

Affibody Presents First-in-Human Clinical Imaging Data with ABY-271 in HER2-positive Metastatic Breast Cancer at SNMMI 2026

Stockholm, Sweden, May 27, 2026. Affibody AB ("Affibody") today announced that initial first-in-human clinical imaging data from the ongoing Phase 1 study with the HER2-targeting Radioligand Therapy (RLT) candidate ABY-271 will be presented at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2026 Annual Meeting, taking place May 30-June 2, 2026, in Los Angeles.

The Phase 1 study is a first-in-human, open-label, 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 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 will be evaluated in 15 patients.

As previously announced, data from the completed part A demonstrated tumor targeting and a favorable safety profile with low uptake in kidneys and other critical organs consistent with preclinical predictions.

The results have been selected for Poster Oral Presentation at SNMMI, a format reserved for the highest-scoring abstracts within the track.

"We are pleased to present encouraging first-in-human data for our lead RLT candidate ABY-271 at SNMMI, one of the world-leading scientific events in nuclear medicine and molecular imaging," said David Bejker, CEO of Affibody. "These initial clinical results mark a significant milestone for our RLT pipeline, and we are honored that it has been selected for Poster Oral Presentation, reflecting the strong scientific interest in innovative approaches to treat HER2-positive metastatic breast cancer."

The presentation details are as follows:

Title: First-in-Human Safety and Biodistribution Phase 1 Study of [¹⁷⁷Lu]Lu-ABY-271 in Subjects with HER2-Positive Metastatic Breast Cancer (NCT07081555)

Presenter: Guido Wuerth, Head Corporate Development, Radiopharma at Affibody

Session: Oncology: Discovery & Translational POPs session

Date/time: June 02, 2026, at 11:00 – 11:30 AM PDT

Abstract no/ screen no: 261321/ MTA11-Screen 17

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.

Contacts (Affibody)

David Bejker, CEO, +46 706 454 948
Peter Zerhouni, CFO and CBO, +46 706 420 044

Contacts (Media)

Richard Hayhurst, 59° North Communications, richard.hayhurst@59north.bio, +44 (0) 7711 8215727

Attachments

[Affibody Presents First-in-Human Clinical Imaging Data with ABY-271 in HER2-positive Metastatic Breast Cancer at SNMMI 2026](#)