

Full-Life Technologies Announces Clearance from FDA of IND Application for $^{225}\text{Ac-FL-020}$ for the Treatment of Metastatic Castration-Resistant Prostate Cancer

Heidelberg, Germany – May 30, 2024 – Full-Life Technologies (Full-Life), a fully integrated global radiotherapeutics company, today announced it has received clearance of its Investigational New Drug (IND) Application from the U.S. Food and Drug Administration (FDA) for clinical trials of $^{225}\text{Ac-FL-020}$, its PSMA-targeted radiopharmaceutical for the treatment of metastatic castration-resistant prostate cancer (mCRPC). The company plans to begin clinical studies in the U.S. and globally in 2024.

$^{225}\text{Ac-FL-020}$ employs targeted alpha-radiotherapy designed to selectively attack cancer cells, reducing the damage to healthy tissues. In preclinical models, radiolabeled FL-020 displayed a very promising in vivo biodistribution profile, with high and sustained tumor uptake and fast systemic clearance. $^{225}\text{Ac-FL-020}$ exhibited robust anti-tumor activity in LNCaP xenograft mice, with a favorable safety profile. The upcoming Phase I clinical trial will evaluate the safety, tolerability, and anti-tumor activity of $^{225}\text{Ac-FL-020}$, and will lay the groundwork for further clinical development, aiming to establish $^{225}\text{Ac-FL-020}$ as a valuable therapeutic option for patients with mCRPC.

“The IND application clearance is a significant regulatory milestone in our development plan for $^{225}\text{Ac-FL-020}$ ”, said Steffen Heeger, M.D., M.Sc., Chief Medical Officer of Full-Life. “This important step underscores our overall commitment to the therapeutic potential of radiopharmaceuticals and once again highlights the value of the team’s effort, dedication, and cross-functional collaboration. We are excited to initiate the Phase I clinical program, which provides the first opportunity to gather human data on $^{225}\text{Ac-FL-020}$ ’s safety and anti-tumor activity.”

About $^{225}\text{Ac-FL-020}$

$^{225}\text{Ac-FL-020}$ is a novel, potential best-in-class, next-generation PSMA-targeting radionuclide drug conjugate (RDC) that will enter global Ph1 clinical studies in 2024. Its targeting vector, FL-020, was discovered using Full-Life’s proprietary UniRDC™ platform, which enables significant improvement of drug uptake in the tumor while maintaining fast systemic clearance. In pre-clinical models, $^{225}\text{Ac-FL-020}$ has demonstrated potent anti-tumor activity and a favorable safety profile.

About Full-Life Technologies

Full-Life Technologies (“Full-Life”) is a fully integrated global radiotherapeutics company with operations in Belgium, Germany, and China. We aim to own the entire value chain for radiopharmaceutical research & development, production & commercialization in order to deliver clinical impact for patients. The Company plans to attack core issues affecting radiopharmaceuticals today through innovative research that targets the treatments of tomorrow. We are comprised of a team of fast-moving entrepreneurs and scientists with a demonstrated track record in the life sciences, as well as radioisotope research and clinical development.

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