

Adcendo ApS Announces FDA Fast Track Designation Granted to ADCE-D01 for the Treatment of Soft Tissue Sarcoma

- *ADCE-D01 is a first-in-class antibody-drug conjugate targeting uPARAP, an endocytic receptor highly overexpressed in mesenchymal cancers including multiple soft tissue sarcoma subtypes*
- *Fast Track designation underscores the potential for ADCE-D01 to address the high unmet clinical need in soft tissue sarcoma*

COPENHAGEN, Denmark, Oct. 9, 2025 /PRNewswire/ -- Adcendo ApS ("Adcendo"), a biotech company focused on the development of first and best-in-class antibody-drug conjugates (ADCs) for the treatment of cancers with high unmet medical need, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ADCE-D01 for the treatment of soft tissue sarcoma (STS).

ADCE-D01 is a first-in-class ADC targeting urokinase plasminogen activator receptor-associated protein (uPARAP) conjugated to the Topoisomerase I inhibitor payload P1021. uPARAP is a novel endocytic ADC target that is overexpressed in tumors of mesenchymal origin, such as sarcomas. Preclinically, ADCE-D01 shows strong anti-tumor activity in a range of mesenchymal tumor models including STS and is well tolerated in non-human primate toxicology studies with a favorable safety profile and no evidence of target-specific toxicity.

ADCE-D01 is currently being evaluated in the ADCElerate1 clinical trial, 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 pharmacokinetics and to evaluate the preliminary efficacy of ADCE-D01. The study is recruiting in the US ([NCT06797999](https://clinicaltrials.gov/ct2/show/study/NCT06797999)) and in Europe. (EUCT number: [2024-516900-41-00](https://eudract.europa.eu/eudract/index.html?view=summary&document=2024-516900-41-00)).

Dr. Lone Ottesen, Chief Medical Officer of Adcendo, said: "This Fast Track designation is an important recognition of the potential of our uPARAP-targeting drug candidate and marks another meaningful milestone for Adcendo. We are committed to further advancing ADCE-D01 and believe that our uPARAP-targeting approach has the potential to transform the sarcoma treatment landscape and overcome the limitations experienced with existing therapies."

Dr. Victoria Marsh, Global Head of Regulatory at Adcendo, said: "With this Fast Track designation the development of ADCE-D01 will now benefit from more frequent interactions with the FDA. Increased FDA engagement will support and expedite the future regulatory review of ADCE-D01 with the aim of making ADCE-D01 available to patients sooner".

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- and potential best-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 us on [LinkedIn](#).

About Fast Track

Fast Track is an FDA process designed to facilitate the development and expedite the review of potential therapies that seek to treat serious conditions and fill an unmet medical need. A drug candidate that receives Fast Track designation is afforded greater access to the FDA for the purpose of expediting the drug's development, review and potential approval. Additionally, the designation allows for eligibility for Accelerated Approval and Priority Review, if relevant criteria are met, as well as a Rolling Review, which means a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be submitted for review.

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