PRESS RELEASE

Debiopharm successfully completes randomized Phase II study for IAP antagonist Debio 1143 in high risk head & neck cancer patients

Lausanne, Switzerland – September 3rd, 2019 – Debiopharm (www.debiopharm.com), a Swiss biopharmaceutical company, announced positive topline results across clinical endpoints following the completion of the two-year follow-up period of its double-blind, randomized Phase II study of Debio 1143 in high-risk, previously untreated patients with locally advanced squamous cell carcinoma of the head and neck (LA-SCCHN). These significant results, including the primary endpoint LRC (locoregional control) being met along with prolonged PFS (progression-free survival), will be presented at the forthcoming European Society for Medical Oncology (ESMO) congress in Barcelona in September 2019 by the lead investigator, Professor Jean Bourhis, Head of the Radio-Oncology department at the University Hospital of Lausanne, Switzerland.

This robust Phase II trial, which included 96 patients, was designed to demonstrate the efficacy and safety of this IAP antagonist, first in its class to be Phase III ready. The results support future clinical assessments of the compound in stage III-IV LA-SCCHN patients as a frontline treatment in combination with CRT.

"*We initiated the Debio 1143 clinical development program to address the high unmet medical need in LA-SCCHN patients who have a poor prognosis, including those who are HPV-negative and heavy smokers. This new data strongly suggests that our product may enhance efficacy of the current standard of care for patients suffering from this particularly debilitating type of tumor.*" **- Angela Zubel, Chief Development Officer, Debiopharm.**

In parallel with the design and initiation of a registration Phase III study, Debiopharm is actively considering potential partnerships with pharmaceutical industry leaders in order to deliver a new therapeutic option to LA-SCCHN patients as soon as possible.

Head and neck cancer is the 6th most common cancer worldwide, with a complex management strategy including the standard administration of CRT along with surgery when possible. The two main pathological causes for SCCHN are tobacco/alcohol consumption and human papillomavirus (HPV) infection. Although the standard of care improves survival and quality of life for many patients, more than half of high-risk patients, notably heavy smokers (>10 pack-years) and those with HPV-negative tumors, will relapse.

About Debio 1143

Debio 1143 is an antagonist of IAPs (inhibitor of apoptosis proteins), acting as chemo-radio-sensitizer to enhance treatment efficacy with a dual mode of action, promoting programmed cell death and fostering anti-tumor immunity. Currently in clinical development in a broad range of cancer types, the compound is being developed in combination with chemo-radiotherapy or with ICIs (PD-1/PD-L1), with reported data consistently showing a favorable safety profile. Over 200 patients have been treated so far with Debio 1143 in various indications and lines of treatment.

Trial information:

- Head & neck cancers: patients.debiopharm.com/head-and-neck-cancer/
- Small cell lung cancers: patients.debiopharm.com/small-cell-lung-cancer-sclc/
- Gastrointestinal cancers: patients.debiopharm.com/gastrointestinal-cancers/
- Gynecologic cancers: patients.debiopharm.com/gynecologic-cancer/

Debiopharm's commitment to cancer patients
Debiopharm aims to develop innovative therapies that target high unmet medical needs in oncology. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds for in-licensing, clinically demonstrate their safety and efficacy and then select large pharmaceutical commercialization partners to maximize patient access globally.

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