

FDA Grants Fast Track designation to Debiopharm Group's antibiotic Debio 1450

– *Debio 1450, oral/IV FabI inhibitor active against all Staphylococcus species has received Fast Track designation for ABSSSI (acute bacterial skin and skin structure infections) –*

Lausanne, Switzerland – January 8, 2015 – Debiopharm Group™ (Debiopharm), a Swiss-based global biopharmaceutical company, today announced that the US Food and Drug Administration (FDA) granted Fast Track designation to its anti-infectious agent Debio 1450, a highly potent antibiotic specifically active against all Staphylococcus species. FDA Fast Track designation facilitates the development and expedites review of drugs and biologics intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Debio 1450 has also received designation as a Qualified Infectious Disease Product (QIDP) in September 2014 for the same indication.

Debio 1450 exhibits a unique selectivity for staphylococcal species, it is expected to prevent development of multiple drug resistant organisms like VRE (vancomycin resistant enterococci) and to reduce antibiotic-associated side effects. “The growing resistance to antibiotics poses a major global threat to public health. Studies estimate that drug-resistant infections result in at least 25,000 deaths in 29 countries in Europe and 23,000 deaths in the U.S. every year” said Jean-Maurice Dumont Vice President, Medical Affairs. “Fast Track designation will surely speed up patients’ access to Debio 1450 by accelerating its entry on the market and provide a new option for physicians to treat patients with serious bacterial skin infections”.

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 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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