

First patient enrolled in Phase 1 clinical trial of Akiram's cancer drug candidate AKIR001

Akiram Therapeutics, a Swedish biotech company specializing in targeted radiotherapy, today announces that the first patient has been enrolled in the Phase 1 clinical trial of its drug candidate ^{177}Lu -AKIR001. The trial is being conducted at Karolinska University Hospital, which also acts as the study sponsor, and marks an important milestone in Akiram's efforts to develop a new targeted treatment for difficult-to-treat cancers.



This is the first-in-human trial with AKIR001 and aims to evaluate the drug's safety, tolerability, and pharmacokinetic profile. The trial follows a dose-escalation design and targets patients with advanced, difficult-to-treat tumors.

Akiram's drug candidate ^{177}Lu -AKIR001 is a targeted radiopharmaceutical that combines an antibody directed against CD44v6—a cancer marker associated with several aggressive tumor types—with the therapeutic radioisotope lutetium-177. Through this mechanism, radiation can be delivered directly to tumor cells while minimizing damage to surrounding healthy tissue.

The trial is enrolling patients with anaplastic and iodine-refractory thyroid cancer, head and neck squamous cell carcinoma, gynecological squamous cell carcinoma, and non-small cell lung cancer. It is expected to run for 18–24 months with patients recruited on a rolling basis. As the sponsor, Karolinska University Hospital is responsible for conducting the trial in accordance with applicable regulations and with patient safety as a top priority.

“The launch of the clinical trial with AKIR001 marks the beginning of a new chapter for Akiram. Our vision has always been to develop a treatment that can offer new opportunities for patients with difficult-to-treat cancers, where treatment options are often limited. Seeing our drug

candidate now being evaluated in collaboration with Karolinska University Hospital—one of Europe’s leading cancer centers—is a major milestone and a strong motivator for our continued work,” says Marika Nestor, CEO of Akiram Therapeutics.

“The enrollment of the first patient means that we have now initiated dose escalation and systematic evaluation of AKIR001’s safety and potential. This is an important first step in understanding how the drug behaves clinically and the potential role a CD44v6-targeted therapy could play in tumor types where treatment options today remain limited,” says Dr. Luigi De Petris, Principal Investigator at Karolinska University Hospital.

The trial is registered at [ClinicalTrials.gov: NCT06639191](https://clinicaltrials.gov/ct2/show/study/NCT06639191).

About Akiram’s drug candidate

Developed through antibody phage display and affinity maturation targeting the CD44v6 cancer marker, ¹⁷⁷Lu-AKIR001 combines the radiation component lutetium-177 with a targeted molecule. Preclinical studies have demonstrated its potential as a promising, first-in-class radiopharmaceutical therapy for cancers with high CD44v6 expression.

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About Akiram Therapeutics

Akiram Therapeutics is a Swedish biotechnology company in clinical phase, developing innovative targeted radiation therapy for cancer. The therapy is based on a proprietary antibody that targets a radiation component to the cancer marker CD44v6. The drug candidate has demonstrated promising preclinical results in cancer types where effective treatments are currently lacking, and the company sees potential to achieve first-in-class status and orphan drug designation. Akiram is dedicated to advancing research in molecular radiotherapy, with a focus on head and neck cancer, lung cancer, and aggressive thyroid cancer. Headquartered in Uppsala, Sweden, the team comprises experts in radiation research, precision oncology, and drug development. For more information, visit Akiram’s [website](#) and follow the company on [LinkedIn](#).