# Adcendo ApS Announces Phase 1 Clinical Data Showing Compelling Safety & Antitumor Activity with ADCE-D01 in Advanced Soft Tissue Sarcoma in Late-Breaking Oral Presentation at 2026 EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics

*30% objective response rate and an 85% disease control rate on every 2-week (Q2W) schedule; all responses ongoing at data cut-off*

*Favorable safety and tolerability profile with very few patients needing dose reduction and no discontinuation for side effects on Q2W schedule*

*Disease control and objective responses observed across a broad range of soft tissue sarcoma subtypes*

**Copenhagen, Denmark, November 19, 2026** – Adcendo ApS ("Adcendo"), a biotech company focused on the development of differentiated antibody-drug conjugates (ADCs) for cancers with high unmet medical need, today announced initial data from the ongoing Phase 1 ADCElerate1 trial evaluating ADCE-D01, a first-in-class ADC against the novel target uPARAP, in patients with advanced soft tissue sarcoma (STS). The data were highlighted in a late-breaking oral presentation during the plenary session on clinical trials at the 38th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics (ENA 2026), taking place November 18-20 in Barcelona, Spain.

**Prof. Dr. Patrick Schöffski, MPH, Head of the Department of General Medical Oncology at the University Hospitals Leuven, Professor in the Department of Oncology at KU Leuven, Belgium, and principal investigator of the ADCElerate1 trial, commented:** "Advanced soft tissue sarcoma remains one of our most challenging clinical areas, where historic second-line options routinely yield response rates of only 4 – 10%. The observed 30% objective response rate and high disease control rate seen with ADCE-D01 could mark an important shift, offering a desperately needed novel therapy across STS subtypes for patients who have exhausted standard therapies."

**Dr. Lone H. Ottesen MD, PhD, Chief Medical Officer of Adcendo, said:** "We are extremely pleased to share the first clinical data for ADCE-D01 at ENA which demonstrate encouraging antitumor activity and disease control across multiple STS subtypes in a population with substantial unmet medical need. We believe these data point to ADCE-D01's transformative treatment potential, while also validating Adcendo's target biology and indication-driven approach to developing a pipeline of highly effective and well tolerated ADCs. Together with world leading sarcoma centers in the US and Europe, we continue to enroll patients in the ADCElerate1 study as we work to further explore ADCE-D01's potential and define the development path."

**ADCE-D01 Demonstrates Compelling Antitumor Activity Across Multiple STS Subtypes**

Among the 27 response-evaluable patients representing 12 different STS subtypes who received ADCE-D01 every 2 weeks (Q2W), 8 patients had a partial response (PR) for an objective response rate of 30%

(5 confirmed, 3 currently unconfirmed), and the disease control rate was 85% (23/27). A trend towards improved efficacy at higher dose levels was observed. Median follow-up was 3.4 months, and the median duration of response had not yet been reached. At data cutoff, all responses were ongoing and 81% (22/27) of evaluable patients remained on treatment.

**ADCE-D01 Demonstrates Manageable Safety and Tolerability**

47 adults with advanced STS including 17 different subtypes, who had received prior systemic treatment including chemotherapy and targeted agents (a median of two prior lines of therapy [range 1-4]) were enrolled into the study. The first 18 patients received ADCE-D01 on a weekly dosing schedule at a dose of 0.5–3.4 mg/kg. After establishing that dosing Q2W was more suitable due to the pharmacokinetics observed on the weekly dosing schedule, the next 29 patients were dosed at 3.4-5.5 mg/kg Q2W. All patients receiving more than 3.4 mg/kg were also given prophylactic treatment with granulocyte colony-stimulating factor (G-CSF).

