PRESS RELEASE

DEBIOPHARM LAUNCHES TRILYNX - A LARGE-SCALE PHASE III CLINICAL TRIAL TO FURTHER EVALUATE XEVINAPANT IN THE TREATMENT OF HEAD & NECK CANCER

First patient dosed in the randomized, placebo-controlled Phase III study of xevinapant (Debio 1143) vs placebo when added to chemoradiotherapy (CRT) in high-risk patients with locally advanced squamous cell carcinoma of the head and neck (LA-SCCHN)

Lausanne, Switzerland – October 1st, 2020 – Debiopharm (www.debiopharm.com), a Swiss biopharmaceutical company, announced today the first patient dosed in their phase III clinical trial (TrilynX) with xevinapant, an orally available antagonist of IAPs (Inhibitor of apoptosis proteins) cancer therapy in combination with CRT for LA-SCCHN patients. This prospective, randomized, double-blind, placebo-controlled, multicenter, 2-arm clinical trial is being conducted to demonstrate the superior efficacy of xevinapant vs. placebo when added to CRT in high risk head and neck patients including those affected in the throat and vocal chords (oropharynx -HPV-negative, hypopharynx and larynx). The TrilynX study is being launched worldwide in 25 countries in over 200 sites with the aim of enrolling approximately 700 patients.

This trial launch follows the positive phase II results observed at 3-year follow-up analysis showing superior and statistically significant locoregional control, progression-free survival, and overall survival vs. the placebo control group. Efficacy during phase III will be evaluated by multiple radiological and clinical variables including event-free survival, progression-free survival, and duration of response.

"The launch of the TrilynX trial follows several key 2020 milestones in the development of xevinapant including the FDA Breakthrough Designation in February and the recent presentation this fall of our clinically meaningful 3-year, phase II data at the ESMO (European Society of Medical Oncology) virtual congress. We expect that this large-scale trial will confirm the strong outcomes observed in phase II, bring us a step further towards positively impacting the lives of high-risk head & neck cancer patients." expressed **Bertrand Ducrey, CEO of Debiopharm.**

Worldwide, head and neck cancer accounts for more than 650,000 cases and 330,000 deaths annually[1], making it the 6th most common cancer type worldwide. LA-SCCHN is a highly debilitating disease, gradually progressing impaired breathing, swallowing, and speech.[2] Risk for the disease is linked with alcohol and tobacco abuse, largely due to exposure to carcinogens in the upper airways. Despite standard of care CRT, at least 50% of patients with LA-SCCHN develop locoregional or distant relapses, which are usually detected within the first 2 years of treatment,[3][4] hence the need to identify new therapeutic solutions.

Debiopharm's commitment to patients

Debiopharm, Swiss Biotech Award Winner 2020, develops innovative therapies that target high unmet medical needs in oncology and bacterial infections. 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.

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[1] Bray F et al. CA Cancer J Clin, 2018 68 (6): 394-424.
[2] Marur S, and Forastiere AA. Mayo Clinic Proceedings 2018, 83 (4): 489-501.
[3] Grégoire V et al. , Annals of Oncology 2010, 21 (suppl_5): v184-v86.
[4] AWMF. 2019. 'S3 guidelines - Laryngeal carcinoma, diagnosis and therapy.

Debiopharm Contact
Dawn Haughton - Communication Manager
dawn.haughton@debiopharm.com
Tel: +41 (0)21 321 01 11