

SK Biopharma seizures/epilepsy drug to launch in Europe

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ONTOZRY® (Cenobamate) receives European Commission approval for the treatment of drug-resistant focal-onset seizures in adults



SK Biopharmaceuticals, Co., Ltd., a global innovative pharmaceutical company, announced that cenobamate received marketing authorization from the European Commission (EC) under the brand name ONTOZRY® for the adjunctive treatment of focal-onset seizures with or without secondary generalization in adult patients who have not been adequately controlled despite a history of treatment with at least two anti-epileptic medicinal products.

The marketing authorization, granted to Arvelle Therapeutics, recently acquired by Angelini Pharma, will be valid in all European Union Member States as well as Iceland, Norway and Liechtenstein. Angelini Pharma plans to launch ONTOZRY® in the European Union and other countries in the European Economic Area (Switzerland and the United Kingdom).

SK Biopharmaceuticals, which discovered and developed cenobamate, will collaborate with Angelini Pharma to launch ONTOZRY® in Europe. Cenobamate was approved by the U.S. Food and Drug Administration (FDA) for the treatment of partial-onset (focal-onset) seizures in adults in 2019 and is commercially available in the U.S. under the brand name XCOPRI® (cenobamate tablets) CV.

Jeong Woo Cho, PhD, President and CEO of SK Biopharmaceuticals and SK life science said “we are committed to discovering, developing and delivering new treatment options for epilepsy and other central nervous system disorders to people around the world.”

Epilepsy is one of the most common neurological diseases in the world, and an estimated six million people in Europe live with seizures.¹ Among adult patients with focal-onset seizures, approximately 40% continues to experience seizures after treatment with two anti-seizure medications (ASMs).