Akiram Therapeutics: Cohort 2a completed and cohort 2b cleared to start in Phase I trial of AKIR001

Akiram Therapeutics, a Swedish biotech company specializing in targeted radiotherapy, announces the completion of cohort 2a in the clinical Phase I trial evaluating the drug candidate ^{177}Lu-AKIR001. Cohort 2a investigated a higher activity dose than the run-in cohort. The results aligned with earlier findings, demonstrating continued favorable safety and encouraging tumor uptake.

The trial is conducted at Karolinska University Hospital, which also serves as the study sponsor. The purpose of the study is to assess safety, tolerability, and pharmacokinetics in patients with advanced, difficult-to-treat solid tumors.

Akiram's drug candidate ^{177}Lu-AKIR001 is a targeted radiopharmaceutical combining a CD44v6-directed antibody with the therapeutic radioisotope lutetium-177. This mechanism enables selective and precise delivery of radiation to tumor cells while limiting exposure to healthy tissue.

All patients planned for cohort 2a have now been enrolled, and no dose-limiting toxicities or other safety concerns have been observed. Following review of the cohort 2a data, the Safety Review Committee has approved initiation of cohort 2b. In this next step of the dose-escalation stage, the protein dose will be increased while maintaining the same activity level used in cohort 2a. Cohort 2b aims to identify the most favorable protein dose for the remaining cohorts in the Phase I trial and for further clinical development of AKIR001.

"Completing cohort 2a marks solid and steady progress in our dose-escalation strategy," says Marika Nestor, CEO of Akiram Therapeutics. "The consistency of the safety profile together

with encouraging tumor uptake provides confidence as the study advances into the next step of the dose-escalation stage and confirms that development remains on track. Protein-dose optimization is central to preparing for subsequent stages of evaluation."

"Following a thorough safety assessment, we are pleased to now proceed to cohort 2b," says Dr. Luigi De Petris, Principal Investigator at Karolinska University Hospital.

The trial enrolls patients with anaplastic and iodine-refractory thyroid cancer, head and neck squamous cell carcinoma, gynecological squamous cell carcinoma, and non-small cell lung cancer.

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

About Akiram's drug candidate AKIR001
Developed through antibody phage display and affinity maturation targeting the cancer marker CD44v6, ^{177}Lu-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 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.