The most common treatment-related side effects on the Q2W schedule were low-grade nausea (59%), infusion related reactions (41%), tiredness (38%), and hair loss (35%). The most common hematological side effect was neutropenia (31%). On the Q2W schedule, side effects led to a dose reduction in 10% of patients, and no patients needed to discontinue treatment for side effects. With prophylactic G-CSF, severe (grade 3 or higher) neutropenia occurred in 14% (3/22) of patients, compared with 43% (3/7) of patients without prophylactic G-CSF, even though the patients given G-CSF were receiving higher doses. The maximum tolerated dose (MTD) for the Q2W regimen has not yet been reached. No cases of interstitial lung disease, febrile neutropenia or stomatitis were observed.

Recruitment on the Q2W schedule is ongoing. ADCE-D01 has received Fast Track and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of STS.

**Oral Presentation Details:**

**Title:** A novel antibody-drug conjugate targeting urokinase plasminogen activator receptor-associated protein in previously treated patients with advanced soft tissue sarcoma: emerging clinical results from the phase 1 ADCElerate1 study (NCT06797999)
**Presenter:** Dr. Patrick Schöffski, University Hospitals Leuven and KU Leuven, Belgium
**Session:** Plenary Session 3 – Proffered Papers: Clinical Trials
**Abstract number:** 4LBA (ENA26-0411)
**Date and time:** Thursday, November 19, 2026, at 10:00 a.m. CET / 4:00 a.m. ET

Following the conclusion of the presentation at the meeting, a copy of the oral presentation will be available on the Key Publications page of the Company's website at www.adcendo.com.

**About the ADCElerate1 Trial**

ADCElerate1 (NCT06797999) is a first-in-human Phase I/II multicenter, open-label, dose escalation and expansion study evaluating 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. The secondary objectives are to characterize the pharmacokinetic profile and to evaluate the preliminary efficacy of ADCE-D01. The study is recruiting in the US and Europe.

**About ADCE-D01**

ADCE-D01 is a novel ADC targeting uPARAP, an endocytic receptor overexpressed in a wide spectrum of cancers of mesenchymal origin, including soft tissue sarcoma (STS), osteosarcoma, GIST, mesothelioma, and glioblastoma.

uPARAP is an attractive ADC target due to its rapid internalization driven by constitutive target recycling, as well as its highly differentiated expression profile between tumor and healthy tissues. ADCE-D01 combines a novel uPARAP binding antibody designed to avoid interference with the natural receptor ligand, collagen, with a clinically validated protease-cleavable linker and potent deruxtecan payload. Preclinical studies have demonstrated strong anti-tumor activity across a range of in vivo models, as well as a highly encouraging toxicology profile, positioning ADCE-D01 as a promising treatment candidate for patients with STS and other cancers of mesenchymal origin, with the potential to deliver meaningful clinical benefit.

ADCE-D01 received Fast Track Designation and Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration (FDA) for the treatment of soft tissue sarcoma.

**About Soft Tissue Sarcoma**

Soft tissue sarcomas are rare and highly heterogeneous cancers comprising more than 100 different tumor subtypes, with an estimated incidence of 4-5 cases per 100,000 people annually in Europe and ~3.5 new diagnoses per 100,000 people in the United States each year.[1, 2]

**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 differentiated antibody-drug conjugates (ADCs) for cancers with high unmet medical need using a disease- and target-driven approach, focused on balancing efficacy and tolerability. Led by a team of experienced biopharma executives with a track record of advancing multiple ADCs to approval, Adcendo integrates deep ADC expertise into target and disease biology, with research, clinical and commercial insight to drive next-generation cancer therapies. Adcendo is currently advancing three clinical-stage ADC programs in indications of high unmet need, such as soft tissue sarcoma, squamous cell cancers, pancreatic ductal adenocarcinoma, and other solid tumors. For further information, please visit www.adcendo.com or follow us on LinkedIn.

**References**

1. Gronchi A, et al. Ann Oncol. 2021;32(11):1348-1365. doi:10.1016/j.annonc.2021.07.006.
2. National Cancer Institute SEER Program. 2026 Estimates. Accessed November 2, 2026.

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