Press Release
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First Patients Enrolled in Diagnostic Phase 2 Imaging Study with Affibody's PET Imaging Agent Tezatabep Matraxetan in Metastatic Breast Cancer

Solna, Sweden, October 21, 2025. Affibody AB ("Affibody") today announced the enrollment of the first patients in a diagnostic Phase 2 imaging study evaluating tezatabep matraxetan, the company's PET imaging agent designed for non-invasive assessment of HER2-status in cancer patients. The aim of the study is to evaluate the role of PET precision imaging with tezatabep matraxetan in enhancing treatment planning for patients with HER2-expressing metastatic breast cancer.

The Phase 2 imaging study is a prospective, multi-center, open-label, exploratory trial with the primary objective to investigate the therapy-predictive value of tezatabep matraxetan for the clinical benefit of treatment with the HER2-specific antibody-drug conjugate Trastuzumab Deruxtecan (T-DXd) in patients with HER2-expressing metastatic breast cancer. The study hypothesis is that PET precision imaging with tezatabep matraxetan can lead to a potentially better identification of patients who benefit from T-DXd treatment, thereby achieving improved treatment responses as well as fewer side effects. Additionally, the study may contribute to a deeper biological understanding of HER2-expressing metastatic breast cancer.

Tezatabep matraxetan is an Affibody® molecule that targets HER2-expressing tumors and is labeled with the radioisotope Gallium-68 to enable non-invasive visualization of HER2-positive cancer lesions throughout the body using PET imaging.

Theranostics Trial Center at the Karolinska University Hospital is sponsor for the study, which is conducted in collaboration with Uppsala University Hospital, and Skåne University Hospital in Sweden.

"Assessing HER2 status from a single biopsy can be difficult as HER2 expression may vary between tumor sites and change over time. In addition, obtaining biopsies from certain sites in the body can be technically challenging," said assistant professor Oscar Wiklander at the Karolinska University Hospital and principal investigator in the study. "By using PET imaging with a HER2-specific tracer like tezatabep matraxetan, we have the opportunity to non-invasively evaluate HER2 expression across the whole body, potentially improving patient selection for HER2-directed therapies to ensure that more patients receive the most appropriate treatment."

About the Phase 2 imaging study

The Phase 2 study is a prospective, multi-center, open-label, exploratory diagnostic imaging trial in approximately 70 patients with metastatic breast cancer with at least one line of systemic therapy. The primary objective of the trial is to investigate the therapy-predictive role of tezatabep matraxetan for the clinical benefit of Trastuzumab Deruxtecan (T-DXd) treatment in patients with HER2-expressing metastatic breast cancer.

All patients will undergo a baseline HER2-PET with tezatabep matraxetan and a tumor biopsy. Patients with HER2-expressing lesions on PET and/or in tumor biopsy will be treated with T-DXd. A second HER2-PET with tezatabep matraxetan will be done in all patients treated with T-DXd at the time of treatment response evaluation after 9-12 weeks of treatment. An optional third HER2-PET with tezatabep matraxetan and tumor biopsy will be conducted at the time of disease progression on T-DXd.

More information about the study can be found on clinicaltrials.gov under NCT06830382.

About tezatabep matraxetan

Tezatabep matraxetan (ABY-025) is a Gallium-68-labeled PET tracer candidate that aims to enable non-invasive visualization of HER2 expression in cancer patients. The high affinity and rapid clearance of tezatabep matraxetan from blood and normal organs allows HER2 assessment within hours.

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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