



# UCB and NewBridge Pharmaceuticals Partner for Middle East and African markets

**Brussels, Belgium and Dubai, UAE: November 21, 2012** – UCB (Euronext Brussels: UCB) and NewBridge Pharmaceuticals, a specialty therapeutics company focused on commercializing pharmaceuticals, biologics, diagnostics and medical devices serving the AfMET markets (Africa, Middle East, Turkey & Caspian regions), today announced an exclusive partnership agreement to make UCB's core products Cimzia<sup>®</sup>, Vimpat<sup>®</sup> and Neupro<sup>®</sup> available in several Middle East and African countries. Under the agreement, NewBridge acquires the rights to Cimzia<sup>®</sup>, Vimpat<sup>®</sup> and Neupro<sup>®</sup> from the RX Group, UCB's previous partner in the region. UCB will now operate with its new partner for the region and will supply NewBridge with the three products on exclusive basis. NewBridge will also be responsible for managing the local regulatory approval process, future commercialization, and pharmacovigilance in each of the relevant countries. This transaction does not impact UCB's financial guidance for 2012

Luc Vermeesch, UCB Head of International Major Markets, said: "Within UCB we are passionate about enabling families with severe diseases to enjoy normal, everyday lives. To reach this objective we are thrilled to be working with NewBridge Pharmaceuticals, and rely on their solid experience and strong leadership team in the Middle East and Africa region. We will be teaming up to help transform the lives of people with severe diseases in the region."

Joe Henein, President and CEO of NewBridge explained: "This transaction represents a major milestone for NewBridge as we execute on our high growth strategy to provide access to innovative therapeutics in our core markets of the Middle East and Africa. We strongly believe that Cimzia®, Vimpat® and Neupro® have great potential in our territory and will contribute significantly to the physicians' abilities to treat patients with immunologic and CNS afflictions respectively, thereby improving quality of life for these patients."

## About Cimzia<sup>®</sup>

Cimzia<sup>®</sup> is the only PEGylated anti-TNF (Tumor Necrosis Factor). Cimzia<sup>®</sup> has a high affinity for human TNF-alpha, selectively neutralizing the pathophysiological effects of TNF-alpha. Over the past decade, TNF-alpha has emerged as a major target of basic research and clinical investigation. This cytokine plays a key role in mediating pathological inflammation, and excess TNF-alpha production has been directly implicated in a wide variety of diseases. The U.S. Food and Drug Administration (FDA) has approved Cimzia<sup>®</sup> for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy and for the treatment of adults with moderately to severely active rheumatoid arthritis. Cimzia<sup>®</sup> in combination with MTX is approved in the EU for the treatment of moderate to



severe active RA in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including methotrexate, has been inadequate. Cimzia® can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. UCB is also developing Cimzia® in other autoimmune disease indications. Cimzia<sup>®</sup> is a registered trademark of UCB PHARMA S.A.

Please visit <u>www.cimzia.com</u> for full prescribing information for CIMZIA<sup>®</sup>.

# About Neupro®

Neupro® (rotigotine) is approved in the European Union for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease, as monotherapy (i.e. without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or on-off fluctuations). Neupro® is also approved in the European Union for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome in adults.

## About Vimpat® (lacosamide)

Vimpat® (film-coated tablets, syrup and solution for infusion) was launched in the European Union in 2008 as adjunctive therapy for the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent (16-18 years) patients with epilepsy. Vimpat® solution for infusion may be used when oral administration is temporarily not feasible. Vimpat® syrup (10mg/ml) was approved for use in the European Union in 2012.

The maximum recommended daily dose for Vimpat $^{\mbox{\ensuremath{\mathbb R}}}$  in the European Union and the U.S. is 400 mg/day.

Vimpat® tablets and injection were launched in the US in May 2009 as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older. Vimpat® injection is a short-term replacement when oral administration is temporarily not feasible. Vimpat® oral solution was launched in June 2010.

The availability of the oral tablets, oral solution, and IV injection allows for consistent treatment in a hospital setting. The most common adverse reactions occurring in greater than or equal to 10 percent of Vimpat® -treated patients, and greater than placebo, were dizziness, headache, nausea and diplopia. Additional important safety information for Vimpat® is available at the end of the press release.

## 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 of the immune system or of the central nervous system. With more than 8 000 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2011. UCB is listed on Euronext Brussels (symbol: UCB).

