News release

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First ten HER2-low patients dosed in Phase 2 basket trial using Affibody's PET imaging agent ABY-025

Solna, Sweden, June 30, 2023. Affibody AB ("Affibody") today announced that the first ten patients have been dosed in a Phase 2 clinical basket study of the PET imaging agent ^{68}Ga-ABY-025 PET for non-invasive quantification of HER2-status in solid tumors.

The dosing of the tenth patient marks the end of the pilot study where participants with a previously biopsy-confirmed HER2-low metastatic breast cancer underwent a HER2-PET with ^{68}Ga-ABY-025 followed by a new tumor biopsy guided by the results from the PET-images.

"*We are excited about studying this important patient group with our unique Affibody® tracer*" commented Fredrik Frejd, CSO of Affibody. "*We are also impressed with the efficient and rapid patient recruitment catalyzed by our collaborators and the team behind the precision medicine initiative Theranostics Trial Center Karolinska (TTC-K).*"

Preliminary results from the first ten patients indicate ^{68}Ga-ABY-025 uptake in cancer lesions in all patients with HER2-low metastatic breast cancer. Interestingly, clear HER2-signals were noted in lesions from two patients with tumor biopsies that were HER2 0.

"*The HER2-signal in metastatic lesions defined as completely HER2-negative (HER2 0) according to biopsy and immunohistochemistry suggest heterogeneity in HER2-expression within individual metastases"* commented Rimma Axelsson, professor in nuclear medicine and principal investigator of the study. "*These preliminary results demonstrate that molecular imaging can add information currently not available using conventional methods".*

All ten patients in the study had lesions with a value above SUV 6, used as cut-off for positive HER2 expression[1], despite being defined as HER2 2+ ISH negative or lower, the classical definition for HER2 negative tumor lesions. Importantly, even patients with no detectable HER2 expression in standard *ex vivo* IHC assessment showed tracer uptake.

"This might imply that even patients with a HER2 0 tumor biopsy could benefit from treatment with HER2-targeted treatments when there is radiotracer uptake" commented

Renske Altena, oncologist, deputy PI in the study and head of the Theranostics Trial Center Karolinska. *"HER2 imaging information may change the way oncologists view HER2 low disease in the future"* she continued.

References

1.) Sörensen et al "Measuring HER2-Receptor Expression In Metastatic Breast Cancer Using [68Ga]ABY-025 Affibody PET/CT". Theranostics. 2016 :262-71.

About the Phase 2 basket trial

The Phase 2 interventional clinical trial is planned to enroll 72 patients at the Karolinska University Hospital with the aim to evaluate the HER2-status in tumor lesions measured by Gallium-68-ABY-025-uptake on PET/CT with HER2-status defined by reference standard (laboratory analyses) in patients with gastroesophageal cancer (GEAC) and metastatic breast cancer with low HER2 expression (HER2-low mBC).

The participants in GEAC cohort of the study will undergo two sessions of HER2 PET and one 18-Fluorodeoxyglucose (^{18}F-FDG) PET/CT for study purposes. The first HER2 PET is performed within 21 days before initiation of the systemic oncological treatment and is followed by tumor biopsies. A second HER2 PET and a second ^{18}F-FDG PET will be performed adjacent to response evaluation after 3 courses of oncological therapy. Data from the PET investigations will be compared to HER2 expression analyses of the biopsy specimen and correlated to disease and survival data at follow-up one year after inclusion. Within the pilot study, participants with HER2-low mBC will undergo one HER2 PET followed by biopsies. The ClinicalTrials.gov Identifier is NCT05619016 and the EudraCT number is 2022-500448-39-00.

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

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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