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Press Release

UCB Receives FDA Orphan Drug Designation for Brivaracetam for the Treatment of Symptomatic Myoclonus

Brussels (Belgium), November 9, 2005: UCB announced today that the Office of Orphan Products Development of the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to brivaracetam for the treatment of symptomatic myoclonus. “Receiving Orphan Medicinal Product Designation for brivaracetam moves us closer toward our goal of providing patients and their physicians with significant treatment options for disabling disorders." said Peter Verdru, MD, Vice-President Clinical Research, Head of Neurology/Psychiatry Clinical Development, UCB.

Earlier this year, in August 2005, the European Commission granted orphan medicinal designation to brivaracetam for the treatment of *progressive myoclonic epilepsies*. UCB plans to accelerate development efforts and will work closely with the regulatory agencies in protocol designs.

Brivaracetam, a SV2A ligand that is differentiated from levetiracetam (Keppra®) by its mechanism of action profile[1] has shown a significant antiepileptic activity in experimental models of epilepsy[2] and myoclonus[3], as well as in a photosensitive epilepsy model in humans[4]. Brivaracetam is currently being studied (Phase 2 clinical trials) in patients with refractory partial onset seizures and in patients with post-herpetic neuralgia.

Notes to Editors

Myoclonus

Myoclonus is defined as sudden, brief, shock-like involuntary movements affecting one or more muscles[5]. It can be a symptom of manifold diseases of varying underlying aetiologies, including different epileptic syndromes.

Orphan Drug Designation

The FDA Orphan Drug designation is reserved for promising new therapies being developed to treat life-threatening or very serious diseases that affect fewer than 200,000 people in the U.S. The Orphan Drug Act guarantees market exclusivity for seven years to the first sponsor that obtains market approval for an orphan-designated product. This designation provides companies with financial and regulatory benefits during the course of orphan drug development, including tax credits related to clinical trial expenses.

About UCB

UCB (www.ucb-group.com) is a global biopharmaceutical leader with headquarters in Brussels, Belgium, specialising in the fields of central nervous system disorders, allergy and respiratory diseases, immune and inflammatory disorders, as well as oncology. UCB key products are Keppra® (antiepileptic), Xyzal® and Zyrtec® (antiallergics), Nootropil® (cerebral function regulator), Tussionex™ (antitussive) and Metadate™ / Equasym XL™ (attention deficit/hyperactivity disorder). UCB employs over 8,500 people operating in over 40 countries. UCB is listed on Euronext Brussels (UCB / UCBBt.BR / UCB BB).

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References

[1] Zona *et al.* UCB 34714 (brivaracetam) a new pyrrolidone derivative inhibits Na^{2+} currents in rat cortical neurons (2004) 58th Annual Meeting of the American Epilepsy Society (AES), New Orleans

[2] Kenda, B.M., Matagne, A.C., Talaga, P.E. *et al.* Discovery of 4-substituted pyrrolidone butanamides as new agents with significant antiepileptic activity J. Med. Chem. 2004; 47(3): 539-549

[3] UCB data on file

[4] Kasteleijn-Nolst Trenite DGA, Parain D, Masnou P *et al.* Proof of principle in the new AED, UCB 34714; use of the photosensitivity model. Presentation at the 58th American Epilepsy Society Congress, New Orleans, 7th December 2004

[5] www.mayoclinic.org