PRESS RELEASE

Debiopharm Group™'s innovative antibiotic Debio 1450 – developed from its proprietary plateform Fabiotics – Receives Qualified Infectious Disease Product (QIDP) Designation from the FDA

Lausanne, Switzerland – September 4, 2014 – Debiopharm Group™ (Debiopharm), a Swiss-based global biopharmaceutical company developing prescription drugs that target unmet medical needs including anti-infective and oncology therapeutics as well as companion diagnostics, today announced that the US Food and Drug Administration (FDA) has designated its anti-infectious agent Debio 1450 as a Qualified Infectious Disease Product (QIDP) for the treatment of acute bacterial skin and skin structure infections (ABSSSI).

QIDP designation will give Debio 1450 access to Priority Review, Fast Track and five additional years of market exclusivity in the United States. Fast Track status is intended to expedite drug development. Priority Review allows for an accelerated review of the marketing authorization, i.e. 6 months compared with the 10-month standard review.

These incentives were established as part of the GAIN Act – Generating Antibiotic Incentives Now -, passed by the US Congress in July 2012 to encourage pharmaceutical companies to develop new antimicrobials.

Debio 1450 (previously known as AFN-1720) is a highly potent oral/IV anti-infective agent that is specifically active against all Staphylococcus species, including all known resistant strains such as methicillin-resistant *S. aureus* (MRSA) and vancomycin-intermediate *S. aureus* (VISA). Debio 1450 is currently in a dose-escalation Phase I study in healthy volunteers. It is one of the most advanced FabI inhibitors issued from the Debiopharm's antibiotic technology platform "Fabiotics". Debiopharm is very actively pursuing the development of new projects from this rich platform as seen in the recently launched *Neisseria gonorrhoeae* and enteric species programs.

"The threat of antibiotic resistance has become a reality", said Frederick Wittke, Medical Director Debiopharm International SA, "and there is a real need for targeted molecules that preserve indigenous gut microbiota and overcome resistance to broad-spectrum antibiotics". We are thrilled that the potential of Debio 1450 has been recognized with the FDA designation. It will clearly accelerate the development process and will give patients a quicker access to the drug" added Thierry Mauvernay, Delegate of the Board of Debiopharm Group. "We are very confident that our powerful platform Fabiotics will continue to provide highly valuable targeted anti-infectives in the future in order to alleviate problems of acquired resistance linked to broad-spectrum antibiotic usage".

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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