Press Release
26 March 2024 08:00:00 CET

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

Solna, Sweden, March 26, 2024. Affibody AB ("Affibody") today announced that the first patients with gastroesophageal cancer have been dosed in a Phase 2 clinical basket study of the PET imaging agent 68Ga-ABY-025 ("HER2 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 tissue allows HER2 assessment within hours.

Gastroesophageal cancer continues to present global challenges in early detection and effective treatment options, with a need for non-invasive diagnostic tools that can guide innovative therapies. Recent advances with HER2 directed therapies hold promise for this patient population.

"This marks an important step in the ABY-025 program as we are now demonstrating use in gastroesophageal cancer," commented Fredrik Frejd, Professor and Chief Scientific Officer of Affibody. *"We appreciate for our close collaboration with the leading clinical experts at Karolinska Institutet and Karolinska University Hospital and believe that the study results will pave the way for our therapeutic candidate ABY-271 in this patient population."*

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. Results from a cohort with breast cancer patients with low HER2 expression have recently been published (JNM, in press). The trial now continues with the inclusion of additional patients with gastroesophageal cancer.

"68Ga-ABY-025 has demonstrated the ability to visualize HER2 metastases with low-HER2 expression in our recently published study of metastatic breast cancer patients," said Rimma Axelsson, Professor of Nuclear Medicine and Principal Investigator (PI) of the study. *"I am excited about the opportunity to investigate this further in additional patients."*

"Patients with gastroesophageal cancer may have a high degree of variability of HER2 expression level in different tumor lesions," said Magnus Nilsson, Professor of Surgery and deputy PI in the study. *"It is important to understand HER2 receptor status in this patient population to guide the use of HER2 targeted treatment."*

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 68Ga-ABY-025 uptake on PET/CT with HER2-status defined by reference standard (tissue analyses) in patients with gastroesophageal cancer (GEAC) and metastatic breast cancer with low HER2 expression (HER2-low mBC).

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

The participants in 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 will be performed adjacent to response evaluation after three 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. The ClinicalTrials.gov Identifier is NCT05619016 and the EudraCT number is 2022-500448-39-00.

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 utilities both as tumor-targeting moieties through their small size and as efficacious disease blocking agents in autoimmune indications by utilizing the inherent properties that allow multi-specific formats.

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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Contacts

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

Affibody Media Contact
Richard Hayhurst/Ola Björkman, RHA Communications, +44 7711 821 527, richard@rhacomms.eu

Attachments

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