Press Release
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First Patient Dosed in Part B of Phase 1 Study with Affibody's Radioligand Therapy Candidate ABY-271 in HER2-positive Metastatic Breast Cancer

Stockholm, Sweden, May 28, 2026. Affibody AB ("Affibody") today announced that the first patient has been dosed in part B of a Phase 1 clinical study with the company's Radioligand Therapy (RLT) candidate ABY-271 in HER2-positive metastatic breast cancer. Part B is designed to evaluate safety and biodistribution of higher levels of radioactivity and additional protein mass doses compared to the completed part A. The first results from part B are expected during 2026.

"Dosing the first patient in part B of this Phase 1 study represents an important milestone for ABY-271 and for Affibody's radioligand therapy platform," said David Bejker, CEO of Affibody. "Part B builds on the encouraging safety, biodistribution and tumor-targeting results observed in part A, and allows us to evaluate ABY-271 at higher radioactivity levels and protein mass doses in a patient population with more advanced disease. This step will significantly strengthen our understanding of ABY-271's clinical profile and guide further development."

ABY-271 is an Affibody® molecule that targets HER2-expressing tumors with high affinity to provide extended tumor retention. It 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 Europe. The substantial amendment to initiate part B was approved by the European Medicines Agency (EMA) in April 2026.

Part B will enroll a total of 15 patients that have progressive disease after receiving at least three lines of standard systemic anti-tumor therapy. The patients will be randomized to three different protein mass dose levels in two sequential cohorts with increasing radioactivity doses. Subjects with at least stable disease, and without any dose-limiting toxicity will have the option to enter an extension trial with continued administration of ABY-271.

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 has been evaluated in two 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 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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