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PRESS RELEASE
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Precirix dosed first patients in Phase I/II clinical study evaluating CAM-H2 in HER2-positive metastatic cancer

Brussels, Belgium, 6 October 2021 – Precirix NV, a clinical-stage biotechnology company developing precision radiopharmaceuticals in oncology, announces that it has dosed the first patients in its Phase I/II clinical study of CAM-H2 for the treatment of HER2-positive metastatic cancer. This is a major milestone in the company's development of its lead therapeutic asset.

The Phase I/II trial (NCT04467515) evaluates safety, tumor uptake, tumor retention and early signs of antitumor activity of single-agent CAM-H2 in HER2-positive metastatic breast and gastric/gastro-esophageal cancer patients that have relapsed or are refractory to available anti-HER2 therapies. The trial is a continuous study composed of two parts: a Phase I dose-escalation phase to establish the recommended dose for Phase II in 3+3 dose-ascending cohorts of patients, followed by a Phase II dose-expansion phase. The Phase I/II clinical study will allow inclusion of patients with brain metastases, a population in dire need of effective therapies, and will enroll a total of appr. 70 patients.

Ruth Devenyns, CEO commented: *"We are very excited to have dosed the first patients in this clinical study, the result of years of thorough scientific research, collaboration and operational excellence of our entire team and partners. Special thanks to our former CMO Ruggero Della Bitta, for his contribution to our global clinical development strategy and securing regulatory clearance for the Phase I/II trial. We look forward to recruiting additional patients and generating efficacy data to confirm the strong results from our preclinical and first-in-human studies, with the goal of bringing new treatment options to cancer patients."*

About CAM-H2

CAM-H2 comprises a single-domain antibody targeting HER2, covalently linked to iodine-131. Single-domain antibodies are ideally suited for targeted delivery of radiation to tumors given their size, specificity and pharmacokinetic characteristics. Imaging studies conducted with the HER2 targeting single-domain antibody labelled with gallium-68 have demonstrated specific uptake and retention in primary, metastatic and brain lesions in HER2-positive breast cancer patients.

About HER2-positive cancer

Worldwide, >1.6 m cases of breast cancer and >1.2m cases of gastric cancer are diagnosed annually, of which >20% are HER2-positive. In breast cancer, some 60% of the patient population develops metastatic disease, with brain metastases occurring in up to 50% of metastatic patients[1,2]. HER2 is also overexpressed in subsets of patients with other solid tumors including biliary tract, colorectal, non-small-cell lung and bladder cancer[3].

HER2 is an established therapeutic target and a variety of agents targeting HER2 have been approved, however none of these cure metastatic disease. Specifically in brain metastases there are limited treatment options. There are no approved HER2 targeting radiopharmaceuticals and CAM-H2 is the lead candidate in therapeutic development, leveraging the advantages of using a single-domain antibody to deliver targeted radiation to the tumor and bringing a new mechanism of action in the current HER2 treatment landscape to address important unmet medical needs, including brain metastases and low HER2 expression.

About Precirix NV

Precirix is a private, clinical-stage biopharmaceutical company dedicated to extending and improving the lives of cancer patients by designing and developing precision radiopharmaceuticals, using camelid single-domain antibodies labeled with radioisotopes. The company has a broad pipeline with one product candidate in a Phase I/II clinical trial and two in advanced preclinical stage. Research on multiple isotopes, linker technology and combination therapies further expand the platform. Precirix' technology also allows for a theranostic approach, where patients can be selected using a low dose/imaging version of the product, followed by a higher therapeutic dose for treatment.

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[1] 'From diagnosis to treatment: Understanding breast cancer', Roche website
[2] 'Real-world characteristics metastatic breast cancer' (ASCO 2018)
[3] Oh et al. *Nature Reviews Clinical Oncology* 2019