***PRESS RELEASE***

# FDA Grants Fast Track designation to Debiopharm International's Debio 1347 for the treatment of patients with unresectable or metastatic tumors with a specific FGFR gene alteration

**Lausanne, Switzerland – May 8, 2018 –** Debiopharm International SA (Debiopharm – www.debiopharm.com), part of Debiopharm Group™, a Swiss-based global biopharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Debio 1347, an FGFR 1-3 Inhibitor, for the treatment of patients with unresectable or metastatic tumors with a specific FGFR gene alteration. The FDA's Fast Track designation facilitates the development of new therapies that treat serious conditions and fulfill an unmet medical need in an effort to get treatments to those in need sooner.

This designation is based on the preliminary efficacy and safety data collected in the phase I study under Investigational New Drug application (IND) of Debio 1347 for the treatment of patients with unresectable or metastatic tumors with a specific FGFR gene alteration. The phase I is a gene alteration-based, open label, multicenter study of oral Debio 1347 (CH5183284) in patients with advanced solid malignancies, whose tumors have an alteration of the FGFR1, 2 or 3 genes.

"This Fast Track designation is an encouraging step in our innovative approach to advance the care of the patients with unresectable or metastatic tumors with a specific FGFR gene alteration, who have little or no other treatment options." said Peggy Lipp, Director, Regulatory Affairs, Market Intelligence & Market Access at Debiopharm International. "It is critical that we address the unmet medical need of these patients and we are looking forward to working with the FDA to accelerate the development of this potential therapy."

## 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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