PRESS RELEASE

DEBIOPHARM GRANTS A WORLDWIDE EXCLUSIVE LICENSE TO MERCK FOR THE DEVELOPMENT AND COMMERCIALIZATION OF XEVINAPANT

- *Xevinapant is the first Inhibitor of Apoptosis Proteins antagonist with FDA Breakthrough Therapy Designation for previously untreated locally advanced squamous cell carcinoma of the head and neck, in combination with current standard of care*
- *A Phase II trial reported that xevinapant plus chemoradiotherapy reduced risk of death by 51% vs standard of care in this patient population; Phase III TrilynX study initiated in September 2020*
- *Merck gains exclusive global development and commercialization rights; Debiopharm to receive €188 million upfront and up to €710 million in milestone, as well as royalty payments*

Lausanne, Switzerland – March 1st, 2021 – Debiopharm (www.debiopharm.com), a Swiss-based global biopharmaceutical company, today announced the signature of an exclusive license agreement with Merck, a leading science and technology company, for the development and commercialization of xevinapant (Debio 1143). Xevinapant, a potent, oral of Inhibitor of Apoptosis Proteins (IAP) antagonist, is the only medicine in its class in late-stage clinical development and has the potential to be first in class. Xevinapant is currently being investigated in the pivotal Phase III TrilynX study for previously untreated high-risk locally advanced squamous cell carcinoma of the head and neck (LA SCCHN), in combination with platinum-based chemotherapy and standard fractionation intensity-modulated radiotherapy. Given their strong commercial footprint in the field of head and neck cancer, Merck is the partner of choice to leverage our outstanding phase II data and make xevinapant a transformative therapy for cancer patients.

Under the terms of the license agreement, Merck receives exclusive rights to develop and commercialize xevinapant worldwide, including in the U.S. Merck will also co-fund with Debiopharm the ongoing Phase III registrational TrilynX study, a global double-blind, placebo-controlled, 700-patient randomized clinical trial to evaluate the efficacy and safety of xevinapant vs. placebo when added to definitive chemoradiotherapy (CRT) in cisplatin-eligible patients with high-risk LA SCCHN.

This global license agreement is a significant achievement that rewards the clinical development efforts conducted by Debiopharm while demonstrating the agility and relevance of the company's specific and unique business model. By focusing on drug development, Debiopharm can bridge the most innovative discoveries with the best commercial pharmaceutical partners.

"At Debiopharm we are driven by the ambition to cure. Our business model is led by the needs of patients and unmet medical needs. The data for xevinapant to date demonstrate an extremely important potential to improve the standard treatment for patients with head and neck cancer, an indication for which no new treatment has been registered for several decades," said **Bertrand Ducrey, Chief Executive Officer of Debiopharm**. "Merck's in-depth knowledge of head and neck cancer and their worldwide commercial capabilities, make them an exceptionally qualified partner to move xevinapant forward, and position it as the next gold standard of care in head and neck cancer and potentially in other indications."

"By bringing our expertise and heritage in head and neck cancer to the development of xevinapant, we have the opportunity to explore an important new treatment option in an area of high unmet need where other approaches, including immunotherapy, have seen limited success," **said Peter Guenter, Member of the Executive Board of Merck and CEO Healthcare.** "The promising long-term efficacy of xevinapant in the Phase II clinical study suggests that antagonism of IAP has the potential to be a transformative approach in this cancer. We will build on this strong proof of concept, shown in Debiopharm's robust clinical program for xevinapant, as we continue to develop this potential new standard of care."

"Locally advanced head and neck cancer is uniquely debilitating, often impairing the ability to swallow, speak and breathe. With the current standard treatments, at least half of patients will relapse, typically within the first two years. Based on the efficacy seen in the Phase II study, in which adding xevinapant to CRT cut the risk of death by half, this investigational medicine has the potential

to offer a much-needed new standard of care," said **Prof. Jean Bourhis, Department Head of Radio-Oncology at the University Hospital of Lausanne and lead investigator of the Phase III TrilynX study**.

Previously reported results from the randomized, double-blind Phase II clinical study showed the addition of xevinapant to standard-of-care CRT provided a statistically significant 21% point improvement in locoregional control rate at 18 months, the primary endpoint, vs. placebo and CRT in patients with high-risk LA SCCHN (54% [95% CI: 39 to 69] vs. 33% [95% CI: 20 to 48]; odds ratio 2·69 [95% CI: 1·13 to 6·42]; p=0·026). A significant progression-free survival (PFS) benefit was also observed vs. the control arm after a two-year follow-up period (HR=0.37, 95% CI: 0.18 to 0.76; p=0.0069)[1]. At three years of follow-up, xevinapant plus CRT showed a statistically significant 51% reduction in the risk of death versus placebo plus CRT (HR=0.49, 95% CI: 0.26 to 0.92; p=0.0261). About two-thirds of patients in the xevinapant arm were alive at three years, compared with 51% in the control arm.

In February 2020, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation to xevinapant for treatment of patients with confirmed diagnosis of previously untreated LA SCCHN in combination with current standard of care, platinum-based chemotherapy and standard-fractionation intensity-modulated radiotherapy, based on the Phase II results.

About Head and Neck Cancer

Worldwide, head and neck cancer accounts for more than 650,000 cases and 330,000 deaths annually, making it the 6th most common cancer type[2]. LA SCCHN is a highly debilitating disease that can lead to impaired breathing, swallowing, and speech as it progresses[3]. Despite standard of care CRT, at least 40% to 60% of patients with LA SCCHN develop locoregional or distant relapses, which are usually detected within the first two years of treatment, underscoring the need to identify new therapeutic approaches[4].

About xevinapant

Xevinapant (Debio 1143) is a potential first-in-class potent oral antagonist of IAPs (Inhibitor of Apoptosis Proteins). In preclinical studies, xevinapant restores sensitivity to apoptosis in cancer cells, thereby depriving them of one of their major resistance mechanisms. As the most clinically advanced IAP antagonist, xevinapant has established proof of efficacy in combination with chemoradiotherapy (CRT) in patients with high-risk locally advanced squamous cell carcinoma of the head and neck (LA SCCHN), with a clinically significant and sustained clinical benefit compared with CRT alone.

Debiopharm's commitment to patients

Debiopharm develops innovative therapies that target high unmet medical needs in oncology and infectious diseases. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy and then select large pharmaceutical commercialization partners to maximize patient access globally. Debiopharm is known for the development of oxaliplatin, worldwide gold standard treatment in colorectal cancer and of triptorelin, a standard of care for the treatment of prostate cancer. Xevinapant is well positioned to become the third transformative therapy arising from Debiopharm in oncology.

For more information, please visit www.debiopharm.com

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