#### About NewBridge Pharmaceuticals

NewBridge Pharmaceuticals is a specialty therapeutics company focused on pharmaceuticals, biologics, and medical diagnostics serving the AfMET markets (Middle East, Africa, Turkey, and



Caspian regions) to address the unmet medical needs of diseases with high regional prevalence. Headquartered in UAE with strong local and international business network, NewBridge is uniquely positioned as the partner-of-choice for companies seeking to create value for their medical products in the high growth emerging AfMET markets. NewBridge was founded by Burrill & Company Venture Capital arm and by the Kuwait Investment Authority's National Technology Enterprise Company – (NTEC°

For more information please visit <u>www.nbpharma.com</u> .

#### For further information

France Nivelle, Global Communications, UCB T +32 2 559 9178, <u>france.nivelle@ucb.com</u>

Laurent Schots, Media Relations, UCB T +32.2.559.9264, <u>laurent.schots@ucb.com</u>

Antje Witte, Investor Relations UCB T +32.2.559.9414, antje.witte@ucb.com

#### 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. UCB is providing this information as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations.

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.

## Cimzia® (certolizumab pegol) in EU/ EEA important safety information

Cimzia<sup>®</sup> was studied in 2367 patients with RA in controlled and open label trials for up to 57 months. The commonly reported adverse reactions (1-10%) in clinical trials with Cimzia<sup>®</sup> and post-marketing were viral infections (includes herpes, papillomavirus, influenza), bacterial



infections (including abscess), rash, headache (including migraine), asthenia, leukopaenia (including lymphopaenia, neutropaenia), eosinophilic disorder, pain (any sites), pyrexia, sensory abnormalities, hypertension, pruritis (any sites), hepatitis (including hepatic enzyme increase), injection site reactions and nausea. Serious adverse reactions include sepsis, opportunistic infections, tuberculosis, herpes zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic edema, cardiomyopathies (includes heart failure), ischemic coronary artery disorders, pancytopaenia, hypercoagulation (including thrombophlebitis, pulmonary embolism), cerebrovascular accident, vasculitis, hepatitis/hepatopathy (includes cirrhosis), and renal impairment/nephropathy (includes nephritis). In RA controlled clinical trials, 5% of patients discontinued taking Cimzia® due to adverse events vs. 2.5% for placebo. Cimzia® is contraindicated in patients with hypersensitivity to the active substance or any of the excipients, active tuberculosis or other severe infections such as sepsis or opportunistic infections or moderate to severe heart failure.

Serious infections including sepsis, tuberculosis and opportunistic infections have been reported in patients receiving Cimzia<sup>®</sup>. Some of these events have been fatal. Monitor patients closely for signs and symptoms of infections including tuberculosis before, during and after treatment with Cimzia<sup>®</sup>. Treatment with Cimzia must not be initiated in patients with a clinically important active infection. If an infection develops, monitor carefully and stop Cimzia<sup>®</sup> if infection becomes serious. Before initiation of therapy with Cimzia<sup>®</sup>, all patients must be evaluated for both active and inactive (latent) tuberculosis infection. If active tuberculosis is diagnosed prior to or during treatment, Cimzia<sup>®</sup> therapy must not be initiated and must be discontinued. If latent tuberculosis is diagnosed, appropriate anti-tuberculosis therapy must be started before initiating treatment with Cimzia<sup>®</sup>. Patients should be instructed to seek medical advice if signs/symptoms (e.g. persistent cough, wasting/weight loss, low grade fever, listlessness) suggestive of tuberculosis occur during or after therapy with Cimzia<sup>®</sup>.

Reactivation of hepatitis B has occurred in patients receiving a TNF-antagonist including Cimzia® who are chronic carriers of the virus (i.e. surface antigen positive). Some cases have had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with Cimzia®. Carriers of HBV who require treatment with Cimzia® should be closely monitored and in the case of HBV reactivation Cimzia® should be stopped and effective antiviral therapy with appropriate supportive treatment should be initiated.

TNF antagonists including Cimzia® may increase the risk of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease; of formation of autoantibodies and uncommonly of the development of a lupus-like syndrome; of severe hypersensitivity reactions. If a patient develops any of these adverse reactions, Cimzia® should be discontinued and appropriate therapy instituted.

With the current knowledge, a possible risk for the development of lymphomas, leukaemia or other malignancies in patients treated with a TNF antagonist cannot be excluded. Rare cases of neurological disorders, including seizure disorder, neuritis and peripheral neuropathy, have been reported in patients treated with Cimzia®.



