PRESS RELEASE

Debiopharm International SA Initiates FUZE, a Clinical Trial Phase II study evaluating Debio 1347 in Advanced Solid Tumors harboring an FGFR fusion

Patients will be recruited in North America, Europe, South America and the Asia Pacific region.

Lausanne, Switzerland – February 14, 2019 – Debiopharm International SA (Debiopharm – www.debiopharm.com/debiopharm-international/), part of Debiopharm Group™, a Swiss-based global biopharmaceutical company, today announced the start of FUZE, a clinical phase II study to evaluate Debio 1347 for the treatment of solid tumors harboring an FGFR fusion (NCT03834220).

The presence of a specific alteration of the fibroblast growth factor receptor (FGFR) genes – called a fusion – deregulates FGFR signaling pathways and drives cancer growth. Debio 1347 is a potent selective inhibitor of FGFRs.

This study will enroll patients with advanced or metastatic tumors whose cells show specific FGFR gene alterations, namely FGFR1, FGFR2 or FGFR3 gene fusions. The purpose of the trial is to demonstrate that Debio 1347 can bring clinical benefit to patients with tumors harboring an FGFR fusion.

"Historically, cancer therapies have been approved for use on the basis of the tumor's location and stage of cancer. The FUZE clinical trial has been designed on the basis of a specific tumor's genetic alteration, rather than its location. This tissue-agnostic approach could therefore benefit cancer patients with a rare genetic alteration, such as an FGFR fusion, irrespective of tumor type. We are committed to using innovative treatment approach guided by advanced technologies to meet unmet needs with the intent to improve outcomes and quality of life for cancer patients".
- Claudio Zanna, Group Medical Director at Debiopharm International SA

About Debio 1347

Debio 1347 is an investigational novel orally available small molecule highly selective FGFR 1, 2, 3 ATP competitive inhibitor. Results from the phase 1 clinical trial showed that patients with solid tumors with activating alterations in FGFR may benefit from treatment with Debio 1347. Debio 1347 is expected to become a tailored treatment which will be developed with a companion diagnostic.

For more information: patients.debiopharm.com/genetic-alterations/

About Debiopharm International SA

Part of Debiopharm Group™, 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/debiopharm-international/

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Debiopharm International SA Contact
Christelle von Büren
Communication Coordinator
christelle.vonburen@debiopharm.com
Tel: +41 (0)21 321 01 11