

Debiopharm Group™ Announces Initiation of a Phase I Study of Debio 1450, an IV/oral Potent Antibiotic Active Against Staphylococcal Infections

Lausanne, Switzerland – June 19, 2014 – Debiopharm Group™ (Debiopharm), a Swiss-based global biopharmaceutical company developing prescription drugs that target unmet medical needs as well as companion diagnostics, today announced the launch of a Phase 1 dose-escalation study of Debio 1450 (previously known as AFN-1720), a highly potent anti-infective agent that is selectively active against a large number of Staphylococcus species, including all known resistant strains such as methicillin-resistant *S. aureus* (MRSA) and vancomycin-intermediate *S. aureus* (VISA).

This is a Phase I, double-blind, placebo-controlled dose-escalation study that will evaluate the safety, tolerability, and pharmacokinetics of single oral doses of Debio 1450 in healthy subjects. This study complements the IV single-ascending dose Phase I trial recently presented at the 24th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2014) in Barcelona.

Debio 1450 is a prodrug of Debio 1452, a potent and selective FabI-inhibitor. FabI is a critical enzyme required for bacterial fatty acid biosynthesis. Debio 1452 has been successfully administered in a series of Phase I studies and a Phase 2 study where it demonstrated high efficacy in the treatment of acute bacterial skin and skin-structure infections (ABSSSI). Due to its unique selectivity for staphylococcal species, Debio 1450 is expected to preserve the human microbiota and thereby reduce antibiotic-associated side effects such as antibiotic-induced diarrhea or *C. difficile* overgrowth. Additionally, development of multiple drug-resistant organisms like VRE (vancomycin-resistant enterococci) is unlikely given the lack of activity on other bacterial species. Debio 1450 is efficiently and rapidly converted to the active metabolite Debio 1452 after both IV and oral administration in animals. Being able to treat staphylococcal infections with a safe treatment that allows for an IV/oral switch will bring much greater flexibility to physicians and patients and will be a major advance in addressing difficult-to-treat infections.

"This study is another step towards the development of an IV/oral anti-infective agent for difficult-to-treat infections", said Jean-Maurice Dumont, Vice-President Medical Affairs, Debiopharm International. "Development of targeted antibiotics that preserve the indigenous microbiota will become an essential tool for the infectious disease doctor. The promising results obtained with Debio 1452 and Debio 1450 make us extremely confident on the high potential of these new drugs."

Thierry Mauvernay, Delegate of the Board of Debiopharm Group, added that "The fast launch of this Phase I study with Debio 1450, only a few months after its acquisition, shows our strong commitment to the rapid development of innovative anti-infectives. This drug represents not only a novel agent but a whole new class of antibiotics – a development driven by our current line of thinking about highly targeted antibiotics. In parallel, we are actively working on the development of new, rapid and powerful diagnostic tools that will allow safe and accurate use of our drugs. Debiopharm is determined to pursue developments in this challenging field and to become a major player in this therapeutic area".

About Debiopharm Group™

Debiopharm Group™ is a Swiss-based global biopharmaceutical group of four companies active in drug development, GMP manufacturing of proprietary drugs, diagnostics, and investments. Debiopharm International SA is focused on the development of prescription drugs that target unmet medical needs. The company in-licenses, develops and/or co-develops promising biological and small molecule drug candidates for global registration. The products are commercialized through out-licensing to pharmaceutical partners to give access to the largest number of patients worldwide.

For more information about Debiopharm Group™, please visit: www.debiopharm.com.

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