Adverse reactions of the hematologic system, including medically significant cytopenia, have been infrequently reported with Cimzia®. Advise all patients to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on Cimzia®. Consider discontinuation of Cimzia® therapy in patients with confirmed significant hematological abnormalities.

The use of Cimzia® in combination with anakinra or abatacept is not recommended due to a potential increased risk of serious infections. As no data are available, Cimzia® should not be administered concurrently with live vaccines. The 14-day half-life of Cimzia® should be taken into consideration if a surgical procedure is planned. A patient who requires surgery while on Cimzia® should be closely monitored for infections.

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information. European SmPC date of revision June 2012.

<u>http://www.ema.europa.eu/docs/en\_GB/document\_library/EPAR\_-</u> Product\_Information/human/001037/WC500069763.pdf

#### *Neupro® in the European Union Important Safety Information*

Neupro<sup>®</sup> is contraindicated in case of hypersensitivity to the active substance or to any of its excipients, and in case of magnetic resonance imaging (MRI) or cardioversion. Neupro<sup>®</sup> should be removed if the patient has to undergo MRI or cardioversion to avoid skin burns.

It is recommended to monitor blood pressure, especially at the beginning of treatment, due to the risk of postural/orthostatic hypotension associated with dopaminergic therapy and reported during Neupro<sup>®</sup> treatment. Neupro<sup>®</sup> has been associated with somnolence and episodes of sudden sleep onset. Patients treated with dopamine agonists including Neupro<sup>®</sup>, have been reported pathological gambling, increased libido and hypersexuality. Symptoms suggestive of neuroleptic malignant syndrome have been reported with abrupt withdrawal of dopaminergic therapy. Therefore it is recommended to taper treatment.

Hallucinations have been reported, and patients should be informed that hallucinations can occur.

Cases of cardiopulmonary fibrotic complications have been reported in some patients treated with ergot-derived dopaminergic agents. Neuroleptics given as antiemetic should not be given to patients taking dopamine agonists. Ophthalmologic monitoring is recommended at regular intervals or if vision abnormalities occur.

External heat, from any source should not be applied to the area of the patch. Exposure of a skin rash or irritation to direct sunlight could lead to changes in the skin color. If a generalized skin reaction (e.g. allergic rash) associated with the use of Neupro<sup>®</sup> is observed, Neupro<sup>®</sup> should be discontinued.

*Caution is advised when treating patients with severe hepatic impairment or acute worsening of renal function, a dose reduction might be needed.* 

The incidence of some dopaminergic adverse events, such as hallucinations, dyskinesia, and peripheral oedema generally is higher when given in combination with L-dopa. This should be considered when prescribing Neupro<sup>®</sup>.

Neupro<sup>®</sup> contains sodium metabisulphite, a sulphite that may cause allergic-type reactions including anaphylactic symptoms and life threatening or less severe asthmatic episodes in certain susceptible people.



Neupro<sup>®</sup> should not be used during pregnancy. Breast-feeding should be discontinued.

In restless legs syndrome augmentation may occur. Augmentation refers to the earlier onset of symptoms in the evening (or even the afternoon), increase in severity of symptoms, and spread of symptoms to involve other body parts.

At the beginning of therapy, dopaminergic adverse reactions, such as nausea and vomiting, may occur. These are usually mild or moderate in intensity and transient, even if treatment is continued.

Adverse drug reactions reported in more than 10% of Parkinson's patients treated with Neupro<sup>®</sup> are nausea, vomiting, application site reactions, somnolence, dizziness and headache. The majority of these application site reactions are mild or moderate in intensity.

Adverse drug reactions reported in more than 10% of RLS patients treated with Neupro<sup>®</sup> are nausea, application site reactions, asthenic conditions (including fatigue, asthenia, malaise) and headache. The majority of these application site reactions are mild or moderate in intensity.

