Adcendo ApS Announces U.S. FDA Clearance of IND Application for Phase I Tiffany-01 Trial of ADCE-T02

ADCE-T02 is a potential first-in-class Topoisomerase I inhibitor-based antibody-drug conjugate (ADC) targeting tissue factor, a validated ADC target overexpressed in multiple solid tumors

Phase I Tiffany-01 trial is designed to evaluate the safety, pharmacokinetics, and preliminary efficacy of ADCE-T02 as a monotherapy in patients with advanced solid tumors

Copenhagen, Denmark – February 26th, 2025 – Adcendo, a biotech company pioneering the development of first and best-in-class ADCs for cancers with a high unmet medical need, today announced that the U.S. Food & Drug Administration (FDA) has provided clearance of the IND application for a Phase I study evaluating ADCE-T02 in patients with advanced solid tumors.

Tiffany-01 is an ongoing first-in-human Phase I multicenter, open-label, dose escalation study of ADCET02 as a monotherapy in patients with advanced solid tumors. The primary objectives of the study are to determine the maximum tolerated dose and recommended Phase II dose and schedule of ADCET02 monotherapy in addition to assessing ADCE-T02 safety and tolerability. The secondary objectives are to characterize the pharmacokinetics and to evaluate the preliminary efficacy of ADCE-T02. The study is currently recruiting in Australia and will start recruiting in the U.S. in the next few months.

“Tissue factor (TF) is a validated ADC target with overexpression in many high unmet need solid tumor indications, however, the currently approved TF targeting ADC has severe limitations due to a suboptimal side effect profile and a limited therapeutic window. The highly differentiated profile of ADCE-T02, based on the use of an improved monoclonal antibody and a next generation Topoisomerase I inhibitor linker/payload technology, could overcome those limitations and offer an enhanced therapeutic window and improved side effect profile, which may lead to better clinical outcomes for patients,” said Dr. Lone Ottesen, Chief Medical Officer of Adcendo. “The U.S. IND clearance of ADCE-T02 is an important milestone for our program and our company, and we look forward to initiating patient enrollment in the U.S. and working closely with all of our investigators to evaluate the therapeutic utility of this drug in multiple advanced solid tumor indications.”

Prof. Vinod Ganju. Managing Director of Peninsula and Southeast Oncology (PASO), Melbourne, Australia and Principal Investigator of Tiffany-01, commented: “ADCs have in the past years shown highly encouraging results and have already become Standard of Care in quite a number of solid tumor indications. ADCE-T02 represents an attractive new option to explore in advanced solid tumors with high unmet need. I am pleased to be working with Adcendo to develop ADCE-T02, potentially offering a broader therapeutic window and a better safety profile for our patients.”

About ADCE-T02

Tissue Factor is a clinically validated ADC target with strong overexpression in multiple tumor indications with high unmet medical need including Cervical Cancer, Head and Neck Cancer, Colorectal Cancer, Non-Small Cell Lung Cancer, and Pancreatic Ductal Adenocarcinoma. ADCE-T02 is a highly differentiated anti-TF ADC, and the first ADC with a Topoisomerase I inhibitor-based linker/payload,

clinically developed in Australia and the U.S. Its unique antibody design minimizes the impact on the coagulation pathway, while the T1000-exatecan linker-payload technology platform has been shown to amplify the bystander effect, improve linker stability, and has the potential to overcome emerging resistance mechanisms. These differentiated features are expected to translate into a superior therapeutic window, a better safety profile, enhanced response rates and longer duration of response.

About Adcendo ApS

Adcendo ApS is a clinical-stage biotechnology company headquartered in Copenhagen, Denmark, with operations in Boston, Massachusetts. The company is developing a pipeline of first-in-class antibody-drug conjugates (ADCs) targeting cancers with high unmet medical needs. Led by a team of industry veterans with a track record of advancing multiple ADCs to approval, Adcendo integrates novel targets, optimized linker-payload combinations, and a rationally designed development strategy to drive next-generation cancer therapies. **For further information, please visit** www.adcendo.com **or follow the company on LinkedIn.**

For further information:

Argot Partners

Tel: +1 (212) 600-1494

E-mail: adcendo@argotpartners.com

Adcendo ApS

Michael Pehl, CEO

Tel: +45 31541824

Email: info@adcendo.com