PRECIRIX®

PRESS RELEASE
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FOR IMMEDIATE RELEASE

Precirix Announces FDA Acceptance of Investigational New Drug (IND) Application for CAM-FAP-Ac-225

Brussels, Belgium, 24th July 2025 — Precirix, a clinical-stage biopharmaceutical company focused on developing innovative targeted radiopharmaceutical therapies, today announced that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug (IND) application for CAM-FAP-Ac-225. This clearance enables Precirix to initiate a Phase 1 clinical trial in patients with FAP-positive tumors.

CAM-FAP-Ac-225 is a best-in-class radiopharmaceutical that combines a fibroblast activation protein (FAP)-targeting single domain antibody 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.

“The FDA’s acceptance of the IND for our CAM-FAP-Ac-225 targeted radiotherapy program marks an extraordinary milestone for Precirix and is a testament to the dedication and scientific excellence of our entire team. The clearance to start our Phase 1 study represents not only the beginning of clinical development for a potentially transformative therapy, but also a major step forward in our mission to deliver precision treatment options to patients with high unmet medical needs. We are incredibly proud of this achievement and energized by the path ahead.” said Tom Plitz, Chief Executive Officer of Precirix.

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 Actinium-225 exhibit 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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