Please refer to the European Summary of Product Characteristics for full prescribing information (Revised August 2012): <u>http://www.ema.europa.eu/docs/en\_GB/document\_library/EPAR\_-</u> \_<u>Product\_Information/human/000626/WC500026397.pdf</u> [Accessed August 2012]

#### Important safety information about Vimpat® in the EU and EEA

Vimpat® (lacosamide) is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent (16-18 years) patients with epilepsy. Vimpat® solution for infusion is an alternative for patients when oral administration is temporarily not feasible. Contraindications: Hypersensitivity to the active substance or any of the excipients; known second- or third-degree atrioventricular (AV) block. Special warnings and precautions for use: Treatment with Vimpat® has been associated with dizziness which could increase the occurrence of accidental injury or falls. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicine. Prolongations in PR interval with Vimpat<sup>®</sup> have been observed in clinical studies. Cases with second- and third-degree AV block associated with Vimpat® treatment have been reported in post-marketing experience. Vimpat® should be used with caution in patients with known conduction problems or severe cardiac disease such as a history of myocardial infarction or heart failure. Caution should especially be exerted when treating elderly patients as they may be at an increased risk of cardiac disorders or when Vimpat® is used in combination with products known to be associated with PR prolongation. In the placebocontrolled trials of Vimpat® in epilepsy patients, atrial fibrillation or flutter were not reported; however both have been reported in open-label epilepsy trials and in post-marketing experience. Patients should be made aware of the symptoms of second-degree or higher AV block (e.g. slow or irregular pulse, feeling of lightheaded and fainting) and of the symptoms of atrial fibrillation and flutter (e.g. palpitations, rapid or irregular pulse, shortness of breath). Patients should be counselled to seek medical advice should any of these symptoms occur. Suicidal ideation and behavior have been reported in patients treated with anti-epileptic agents in several indications. Therefore patients should be monitored for signs of suicidal ideation and behaviors and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behavior emerge. Vimpat<sup>®</sup> syrup contains sodium methyl parahydroxybenzoate (E219) which may cause allergic reactions (possibly delayed). It contains 3.7 g sorbitol (E420) per dose (200 mg Page 6 of 7



lacosamide), corresponding to a calorific value of 9.7 kcal. Patients with rare hereditary problems of fructose intolerance should not take this medicine. The syrup contains aspartame (E951), a source of phenylalanine, which may be harmful for people with phenylketonuria. It contains 1.24 mmol (or 28.36 mg) sodium per dose (200 mg lacosamide). Vimpat® syrup and the solution for infusion contain sodium, which should be taken into consideration for patients on a controlled sodium diet. Effects on ability to drive and use machines: Vimpat® may have minor to moderate influence on the ability to drive and use machines. Vimpat® treatment has been associated with dizziness or blurred vision. Accordingly patients should be advised not to drive a car or to operate other potentially hazardous machinery until they are familiar with the effects of Vimpat<sup>®</sup> on their ability to perform such activities. Undesirable effects: The most common adverse reactions ( $\geq 10\%$ ) are dizziness, headache, diplopia, and nausea. They were usually mild to moderate in intensity. Some were dose-related and could be alleviated by reducing the dose. Incidence and severity of CNS and gastrointestinal (GI) adverse reactions usually decreased over time. Other common adverse reactions ( $\geq 1\%$  - <10%) are depression, confusional state, insomnia, balance disorder, coordination abnormal, memory impairment, cognitive disorder, somnolence, tremor, nystagmus, hypoesthesia, dysarthria, disturbance in attention, vision blurred, vertigo, tinnitus, vomiting, constipation, flatulence, dyspepsia, dry mouth, pruritus, rash, muscle spasms, gait disturbance, asthenia, fatigue, irritability, injection site pain or discomfort (specific to solution for infusion), irritation (specific to solution for infusion), fall, and skin laceration. The use of Vimpat® is associated with dose-related increase in the PR interval. Adverse reactions associated with PR interval prolongation (e.g. atrioventricular block, syncope, bradycardia) may occur. Laboratory abnormalities: Abnormalities in liver function tests have been observed in controlled trials with Vimpat® in adult patients with partial-onset seizures who were taking 1-3 concomitant antiepileptic drugs. Elevations of ALT to  $\geq$  3XULN occurred in 0.7% (7/935) of Vimpat® patients and 0% (0/356) of placebo patients. Multiorgan Hypersensitivity Reactions: Multiorgan hypersensitivity reactions have been reported in patients treated with some antiepileptic agents. These reactions are variable in expression but typically present with fever and rash and can be associated with involvement of different organ systems. Potential cases have been reported rarely with Vimpat® and if multiorgan hypersensitivity reaction is suspected, Vimpat® should be discontinued.

Refer to the European Summary of Product Characteristics for other adverse reactions and full prescribing information. Date of revision: 24<sup>th</sup> October 2012.

http://www.ema.europa.eu/docs/en\_GB/document\_library/EPAR\_-Product\_Information/human/000863/WC500050338.pdf