



Debiopharm Group[™] Announces Progress in Phase I Single and Multiple Ascending Dose Study of Debio 1450, its Potent Anti-staphylococcal Agent

Lausanne, Switzerland – October 07, 2014 – Debiopharm Group[™] (Debiopharm), a Swiss-based global biopharmaceutical company developing prescription drugs that target unmet medical needs as well as companion diagnostics, announced today excellent progress of its Phase I single and multiple ascending dose study of Debio 1450, a highly potent anti-infective agent selectively active against Staphylococcus species, including all known resistant strains such as methicillin-resistant *S. aureus* (MRSA) and vancomycin-intermediate *S. aureus* (VISA).

This Phase I clinical trial in healthy subjects is a two part study to assess the safety, tolerability, and pharmacokinetics of Debio 1450. Part A, in particular, investigates the food and gastric pH effect of a single oral dose of Debio 1450 as well as the absolute bioavailability when compared to IV Debio 1450. Part B examines the dose proportionality of multiple ascending doses of Debio 1450 administered orally and IV. To date 20 subjects have been enrolled. This trial follows closely a single ascending dose study of Debio 1450 that is currently in its final stages.

Frederick Wittke, Medical Director, Debiopharm International SA, said: "The team is highly enthusiastic about the first safety and pharmacokinetic results. This is most encouraging as we now have data to show that it is a very well-tolerated drug candidate."

Debio 1450 is a prodrug of Debio 1452, a potent and selective Fabl-inhibitor (a critical enzyme required for bacterial fatty acid biosynthesis). 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 with Debio 1450 given its 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. Treatment of staphylococcal infections with a molecule that allows a switch from the IV to the oral route will bring a tremendous benefit to patients with difficult-to-treat infections.

Debio 1450 stems from Debiopharm's recently acquired platform of novel, targeted, narrow-spectrum antibacterial therapeutics 'Fabiotics'. Debiopharm is actively pursuing new development projects from this rich platform, directed against pathogens such as *Neisseria gonorrhoeae* or enteric species. These programs were launched in June 2014.

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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