



Akiram Therapeutics: AKIR001 advances to cohort 3 in Phase I trial

Akiram Therapeutics, a Swedish biotech company specializing in targeted radiotherapy, announces that cohort 2b in the ongoing Phase I clinical trial evaluating the drug candidate ^{177}Lu -AKIR001 has been completed. Following the safety review, the study has advanced to cohort 3. The results continue to support a favorable safety profile, enabling further dose escalation and evaluation of higher activity levels according to the study protocol.



The trial is conducted at Karolinska University Hospital, which also serves as the study sponsor, and is designed to evaluate the safety, tolerability, and pharmacokinetic profile of the drug candidate.

In cohort 2b, the protein dose was evaluated while maintaining the same activity level as in the previous cohort. Following review of the cohort 2b data, the Safety Review Committee approved continued dose escalation, allowing the study to proceed to cohort 3.

Across the cohorts evaluated to date, no dose-limiting toxicities have been observed, and imaging data have demonstrated selective tumor uptake and accumulation in tumor tissue in treated patients. Several patients have also received repeat treatment based on medical assessment, further supporting the tolerability, manageability, and feasibility of repeated administration. Taken together, the findings support continued clinical evaluation in the ongoing trial.

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 selectively to tumor cells while minimizing exposure to healthy tissue.

“Advancing to cohort 3 marks an important step in our clinical development program. The results support further evaluation of dose levels, and the next stage will be central to further defining dosing parameters and treatment characteristics ahead of future stages of development,” says Marika Nestor, CEO of Akiram Therapeutics.

“The decision to proceed to cohort 3 follows a thorough safety evaluation. We look forward to continuing the study and collecting additional clinical data,” says Dr. Luigi De Petris, Principal Investigator at Karolinska University Hospital.

The trial enrolls patients with CD44v6-positive solid tumors who currently lack available treatment options.

The project is the result of a successful national collaboration between leading clinical and academic institutions in precision oncology and has been supported by the Swedish Cancer Society, the Sjöberg Foundation, the Erling-Persson Foundation, the Swedish Research Council, and Vinnova, Sweden’s Innovation Agency.

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

About Akiram’s drug candidate AKIR001

Developed through antibody phage display and affinity maturation targeting the cancer marker CD44v6, ¹⁷⁷Lu-AKIR001 combines a CD44v6-directed antibody with the therapeutic radioisotope lutetium-177. Preclinical studies have demonstrated high tumor specificity, favorable dosimetry, and antitumor activity in CD44v6-expressing xenograft models.

For more information, please contact:

Marika Nestor, CEO

Email: marika.nestor@akiramtherapeutics.com

About Akiram Therapeutics

Akiram Therapeutics is a Swedish clinical-stage biotechnology company developing innovative targeted radiation therapy for cancer. The therapy is based on a proprietary antibody targeting the cancer marker CD44v6, linked to a radiation component. 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](#).