PRESS RELEASE

Debiopharm's novel IAP antagonist Debio 1143 achieves outstanding Phase II results for high-risk Head and Neck cancer patients

Late breaking abstract results presented today at ESMO with chemo-radio sensitizer Debio 1143 present a promising breakthrough strategy to improve the front-line treatment of H&N cancer patients

Lausanne, Switzerland – September 30, 2019 – Debiopharm, a Swiss-based global biopharmaceutical company, presented today, at the ESMO Congress (European Society for Medical Oncology), compelling results from a robust, randomized, Phase II study of Debio 1143 for the treatment of high-risk, locally advanced squamous cell carcinoma of the head and neck (LA-SCCHN) patients in combination with current standard of care, chemo-radiotherapy (CRT). Clinical results with Debio 1143, the most clinically advanced IAP antagonist, revealed a statistically significant improvement of the primary endpoint locoregional control rate (LRC - 21% improvement at 18 months after CRT vs. control arm) and a striking progression-free survival (PFS) benefit vs. the control arm after a 2-year follow-up period.

This double-blind, randomized, control group study, combined Debio 1143 with CRT in patients with previously untreated stage III, IVA or IVB SCCHN. The majority of patients enrolled were considered high-risk, facing a poor prognosis, including HPV-negative oropharyngeal cancer (OPC) patients and heavy smokers (>10 pack-years). Ninety-six patients were enrolled at 19 centers across France and Switzerland. The study explored whether the addition of Debio 1143 at 200 mg/d to standard CRT could increase treatment efficacy compared to CRT and placebo. The primary endpoint of LRC-rate at 18 months was met. For key secondary endpoints, clinically compelling and statistically significant outcomes in Progression-Free survival (PFS) at 24-months were observed along with positive trends for overall survival (OS) and complete response (CR) rates in the active treatment group vs. CRT+placebo, although these parameters have not yet reached statistical maturity.

"Combined with the standard of care, Debio 1143 has demonstrated significant efficacy – especially in locoregional control rate and progression free survival – in high-risk previously untreated LA-SCCHN patients", **commented Pr. Jean Bourhis, Head of the Radio-Oncology Department CHUV, Lausanne, Switzerland, and Lead Investigator of the study.** *"The chemo-radio-sensitizing effect of Debio 1143 constitutes a highly promising strategy to ultimately allow high-risk head and neck patients to achieve better control over their disease for longer."*

"The positive topline results are very encouraging and support our efforts to provide head and neck cancer patients and clinicians with this potential new treatment option", **said Bertrand Ducrey, CEO of Debiopharm International.** *"This data demonstrates proof of concept for the potential use of Debio 1143 in other CRT applications, potentially expanding therapeutic reach and making a difference in a wide range of indications."*

In addition, Debio 1143 showed a predictable and manageable safety profile, without substantial additional toxicity to standard CRT.

ESMO 2019 Session Details	Abstract	Presenting investigator
Sept. 30th , 10:15am Cordoba Auditorium (Hall 7) Preferred Paper – Head and neck cancer	LBA65 - Double-blind Randomized Phase 2 Results Comparing Concurrent Highdose Cisplatin Chemorradiation (CRT) plus Debio 1143 or Placebo In High-risk Patients with Locally Advanced Squamous Cell Carcinoma of the Head and Neck (SCCHN): A GORTEC Study	Prof. Jean Bourhis, Head of the Radio-Oncology Department CHUV, Lausanne, Switzerland, Lead study author

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.

Ongoing trials for Debio 1143:

- 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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