Press Release
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First Patient Dosed in Phase 1 Clinical Study with Affibody's Radiotherapeutic ABY-271 in HER2-positive Metastatic Breast Cancer

Solna, Sweden, October 7, 2025. Affibody AB ("Affibody") today announced that the first patient has been dosed in a Phase 1 clinical study with the company's radiotherapeutic candidate ABY-271 in HER2-positive metastatic breast cancer. The study will evaluate safety, tolerability, and biodistribution of ABY-271. This is an important milestone for Affibody in the development of its innovative radiotherapeutic pipeline. The first results from the study are expected during 2025.

The Phase 1 study is a first-in-human open-label, two-stage, randomized trial to assess the safety, tolerability, and biodistribution of ABY-271 in tumors and critical organs in subjects with HER2-positive metastatic breast cancer. The study will be conducted at sites specialized in breast cancer and nuclear medicine in Sweden and Germany. The first patient was enrolled at Uppsala University Hospital in Sweden.

"There remains a significant unmet medical need for more effective and targeted treatments for cancer patients with advanced disease," said Henrik Lindman, MD, Associate Professor, Head of the Department of Hematology and Oncology at Uppsala University Hospital in Sweden. "We are proud to be the first site to dose a patient with ABY-271 and look forward to continuing to collaborate with Affibody and the other clinics to rapidly enroll patients in this first-in-human trial."

ABY-271 is an Affibody® molecule that targets HER2-expressing tumors and is labeled with the radioisotope lutetium-177, which emits cytotoxic beta radiation exerting irreversible damage to the tumor cells upon binding.

"We are thrilled to announce the enrollment of the first patient in the Phase 1 clinical trial with our lead radiotherapeutic, ABY-271. This milestone is a testament to our team's dedication and hard work to bring next-generation radiotherapeutics to patients in need of new treatment options," said David Bejker, CEO of Affibody. "We believe ABY-271's targeted mechanism has the potential to significantly improve the lives of patients battling metastatic breast cancer and we look forward to the study results with great excitement."

About the Phase 1 clinical study

The clinical study is a phase 1, open-label, two-stage, randomized trial to assess the safety, tolerability, and biodistribution of ABY-271 in tumors and critical organs in subjects with HER2-positive metastatic breast cancer.

The trial consists of two parts, part A in which the uptake of ABY-271 in tumors and critical organs will be evaluated in up to six sequentially enrolled patients, and part B in which the optimal protein mass dose range for subsequent clinical trials will be evaluated in a total of 15 randomized patients. Patients will receive a single intravenous infusion of ABY-271 in both part A and part B. Dr Oscar Wiklander at Karolinska University Hospital is the coordinating investigator in Sweden. More information about the study can be found on clinicaltrials.gov under NCT07081555.

About ABY-271

ABY-271 is a radiotherapeutic candidate aimed at tumor cells that express HER2, regardless of their position in the body. The project builds on previous clinical research insights from the development of tezatabep matraxetan (ABY-025), showing that the candidate substance can bind to HER2 independently of the tumor origin. ABY-271 with the radioisotope lutetium-177 emits therapeutic beta radiation, exerting irreversible damage to the cancer cells upon binding.

About metastatic breast cancer

Metastatic breast cancer is cancer that has spread beyond the breast and nearby lymph nodes to other parts of the body, such as the bones, liver, lungs, or brain. It carries a poor prognosis and cannot be treated curatively with surgery or systemic therapies. Instead, the treatment goal shifts to delaying disease progression, controlling symptoms, and improving quality of life. Approximately 6-10% of women are diagnosed with metastatic breast cancer at their initial diagnosis. However, nearly 30 percent of women initially diagnosed with early-stage breast cancer will experience metastatic recurrence during their lifetime.

About HER2

HER2 is a protein that is involved in cell growth. HER2 is overexpressed by some types of cancer cells, including breast, stomach, esophageal, ovarian, bladder, and pancreatic cancers. HER2 may cause cancer cells to grow more quickly and spread to other parts of the body and HER2-positive cancers are therefore considered more aggressive than HER2-negative cancers. However, they are much more likely to respond to treatments that target the HER2 protein. HER2-targeted therapies can remain effective even after multiple lines of treatment.

About Affibody® molecules

Affibody® molecules are a novel drug class of small therapeutic proteins with characteristics surpassing monoclonal antibodies (mAbs) and antibody fragments. The Company has created a large library consisting of more than ten billion Affibody® molecules, all with unique binding sites, from which binders to given targets are selected. Affibody® molecules are only 6 kDa in size.

They have demonstrated clinical utilities both as tumor-targeting moieties through their small size and as efficacious disease blocking agents in autoimmune indications by utilizing the inherent properties that allow multi-specific formats.

About Affibody

Affibody is a clinical stage integrated biopharmaceutical company with a broad product pipeline focused on developing innovative bi- and multi-specific next generation biopharmaceutical drugs based on its unique proprietary technology platform, Affibody® molecules.

Through its validated business model, the company has a proven capability of identifying and prioritizing strategic projects in a timely and de-risked way. Affibody has established several partnerships for the development and commercialization of its innovations with international pharmaceutical companies.

Affibody's main shareholder Patricia Industries is a part of Investor AB.

Further information can be found at: www.affibody.com.

Disclaimer

This press release contains forward-looking statements. While Affibody consider the projections to be based on reasonable assumptions, these forward-looking statements may be called into question by several hazards and uncertainties, so that actual results may differ materially from those anticipated in such forward-looking statements.

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Attachments

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