UCB News

UCB announces approval of VIMPAT® in China

- **VIMPAT® (lacosamide) now approved in China as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent patients 16 years of age and older with epilepsy.**
- **VIMPAT will offer Chinese people living with epilepsy an additional treatment choice to support them in managing their disease.**
- **VIMPAT approval reinforces and strengthens UCB's leadership in epilepsy and the company's ongoing commitment to supporting patient value creation across China.**

Brussels (Belgium), 3 December – 07:00 (CET): Belgium-based global bio-pharmaceutical company UCB today announced it has received an Import Drug License (IDL) from the National Drug Administration of China (CNDA), creating a pathway to make VIMPAT® (lacosamide) available to treat people living with epilepsy in China.

With this IDL, VIMPAT is now indicated in China as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent patients 16 years of age and older with epilepsy.

There are close to 10 million patients living with epilepsy in China[1], and an estimated 400,000 new cases are diagnosed each year[1]. The approval of VIMPAT provides an exciting new choice for those affected by epilepsy in China which could help support patients on their journeys towards seizure freedom.

Results from a national survey reveal the extent to which epilepsy can impact a patient's ability to live their lives at their ideal. The survey shows for example that poorly managed seizures contribute to an unemployment rate in China for people with epilepsy of nearly 70%[1]. This suggests a clear need in China for medicines which can support patients in better managing their disease.

"The approval of VIMPAT® in China is a very important milestone for UCB - and for those living with epilepsy. Although great progress has been made in the management of epilepsy in China, we know there are still millions of people living with uncontrolled seizures who are unable to access some of the newer anti-epilepsy medicines which could be beneficial for them," said Jeff Wren, Executive Vice-President, Head of UCB's Neurology Patient Value Unit. "*By making VIMPAT® available in China, UCB continues to play an important role that started with KEPPRA® in improving the lives of people with epilepsy around the world, addressing some of the gaps in epilepsy management and creating pathways which we hope will support patients in managing their individual epilepsy journeys. We look forward to making VIMPAT® available to patients in China as quickly as possible".*

The approval of VIMPAT®, alongside the recent approval of UCB's 24-hour continuous delivery transdermal rotigotine patch NEUPRO® for the treatment of Parkinson's Disease, and the CNDA's decision to grant a Priority review of CIMZIA® for the treatment of moderate-to-severe rheumatoid arthritis, reinforce UCB's ongoing commitment to making our newest medicines available to support patients living with severe diseases in China.

UCB has been present in China since 1996 and has a prominent presence in the country, having launched KEPPRA® (levetiracetam) for the treatment of various forms of epilepsy in 2007. This important landmark helped established the company's reputation as a leader in neurology. Additionally, in 2014, UCB inaugurated a new state of the art 13,000 m² manufacturing site in Zhuhai, which strengthened our footprint in the country.

For further information:

Corporate Communications	**Investor Relations**
France Nivelle,	Antje Witte,

Global Communications, UCB
T+32.2.559.9178,
France.nivelle@ucb.com

Jim Baxter,
Neurology Communications, UCB
T+32.2.473.78.85.01,
jim.baxter@ucb.com

Laurent Schots,
Media Relations, UCB
T+32.2.559.92.64,
laurent.schots@ucb.com

Investor Relations, UCB
T+32.2.559.94.14,
antje.witte@ucb.com

Isabelle Ghellynck,
Investor Relations, UCB
T +32.2.559.9588,
isabelle.ghellynck@ucb.com

About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases in immunology or neurology. With around 7 500 people in approximately 40 countries, the company generated revenue of € 4.5 billion in 2017. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

Forward looking statements

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees.

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There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed.

Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.

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References

1. China Association Anti Epilepsy. Clinical diagnosis and treatment guidelines, Epilepsy. 2015, Version 2, People's Medical Publishing House