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.
## 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

**Presenting investigator:**

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/](patients.debiopharm.com/head-and-neck-cancer/)
- Small cell lung cancers: [patients.debiopharm.com/small-cell-lung-cancer-sclc/](patients.debiopharm.com/small-cell-lung-cancer-sclc/)
- Gastrointestinal cancers: [patients.debiopharm.com/gastrointestinal-cancers/](patients.debiopharm.com/gastrointestinal-cancers/)
- Gynecologic cancers: [patients.debiopharm.com/gynecologic-cancer/](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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