Press Release
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Affibody Accelerates Phase 1 Study with ABY-271 Following Initial Patient Data

Stockholm, Sweden, December 16, 2025. Affibody AB (“Affibody”) today announced that the Trial Review Committee (TRC) has recommended to advance the Phase I clinical study with the Radioligand Therapy (RLT) candidate ABY-271 in HER2-positive metastatic breast cancer to its second part, where higher radioactivity levels will be evaluated.

The TRC has based its positive recommendation on safety, tolerability, dosimetry and biodistribution data from the first enrolled cohort of patients, demonstrating tumor targeting and a favorable safety profile with low uptake in kidneys and other critical organs.

"The initial data from the ABY-271 study are very promising. We observed a favorable safety profile and encouraging biodistribution data, supporting progression of the study to the next stage,” said assistant professor Oscar Wiklander at the Karolinska University Hospital, coordinating investigator in the study. “These results offer important insight into how the therapy behaves in patients, and we are eager to advance the study to deepen our understanding of its clinical potential.”

“I am thrilled that these early clinical results with ABY-271 mirror the preclinical findings and dosimetry predictions remarkably well. I am especially excited about the low kidney uptake,” said David Bejker, CEO of Affibody. “The positive outcome not only marks an important milestone for this program but also for the Affibody® platform as a powerful technology for developing next-generation targeted radiotherapeutics.”

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. Affibody is evaluating ABY-271 in a first-in-human, open-label, two-stage, randomized Phase 1 clinical study 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 is conducted at sites specialized in breast cancer and nuclear medicine in Sweden and Germany.

The TRC, including principal investigators, medical monitor, dosimetry and nuclear medicine specialists, has reviewed safety, tolerability, dosimetry and biodistribution data from a pre-specified number of enrolled patients. The TRC confirmed favorable safety and biodistribution, with low uptake in kidneys and other critical organs. The TRC recommends advancing the study to part B, which will evaluate higher radioactivity levels and additional protein mass doses. In line with this recommendation, Affibody will submit a protocol amendment to the European Medicines Agency (EMA) to accelerate the transition to the second part, which is expected to start in H1 2026 with the first results anticipated in H2 2026.

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 higher radioactivity levels and additional protein mass doses 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 Radioligand Therapy (RLT) candidate aimed at tumor cells that express HER2, regardless of their location in the body. The project builds on previous clinical research insights from the development of the PET imaging agent 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.

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 benefit both as tumor-targeting moieties and as efficacious disease modifying agents in autoimmune indications by utilizing the inherent differentiated properties of the platform.

About Affibody

Affibody is a clinical stage radiopharmaceutical company developing next generation Radioligand Therapies (RLTs) designed to deliver highly selective tumor targeting across a wide range of cancers. Leveraging decades of innovation in Affibody® molecule discovery and engineering, together with deep understanding of the RLT field, the company is advancing a novel pipeline focused on oncology indications with high unmet medical need. Affibody's lead RLT candidate, ABY-271, is currently being evaluated in a first-in-human clinical study in HER2 positive metastatic breast cancer.

The Affibody® platform has also demonstrated clinical value in immunology and inflammation, with multiple programs being advanced through strategic partnerships.

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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