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UCB inches toward the FDA with its latest epilepsy contender

by *Damian Garde* | Jul 23, 2014 9:34am

A new epilepsy treatment from Belgian drugmaker UCB helped reduce the rate of seizures in a Phase III trial, the company said, setting the stage for an FDA application and a shot at widening its footprint in the field.

In a 12-week study, UCB's brivaracetam beat out placebo in cutting back partial-onset seizure frequency and improving response rates among 768 patients whose disease isn't fully controlled despite taking one or two antiepileptic drugs (AEDs). The treatment hit statistical significance on both measures, according to the company, although it is saving detailed data for a later medical congress.

The positive results cap an 8-year, 3,000-patient clinical program for brivaracetam, and UCB now has the data to fuel global regulatory applications, the company said, planning to file with the FDA and the European Medicines Agency early next year.

"Today's positive results with brivaracetam represent a significant milestone in our strategy to deliver new treatment options for people with severe diseases," incoming UCB CEO Jean-Christophe Tellier said in a statement. "... We are proud to provide AED options for the epilepsy community today, and remain committed to addressing the unmet needs of adult patients who continue to experience uncontrolled seizures."

If approved, brivaracetam would be UCB's third marketed treatment in the company's banner epilepsy franchise. Keppra, UCB's top-selling drug, is on the decline after coming off patent in 2011, and sales fell another 15% to €712 million ($959 million) last year. Vimpat, approved as an adjunctive therapy in

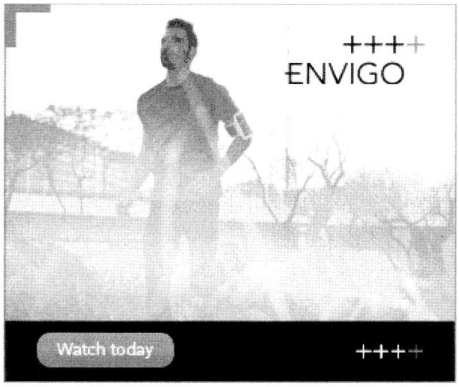

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EXHIBIT

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2008, is on the upswing, growing 23% in 2013 to bring in €411 million ($553 million). UCB is working through a late-stage effort to get that drug OK'd for pediatric patients and as a monotherapy for adults.

Tellier, poised to take over for longtime chief Roch Doliveux next year, is plotting to wean UCB off of its dependence on central nervous system treatments and build up a new franchise of biologics for immunology. Building off the success of Cimzia, a monoclonal antibody for arthritis and inflammatory bowel diseases, UCB is developing candidates for lupus, osteoporosis and other immunological diseases.

- read the statement

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