



Press release

August 30, 2023

## **Data demonstrating that Affibody's PET imaging agent ABY-025 can be used to predict therapeutic response will be presented at EANM**

**Solna, Sweden, August 30, 2023. Affibody AB ("Affibody") today announced the presentation of data from patients in a clinical study of the PET imaging agent 68Ga-ABY-025 for non-invasive quantification of HER2-status in solid tumors. The data will be presented at the upcoming Annual Congress of the European Association of Nuclear Medicine.**

The data was generated in an open label Phase 2 study conducted at Uppsala University Hospital as part of Affibody's radiopharmaceutical program. The aim of the study was to investigate 68Ga-ABY-025 for non-invasive quantification of HER2 status in solid tumors by PET/CT and monitoring of early treatment response in both primary breast cancer planned for neoadjuvant chemotherapy and metastatic breast cancer.

The study included 40 patients with positive HER2 status as determined by biopsy, 19 with primary breast cancer, and 21 with metastatic breast cancer. 68Ga-ABY-025 PET/CT, 18F-FDG PET/CT, and core needle biopsies from targeted tumors were performed at baseline. 18F-FDG PET/CT was repeated after two cycles of HER2-targeted therapy to calculate the change in tumor lesion glycolysis (delta-TLG, a measure of tumor growth rate). Standardized uptake values (SUV) from 68Ga-ABY-025 PET/CT were compared with HER2 status from biopsy and delta-TLG.

Metabolic response (delta-TLG) to therapy was more pronounced in primary breast cancer than metastatic breast cancer. An additional analysis demonstrated that global delta-TLG was positively associated with the number of previous treatments and negatively with 68Ga-ABY-025 uptake (SUV) but not with HER2 status as determined by biopsy.

In conclusion, 68Ga-ABY-025 PET may predict early metabolic response to HER2-targeted therapy in HER2-positive breast cancer. 68Ga-ABY-025 PET thus appears to provide an estimate of the HER2-receptor expression required to induce tumor metabolic remission by targeted therapies.

The data will be presented by Dr. Jens Sörensen, Uppsala University, during a session for Top Rated Oral Presentations at the Annual Congress of the European Association of

Nuclear Medicine, in Vienna, Austria (“EANM”) on September 12, 2023. The title of the presentation is: “HER2-targeting [68Ga]Ga-ABY-025 PET Predicts Early Metabolic Response in Metastatic Breast Cancer”.

Additionally, a second Top Rated Oral Presentation related to Affibody’s radiopharmaceutical program will be presented by Dr Vladimir Tolmachev at the same session. The presentation with the title “HER2-specific Affibody Molecule [99mTc]Tc-ZHER2:41071: phase I clinical trial” will highlight results of a Phase 1 study to evaluate the use of a Single-photon emission computed tomography (“SPECT”) imaging agent to assess HER2 uptake.

### **About ABY-025**

ABY-025 is based on an Affibody® molecule that binds strongly to HER2 – a cell surface protein implicated in several forms of cancer. The high affinity and rapid clearance of ABY-025 from blood and normal organs allows HER2 assessment within hours.

### **About Affibody® molecules**

Affibody® molecules are a novel class of antibody mimetics 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, have an inert format (no Fc function), and have demonstrated clinical utilities as tumor-targeting moieties. The inherent properties of Affibody® molecules allow more efficacious disease blocking by using multi-specific constructs as shown in clinical trials in autoimmunity indications.

### **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](http://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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