsy treatment market. In addition, epilepsy treatment methods for children differ from those for adults. A child's brain is still developing up to 6-8 years of age and childhood brain functions are different from those of an adult brain. In many cases, drugs used to treat adults do not work for children.

Where our research differs from others

We think that the lead product FINTEPLA ZX008, which received Breakthrough Therapy Designation from the FDA, is a best-in-class anti-epileptic for Dravet Syndrome. We estimate that the FINTEPLA program for the Lennox Gastaut Syndrome (LGS) benefits from a 65% chance of success. As drugs for adult epilepsy treatment are often ineffective for children, medication like FINTEPLA with antiepileptic properties to treat children specifically will be in high demand.