PRESS RELEASE

EMA grants Orphan Drug Designation to Debiopharm International SA's FGFR inhibitor Debio 1347 in the treatment of biliary tract cancer

Lausanne, Switzerland – November 14, 2017 – Debiopharm International SA (Debiopharm – www.debiopharm.com), part of Debiopharm Group™, a Swiss-based global biopharmaceutical company, today announced that the European Medicines Agency (EMA) granted Orphan Drug Designation to Debio 1347 for treatment of Biliary Tract Cancer affecting around 77,000 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 1347 is an orally available small molecule selectively targeting FGFR 1, 2, 3 signaling pathways and is currently tested in a phase I study in patients with FGFR genomically activated advanced solid tumors (including patients with biliary tract cancer).

Further to the encouraging signs of efficacy observed during clinical phase I and supported by this significant regulatory milestone, Debiopharm will expand the clinical development of this therapy to these patients.

"Obtaining orphan designation for Debio 1347 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 1347'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

Part of Debiopharm Group™ – a Swiss-headquartered global biopharmaceutical group including five companies active in the life science areas of drug development, GMP manufacturing of proprietary drugs, diagnostic tools 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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