Adcendo Announces US FDA Clearance of IND Application for Phase I/II First-in-Human ADCElerate-01 Trial of ADCE-D01 (uPARAP Receptor Targeting ADC) Trial in Patients With Metastatic and/or Unresectable Soft Tissue Sarcoma (STS)

- *ADCE-D01 is a first-in-class antibody-drug conjugate (ADC) targeting uPARAP, an endocytic receptor which is highly overexpressed in mesenchymal cancers including multiple STS subtypes*
- *The Phase I/II ADCElerate-01 trial is designed to evaluate the safety, pharmacokinetics, and preliminary efficacy of ADCE-D01 as a monotherapy in patients with metastatic and/or unresectable STS*

Copenhagen, Denmark, October 8th, 2024 – Adcendo, a biotech company focused on the development of first-in-class ADCs for the treatment of cancers with a high unmet medical need, today announced that the US Food & Drug Administration (FDA) has provided clearance of the IND application for the Phase I/II study of ADCE-D01 in patients with metastatic and/or unresectable STS (the ADCElerate-01 Trial).

ADCElerate-01 is a first-in-human Phase I/II multicenter, open-label, dose escalation and expansion study of ADCE-D01 as a monotherapy in patients with metastatic and/or unresectable STS. The primary objective of the study is to evaluate the safety and tolerability of ADCE-D01, to determine the maximum tolerated dose, as well as the recommended Phase II dose and schedule of ADCE-D01 monotherapy. The secondary objectives are to characterize the pharmacokinetics and to evaluate the preliminary efficacy of ADCE-D01. The study will recruit in the US and Europe, with a CTIS submission planned in the EU during the coming months.

Dr. Lone Ottesen, Chief Medical Officer of Adcendo, said: "uPARAP is a highly attractive target for the development of an ADC in mesenchymal cancers including soft tissue sarcoma, as it is highly overexpressed in multiple STS subtypes, has unique internalization properties and shows only very low expression in healthy tissues. The IND clearance of ADCE-D01 is an important milestone for our program and our company, and we look forward to initiating patient enrolment for this study and working with our investigators to evaluate the therapeutic utility of this drug in STS patients as soon as possible."

Prof. Patrick Schöffski, Head of the Department of General Medical Oncology at the University Hospitals and the Laboratory of Experimental Oncology at the Catholic University in Leuven (KU Leuven), and Principal investigator of the ADCElerate-01 trial, commented: "Patients with metastatic soft tissue sarcoma have very limited treatment options and an extremely poor prognosis. We are intrigued by the biology and expression profile of uPARAP, as well as the extensive pre-clinical data package generated for ADCE-D01. ADCs have already significantly altered the therapeutic landscape for many solid tumor indications, and we are excited to be working with Adcendo to develop a potential pan-sarcoma ADC for our STS patients."

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About ADCE-D01:

ADCE-D01 is an antibody-drug conjugate targeting the uPARAP receptor. uPARAP is a recycling endocytic receptor involved in collagen homeostasis and turnover. uPARAP exhibits a limited expression profile in healthy tissues but is highly upregulated in multiple mesenchymal cancers, including soft tissue sarcoma, bone sarcoma, GIST as well as mesothelioma and glioblastoma, making it a highly attractive target for ADC development.

About Adcendo ApS:

Adcendo ApS is developing breakthrough antibody-drug conjugates for the treatment of underserved cancers. In 2024, the company completed a Series A extension financing round, increasing the total funds raised to 98M EUR to advance, broaden, and accelerate the development of its first-in-class ADC pipeline assets. Investors include Novo Holdings, Ysios Capital, Pontifax Venture Capital, RA Capital Management, HealthCap, Gilde Healthcare and Dawn Biopharma, a platform controlled by KKR. For further information, please visit www.adcendo.com.