

Debiopharm International SA initiates clinical phase II study evaluating Debio 1450 in Staphylococcal skin infections

One year after the initiation of Phase I, Debiopharm announced the start of clinical phase II for Debio 1450 in ABSSSI and presentation of new data at ECCMID

Lausanne, Switzerland – April 23, 2015 – Debiopharm International SA (Debiopharm), part of Debiopharm Group™, a Swiss-based global biopharmaceutical company, today announced the start of a clinical phase II study to evaluate Debio 1450 for the treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) due to Staphylococci, including all resistant *Staphylococcus* strains, tested so far.

This study is designed as a dose-response study to evaluate the efficacy of Debio 1450 in both intravenous (IV) and oral formulations versus intravenous vancomycin switched to oral linezolid in the treatment of ABSSSI. Safety and tolerability of both the IV and oral formulations of Debio 1450 will be evaluated by conventional endpoints.

Moreover, Debiopharm will present data regarding Debio 1450 PK/PD at the 25th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), which will be held from 25 - 28 April 2015 in Copenhagen.

During ECCMID, Debiopharm will also take part in the Pipeline Corner project, a unique event organized on behalf of the European Society of Clinical Microbiology and Infectious Diseases, allowing companies to present their innovative anti-infective projects and meet stakeholders in this field. Please visit us at Pipeline Corner: Hall K – L

“Only one year after the enrollment of the administration of the first patient in Phase I, we are happy to announce the initiation of clinical PhII in ABSSSI”, said Dr Jean-Maurice Dumont, Vice President, Medical Affairs, Debiopharm International. “It emphasizes our commitment to develop highly valuable targeted antibiotics in order to alleviate problems of acquired resistance linked to broad-spectrum antibiotic usage”.

Details of Debiopharm’s presentations at ECCMID

	POSTER	ORAL PRESENTATION	EVENT
Date	Sat, Apr 25 Session EV27 Methods for antibacterial susceptibility testing	Mon, Apr 27 Session OS22 New studies in antibacterial drug PK/PD	Mon, Apr 27 1:00 – 2:00 pm
Title	Debio 1452 MIC quality control range with <i>Staphylococcus</i> <i>aureus</i> ATCC 29213 using a multi- laboratory study design (EV0763)	Translational pharmacokinetic/pharmacodynamic modeling of oral and intravenous Debio 1450, a new staphylococcal specific antibiotic	Debiopharm “elevator pitch” with a focus on antibacterials
Speaker		Valérie Nicolas	Fabien Sebillé
Location	ePoster Area	Hall F	Pipeline Corner Hall K-L

About Debio 1450

Debio 1450 is a prodrug of Debio 1452, it is a highly potent 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). Oral and IV Debio 1450 formulations are being developed for clinical use in several serious infections. Moreover Debio 1452 had a successful phase IIa with 103 patients in ABSSSI.

About Debiopharm International SA

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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