Press Release
04 January 2023 08:00:00 CET

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

Solna, Sweden, January 4, 2023. Affibody AB ("Affibody") today announced that the first patients have been dosed in a Phase 2 clinical basket study of the PET imaging agent 68Ga-ABY-025 PET for non-invasive quantification of HER2-status in solid tumors. 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.

The aim of the trial, which is part of Affibody's radiopharmaceutical program, is to investigate 68Ga-ABY-025 for non-invasive quantification of HER2 status in solid tumors by PET/CT for selection and monitoring of treatments. The Phase 2 basket trial includes patients with gastro-esophageal cancer (GEAC) with HER2-overexpression, and breast cancer patients with low HER2 expression.

The trial is led by Rimma Axelsson, principal investigator and Professor of Nuclear Medicine at the Department of Molecular Medicine and Surgery, Karolinska Institutet, Renske Altena, Clinician Scientist and principal investigator in oncology and internal medicine, Karolinska Comprehensive Cancer Center, Karolinska Institutet and Magnus Nilsson, Professor of Surgery at the Department of Clinical Science, Intervention and Technology, CLINTEC with colleagues at Karolinska University Hospital.

"*We are excited to collaborate with leading clinical experts at Karolinska Institutet to strengthen precision medicine through molecular imaging,*" commented Fredrik Frejd, CSO of Affibody. "*We look forward to working closely with our research colleagues at the Karolinska University Hospital as the study progresses.*"

Determination of HER2 overexpression is today achieved by immunohistochemistry (IHC3+, IHC2+) (HercepTest) and/or gene amplification by in-situ hybridization (ISH), all of which require a biopsy or surgical specimens thereby reflecting only the site from where the biopsy was obtained.

"There is a high need to reliably assess levels of HER2 in all metastatic lesions, but challenges exist as current determination of HER2 overexpression is largely limited to HER2 expression at the biopsy site. 68Ga-ABY-025 is a highly promising agent for molecular imaging of HER2 disease across lesions, allowing readable results within hours," said Rimma Axelsson, nuclear medicine physician and principal investigator of the study.

Lower levels of HER2 expression are assessed using IHC 0, 1+ or 2+ (HercepTest). There is no established standard to understand the therapeutic relevance of different low expression levels.

"It was recently presented that even patients with low levels of HER2-expression on tumor cells (so called HER2-low) may benefit from HER2-targeted therapies" said Renske Altena, oncologist, and deputy PI in the study 1.). *"It is estimated that about 50% of breast tumors can be classified as HER2-low and there is an urgent clinical need to develop refined and accessible methods to identify which patients have an optimal risk-benefit balance from HER2-targeted therapies. The first images in the present study seem to confirm the study hypothesis that metastatic lesions with HER2-low expression*

can be visualized by PET-imaging with 68Ga-ABY-025 and indicate a significant heterogeneity of HER2-expression in metastatic tumors – suggesting presence of targetable lesions beyond what is expected for HER2-low patients judged by immunohistochemistry of biopsies. Further study will confirm how widespread this finding may be"

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).

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 2.), 3.).

The participants in GEAC cohort of the study will undergo two sessions of HER2 PET and one 18-Fluorodeoxyglucose (18F-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 18F-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 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

References

1. Modi et al (2022), Trastuzumab Deruxtecan in Previously Treated HER2-Low Advanced Breast Cancer. *N Engl J Med* 2022; 387:9-20 https://www.nejm.org/doi/pdf/10.1056/NEJMoa2203690
2. Sörensen et al (2016), Measuring HER2-Receptor Expression In Metastatic Breast Cancer Using [68Ga]ABY-025 Affibody PET/CT, *Theranostics* Jan 1;6(2):262-71

3. Alhuseinalkhudhur et al (2022), A phase II study of 68Ga-ABY-025 PET for non-invasive quantification of HER2 expression in breast cancer [abstract]. In: Proceedings of the 2021 San Antonio Breast Cancer Symposium; 2021 Dec 7-10; San Antonio, TX. Philadelphia (PA): *AACR; Cancer Res* 2022;82(4 Suppl):Abstract nr P3-02-06.

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
Camilla Danell, CFO, +46 761 148 910

Affibody Investor Contact
Alexandra Roy, aroy@soleburytrout.com

Affibody Media Contact
Richard Hayhurst/Ola Bjorkman, RHApr, +44 7711 821 527, richard@rhapr.eu

Attachments

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