PRESS RELEASE



Debiopharm International SA Reaches Important Development Milestones for its Staphylococcus-selective antibiotic Debio 1450

Debiopharm has completed a phase II study in ABSSSI, received Orphan Drug Designation from the EC for the treatment of osteomyelitis and demonstrated the protective effect of Debio 1450 on the gut microbiota

Lausanne, Switzerland – October 25, 2016 – Debiopharm International SA (Debiopharm – www.debiopharm.com), a Swiss-based company, part of Debiopharm Group[™], today announced several significant achievements in the development of its new antibiotic Debio 1450, selectively active on staphylococcal species including hard-to-treat methicillin-resistant Staphylococcus *aureus* (MRSA).

Debiopharm completed a double-blind randomized phase II study evaluating the efficacy of two different doses of intravenous and oral Debio 1450 compared to intravenous vancomycin and oral linezolid in the treatment of 330 patients with staphylococcal Acute Bacterial Skin and Skin Structure Infections (ABSSSI).

In addition, the European Commission (EC), granted Orphan Drug Designation to Debio 1450 for treatment of Osteomyelitis affecting around 87,000 people in the European Union (EU). Orphan Drug Designation by the EC provides regulatory and financial incentives to develop therapies for life-threatening or chronically debilitating conditions affecting no more than five in 10,000 persons in the EU, and for which no satisfactory treatment is available. This ODD is a strong incentive to pursue the development of the product in hard-to-treat infections for which patients need new treatment options.

Finally, Debiopharm has generated important non-clinical data on preservation of gut microbiota after 10 days of treatment with Debio 1450 when compared to other widely used broad-spectrum antibiotics. These data will be presented at the forthcoming IDWeek convention in New Orleans and they nicely illustrate the benefit of more targeted antibiotherapies that limit collateral damage to a healthy microbiome.

Abstract Information

Title	Date & Time	N°
The Staphylococcal-specific Antibiotic Debio 1450 Minimizes Disturbance to the Gut Microbiota in Mice	Saturday, October 29, 2016 12:30 PM	2244

"We are delighted to share these recent successes in the Debio 1450 program and in particular the first ever ODD in osteomyelitis", said Bertrand Ducrey, CEO of Debiopharm International. "Altogether these achievements are extremely encouraging and supportive of our strategy to improve patients' outcome through more selective antibiotics".

About Debio 1450

Debio 1450 is a new antibiotic benefiting from both oral and IV formulations. It is a highly potent, staphylococcus-selective antibiotic with a low propensity to emergence of resistance. This first-inclass Fabl inhibitor retains its activity on staphylococci resistant to antibiotics currently in clinical use including beta lactams, vancomycin, daptomycin or linezolid. Debio 1450 completed a Phase II study in ABSSSI in October 2016 and is perfectly suited to tackle several additional hard-to-treat infections caused by staphylococci.

About Debiopharm International SA

Debiopharm Group[™] is a Swiss-headquartered global biopharmaceutical group of five companies active in drug development, GMP manufacturing of proprietary drugs, diagnostics tools and investment management. Debiopharm International SA is focused on the development of prescription drugs that target unmet medical needs. The company in-licenses and develops promising drug candidates. The products are commercialized by pharmaceutical out-licensing partners to give access to the largest number of patients worldwide.

For more information, please visit www.debiopharm.com

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