

Precirix Submits Investigational New Drug (IND) Application to FDA for CAM-FAP-Ac-225, a Novel Radiopharmaceutical Targeting Fibroblast Activation Protein (FAP)

Brussels, Belgium, 24th June 2025 — Precirix, a clinical-stage biotechnology company focused on developing targeted radiopharmaceutical therapies, today announced the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for **CAM-FAP-Ac-225**, a novel targeted alpha therapy (TAT) designed to treat FAP-expressing solid tumors.

CAM-FAP-Ac-225 is a best-in-class radiopharmaceutical that combines a fibroblast activation protein (FAP)-targeting single domain antibody targeting vector, with the potent alpha-emitting isotope Actinium-225. FAP is highly expressed in cancer-associated fibroblasts (CAFs) across a broad range of epithelial tumors, making it a promising target for broad therapeutic application.

“This IND submission marks a major milestone for Precirix and our mission to develop innovative and highly targeted cancer therapies” said Tom Plitz, Chief Executive Officer of Precirix. “We are excited to advance CAM-FAP-Ac-225 into clinical development and believe that it has potential to set a new standard for FAP-directed radiopharmaceuticals”.

Following FDA clearance, the company plans to initiate a Phase 1 clinical trial to evaluate the safety, tolerability, dosimetry, and preliminary efficacy of CAM-FAP-Ac-225 in patients with advanced solid tumors known to express FAP.

About CAM-FAP-Ac-225

CAM-FAP-Ac-225 is an investigational targeted alpha therapy that delivers Actinium-225 directly to the tumor microenvironment via a FAP-targeting ligand. The alpha particles emitted by Ac-225 have high linear energy transfer (LET), enabling potent and localized cytotoxicity with minimal off-target effects.

About Precirix

Precirix is a private biopharmaceutical company dedicated to extending and improving the lives of cancer patients by designing and developing precision radiopharmaceuticals, using camelid single domain antibodies (sdAb) labelled with a variety of radioisotopes.

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