Same-Day Analysis

UCB Heralds Successor to Keppra as EU Approves Vimpat for Epilepsy

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The approval marks an important step on the road to rebuilding UCB's fortunes, but a regulatory nod from the United States will prove to be even more critical.

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Significance The European Commission has approved UCB's drug Vimpat (lacosamide) as an adjunctive treatment for partial-onset seizures with or without secondary generalisation in epilepsy patients aged 16 or over.

Implications The approval is the first regulatory green light for Vimpat, which UCB has developed as a follow-on to current blockbuster Keppra (levetiracetam). UCB is still awaiting a decision on marketing from the FDA in the United States.

Outlook Keppra's U.S. patent will

expire next year, and Vimpat's success in both the United States and Europe will be crucial to UCB's fortunes in years to come. The drug faces stiff competition, however, from the likes of Lamictal, Lyrica and Topamax, and UCB will need to invest in proving Vimpat's therapeutic advantages over these rivals.

EU Green Light for Vimpat

The European Commission has granted marketing approval to Vimpat (lacosamide), produced by Belgian drug-maker UCB, as an adjunctive treatment for partial-onset seizures with or without secondary generalisation in patients aged 16 and above. The approval comes just over two months after a committee from the European Medicines Agency (EMEA) gave its support for the drug, and therefore has not come as a surprise. Vimpat will now be available across the European Union (EU) in several doses and formulations, which UCB says will offer patients a broader range of dosage options:

- Oral tablets (50, 100, 150 or 200 mg)
- Oral syrup (15 mg/mL)
- Solution for infusion (10 mg/mL)

Vimpat's imminent European launch will see the drug prescribed in tandem with at least one other epilepsy treatment, as its approval was based on clinical trials which examined Vimpat's use in patients whose partial-onset seizures were not adequately controlled with between one and three other epilepsy medicines. UCB's existing epilepsy blockbuster Keppra (levetiracetam) is also approved for adjunctive treatment, and saw blockbuster sales of just over 1 billion euro (US$1.5 billion)—up 43% year-on-year in comparable terms—in 2007. Keppra is due to lose patent protection in the United States next year, and UCB has already filed regulatory applications with the U.S. FDA, seeking marketing approval for Vimpat as an adjunctive epilepsy therapy as well as a treatment for diabetic neuropathic pain. The Belgian pharma giant also sought European marketing approval for Vimpat in this second indication back in August 2007, and is currently awaiting a verdict from the EMEA.

Outlook and Implications

European marketing approval for Vimpat in the most potentially lucrative of its two developed indications is a much-needed sign of encouragement for UCB, which recently revealed plans to axe 17% of its staff in order to optimise costs at a time of financial uncertainty (see **Belgium: 28 August 2008: UCB Unveils SHAPE Restructuring Programme, Prepares to Downsize 17% of Staff**). What the company needs now is for the U.S. FDA to follow suit and approve Vimpat for epilepsy in the United States, where UCB stands to lose revenue most heavily once Keppra's patent protection expires.

In the past, UCB has said that between 20-30% of epileptic patients, equivalent to 10-15 million people globally, are inadequately treated by existing epilepsy treatments, offering a potentially large patient population that could benefit from Vimpat. However, the treatment will be competing against other well-established adjunctive epilepsy drugs, including Lamictal (lamotigrine; GlaxoSmithKline, U.K.), Topamax (topamirate; Johnson & Johnson, U.S.), and Neurontin (gabapentin; Pfizer, U.S.). On the U.S. market, Vimpat will also be competing against Pfizer's formidable blockbuster Lyrica (pregabalin), which has been approved as an adjunctive treatment for partial-onset seizures in adult epilepsy patients since 2005.

In order to make Vimpat stand out from rival products, UCB will need to employ aggressive marketing tactics, but will also need to invest in further studies examining the drug's unique mode of action. UCB claims that Vimpat has shown to modulate the activity of sodium channels—which help regulate activity in the nervous system—differently to other epilepsy drugs, and that it is the only epilepsy treatment known to bind to the collapsing response mediator protein-2 (CRMP-2). How this distinguishes Vimpat in terms of therapeutic effect is not yet fully understood, but demonstrating this through further clinical trials could help improve the drug's fortunes in years to come.

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