PRESS RELEASE

EMA grants Orphan Drug Designation to Debiopharm International SA's IAP inhibitor Debio 1143 in the treatment of Ovarian Cancer

Lausanne, Switzerland – December 8, 2015 – Debiopharm International SA (Debiopharm), part of Debiopharm Group™, a Swiss-based global biopharmaceutical company, today announced that the European Medicines Agency (EMA) granted Orphan Drug Designation to Debio 1143 for treatment of Ovarian Cancer affecting around 154 000 people in the European Union (EU).

Orphan Drug Designation by the EMA provides regulatory and financial incentives to develop therapies for life-threatening or chronically debilitating conditions affecting no more than five in 10,000 persons in EU, and for which no satisfactory treatment is available.

Debio 1143 is an oral, small molecule inhibitor of IAPs (Inhibitor of Apoptosis Proteins) with a dual pro-apoptotic and immunomodulatory mode of action developed as a potent chemo/radiosensitizer in oncology. Further to the encouraging signs of efficacy seen in clinical phase I and supported by this significant regulatory milestone, Debiopharm will expand the clinical development of this therapy to patients with Ovarian Cancer.

"Obtaining orphan designation for Debio 1143 in the European Union is an important regulatory milestone", stated Peggy Lipp, Director, Regulatory Affairs, Business Intelligence & Market Access, Debiopharm International S.A. "It speaks to the need for new treatment options in this chronically debilitating and life threatening condition and the potential role of Debio 1143's mode of action. This orphan drug designation is a proof of our commitment to developing innovative therapies for oncology patients".

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 investment management. Debiopharm International SA is focused on the development of prescription drugs that target unmet medical needs. The company in-licenses and 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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