PRESS RELEASE

DEBIOPHARM'S IAP ANTAGONIST SIGNIFICANTLY IMPROVES OVERALL SURVIVAL OF HIGH-RISK HEAD & NECK CANCER PATIENTS

Promising overall survival outcomes at 3-years for high-risk, locally advanced squamous cell carcinoma of the head and neck (LA-SCCHN) patients observed with Debio 1143 + CRT

Lausanne, Switzerland – August 13th, 2020 – Debiopharm (www.debiopharm.com), a Swiss-based, global biopharmaceutical company, today announced the release of compelling 3-year follow-up results from the randomized phase II study assessing the efficacy and safety of Debio 1143 in combination with chemo-radiation therapy (CRT) vs. CRT alone for the treatment of high-risk *LA-SCCHN patients.* This potential first-in-class inhibitor of apoptosis proteins (IAP) antagonist with CRT showed a statistically and clinically significant improvement in Overall Survival (OS) vs. the control group, suggesting a halving of the risk of mortality (*p*=0.0261).

In addition, these 3-year follow-up results in 96 LA-SCCHN patients also confirm the sustainability of the promising 2-year outcomes recently published in **Lancet**[1] by demonstrating continued, statistically significant improvements across all other major endpoints including the doubling of the progression free survival rate along with superior duration of response. The predictable and manageable safety profile observed with Debio 1143 + CRT at 2 years remained largely unchanged at year 3, keeping in mind that study treatments were administered over three 3-week cycles at study initiation.

In February of this year, the compound received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA), reaffirming its potential to offer a significant benefit over the current standard of care in LA-SCCHN, responding to the high unmet need in this debilitating cancer type. Head & Neck cancer is the 6th most common cancer with a heavy impact on both the survival of high-risk patient types and on patient quality of life, including major dysfunctional impact relative to eating, breathing and talking. Debio 1143 represents one of the few new clinical advances in Head & Neck cancer, which has not seen any newly approved therapies over the last 25 years.

"This is an important step forward for Head & Neck cancer patients and the research community as this potential front-line therapy could change the way these patients are treated from the start**," stated Angela Zubel, Chief Development Officer, Debiopharm.** "I am very encouraged by improvement of long-term outcomes observed in our study. These results indicate that Debio 1143 in combination with CRT has the potential to prolong patient lives and achieve better control over their disease."

"These 3-year follow-up results could have major implications for high risk Head & Neck cancer patients, especially those with negative HPV status who appear to be associated with the poorest prognosis. As the compound is now advancing into phase III, we will be able to gather further evidence for this radio-chemo enhancing IAP antagonist that has the potential to become a standard-of-care treatment for radiation oncology," **expressed Prof. Jean Bourhis, Department Head of Radio-Oncology at the University Hospital of Lausanne and Lead Investigator of the study.**

About Debio 1143

Debio 1143 is a potential first-in-class oral antagonist of IAPs (inhibitor of apoptosis proteins), that sensitizes tumor cells to radio-chemo therapy by promoting programmed cell death and fostering anti-tumor immunity. The clinical benefit observed in *LA-SCCHN patients* suggests that the

integration of Debio 1143 into widely used CRT regimens is a promising investigational approach over a broad range of cancer types. The compound is currently poised to enter into a Phase III, pivotal trial this September in combination with CRT in Head & Neck cancer. Over 200 patients have been treated so far in various indications and lines of treatment, showing an adequate and consistent safety profile across studies.

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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1. Xu-ShanSunMD et al. *Lancet Oncol.* August 2020. Published online https://doi.org/10.1016/S1470-2045(20)30327-2