Akiram: Clinical Phase I clinical trial with AKIR001 progresses to next step following completion of first cohort

Akiram Therapeutics, a Swedish biotech company specializing in targeted radiotherapy, announces the completion of the first cohort in the clinical Phase I trial evaluating the drug candidate 177Lu-AKIR001. No safety signals have been observed, and the trial is now proceeding to the next stage as planned.

The trial is being conducted at Karolinska University Hospital, which also serves as the study sponsor. The aim is to evaluate safety, tolerability, and pharmacokinetics in patients with advanced, difficult-to-treat solid 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 impact on surrounding healthy tissue.

All patients planned for the first dose cohort have now been enrolled. No dose-limiting toxicities or other safety concerns have been observed.

"Completing the first cohort marks an important milestone for AKIR001. Our goal is to develop a treatment that reaches tumors with high selectivity and has a favorable safety profile. These initial clinical data support the next step in development," says Marika Nestor, CEO of Akiram Therapeutics.

"The completion of cohort 1 without unexpected side effects represents an important step forward. The results suggest that the drug is well tolerated at the doses tested so far, and we are pleased to proceed as planned," says Dr. Luigi De Petris, Principal Investigator at Karolinska University Hospital.

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. In the next phase, additional patients will be included to gather further data on dose response, safety, and early signs of efficacy.

The study is the result of a successful national collaboration between leading clinical and academic institutions in the field of precision oncology. The project is 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.

About Akiram's drug candidate
Developed through antibody phage display and affinity maturation targeting the CD44v6 cancer marker, ^{177}Lu-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 tumor types with high CD44v6 expression.

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About Akiram Therapeutics
Akiram Therapeutics is a Swedish biotech company focused on the development of targeted radioimmunotherapy for cancer, which is based on a proprietary antibody targeting the cancer marker CD44v6 combined with a radiation component. The therapy has generated strong preclinical results in cancer models in conditions that currently lack effective treatments. With the potential for its drug candidate to be classified as an orphan drug and recognized as first-in-class, the company is dedicated to advancing research in this field, including indications in head and neck cancer, lung cancer, and aggressive thyroid cancer. Headquartered in Uppsala, Sweden, Akiram Therapeutics is staffed with experts in radiation science research, cancer precision medicine, and drug development. To learn more, please visit Akiram's website and follow Akiram on LinkedIn.