# Full-Life Technologies' Partner SK Biopharmaceuticals Secures FDA IND Approval for Alpha-Emitter Radiopharmaceuticals Drug Candidate Accelerating Global Clinical Development

- Full-Life Technologies' partner SK Biopharmaceuticals receives U.S. FDA approval for a Phase 1 Investigational New Drug (IND) application for an alpha-emitter-based radiopharmaceutical therapy
- SK Biopharmaceuticals accelerates its next-generation oncology strategy and takes its first step as a global radiopharmaceutical therapy player
- Global clinical development proceeds based on FDA IND approval, alongside sequential IND submission to Korea's Ministry of Food and Drug Safety (MFDS)
- Full-Life Technologies entered into an exclusive global licensing agreement with SK Biopharmaceuticals in July 2024 for its radiopharmaceutical compound FL-091 (now SKL35501), a transaction valued at up to $571.5 million

**Chengdu, China – January 12, 2026** – Full-Life Technologies ("Full-Life"), a fully-integrated global radiopharmaceutical company today congratulates its partner SK Biopharmaceuticals Co., Ltd. ("SK Biopharmaceuticals") on receiving the U.S. Food and Drug Administration ("FDA") approval of the Phase 1 Investigational New Drug ("IND") for its radiopharmaceutical therapeutic candidate SKL35501 and imaging agent SKL35502. The therapeutic candidate SKL35501 was in-licensed by SK Biopharmaceuticals from Full-Life in July 2024. The imaging agent SKL35502 utilizes the same NTSR1 target as SKL35501.

With this FDA IND approval, SK Biopharmaceuticals enters the global clinical development stage for its alpha-emitter[1]-based radiopharmaceutical therapy pipeline. The program advances to clinical development approximately 18 months after in-licensing, marking execution of SK Biopharmaceuticals' radiopharmaceutical therapy development strategy.

This FDA IND approval for SK Biopharmaceuticals marks a significant validation of Full-Life's proprietary UniRDC™ discovery platform and Full-Life's strategy of selectively partnering with global pharmaceutical and biopharmaceutical companies on innovative assets to advance global cancer care. The progression of SKL35501 and SKL35502 to clinical development approximately 18 months after licensing demonstrates the efficiency and translational potential of Full-Life's R&D engine.

Based on FDA IND approval, SK Biopharmaceuticals initiates global clinical development with a primary focus on the United States. In parallel, SK Biopharmaceuticals submits the same IND dossier to Korea's Ministry of Food and Drug Safety and proceeds with regulatory review. Clinical development is conducted concurrently in the U.S. and Korea to accelerate next-generation oncology radiopharmaceutical therapy development.

The Phase 1 study enrolls patients with advanced solid tumors expressing NTSR1 (Neurotensin Receptor 1)[2]. The trial is designed as a first-in-human, open-label,

1. A radioactive isotope that releases high energy over a short distance to directly damage cancer cell DNA. Due t o its short radiation range, it has the characteristic of relatively reducing local tissue damage. (In contrast, beta-e mitters have a relatively longer radiation range, which carries a higher potential for exposure to a wider area.)
2. A receptor protein that is expressed at elevated levels across multiple types of solid tumors.

multicenter study in the United States and Korea. Eligible patients include those who have failed or relapsed after standard treatment options. The study initiates with dose escalation to evaluate safety and biologically active dose range, followed by dose optimization and expansion according to the clinical protocol.

SKL35501 is an alpha-emitter-based radiopharmaceutical therapy designed to increase targeting precision within tumor tissue through high binding affinity for NTSR1. The candidate delivers high-energy alpha particles emitted from actinium-225 ($^{225}$Ac) to refractory and treatment-resistant cancer cells. Utilizing the characteristic of alpha emitters to release high energy over a short distance, it is expected to achieve high cell-killing effects while minimizing local tissue damage.

SK Biopharmaceuticals applies a theranostics[3] clinical strategy using imaging agent SKL35502 to identify patients with NTSR1-expressing tumors prior to treatment with SKL35501. The strategy enables early and precise assessment of treatment response and supports stepwise validation of companion diagnostic-based personalized therapy.

SK Biopharmaceuticals entered the radiopharmaceutical therapy field in July 2024 through in-licensing from Full-Life. Under the terms of the exclusive worldwide license agreement announced in July 2024, SK Biopharmaceuticals secured rights to clinical research, development, manufacturing, and commercialization of Full-Life's FL-091 program (now SKL35501/SKL35502) targeting NTSR1-positive cancers. The agreement, with a total value of **$571.5 million**, includes an upfront payment, development and commercial milestones, and royalties. SK Biopharmaceuticals also obtained a right of first negotiation for other selected RDC programs from Full-Life.

**About SKL35501**
SKL35501 is an alpha-emitter-based radiopharmaceutical therapy targeting NTSR1. The candidate selectively binds to NTSR1-expressing tumor lesions and induces DNA damage and tumor cell death through high-energy alpha particles emitted from actinium-225 ($^{225}$Ac). The short radiation path length supports selective antitumor effects.

**About SKL35502**
SKL35502 is a radiopharmaceutical imaging agent utilizing the same NTSR1 target as SKL35501. Labeled with indium-111 ($^{111}$In), the agent enables visualization and quantitative assessment of NTSR1-expressing tumors via single-photon emission computed tomography (SPECT). The agent is developed as a companion diagnostic within a theranostics pipeline.

**About Full-Life Technologies**
**Full-Life Technologies** ("Full-Life") is a fully-integrated clinical-stage global radiotherapeutics company with operations in Belgium, Germany, and China. We aim to own the entire value chain for radiopharmaceutical research & development, production & commercialization to deliver clinical impact for patients. The Company endeavors to tackle fundamental challenges affecting radiopharmaceuticals today by pioneering innovative research that will shape the treatments of tomorrow. We are comprised of a

3. A portmanteau of therapy and diagnostics, referring to an integrated approach that uses a single target or me chanism to enable both disease diagnosis and treatment.

team of fast-moving entrepreneurs and seasoned scientists with a proven history of success in the life sciences, alongside radioisotope research and clinical development.

**About SK Biopharmaceuticals Co., Ltd. and SK Life Science, Inc.**
**SK Biopharmaceuticals Co., Ltd.** is part of **SK Group**, South Korea's second-largest conglomerate. SK Group is a collection of global industry-leading companies driving innovations in energy, advanced materials, biopharmaceuticals and digital business. Based in Seoul, SK invests in building sustainable businesses around the world with a shared commitment to reducing global greenhouse gas emissions. SK companies combined have $151 billion in global annual revenue and employ more than 100,000 people worldwide. SK Group is one of TIME's 100 Most Influential Companies of 2023. **SK Inc.**, the parent company of SK Biopharmaceuticals, continues to enhance its portfolio value by executing long-term investments with a number of competitive subsidiaries in various business areas, including pharmaceuticals and life science, energy and chemicals, information and telecommunication, and semiconductors. In addition, SK Inc. is focused on reinforcing its growth foundations through profitable and practical management based on financial stability, while raising its enterprise value by investing in new future growth businesses. For more information about SK Inc., visit https://sk-inc.com/en/main/mainpage.aspx. For more information about SK Biopharmaceuticals, visit www.skbp.com/eng.

**SK Life Science, Inc.**, with headquarters in Paramus, New Jersey, is a U.S. subsidiary of **SK Biopharmaceuticals Co., Ltd.**, a pioneering South Korean biopharmaceutical company in drug development and commercialization. Together, they are advancing innovative treatments for central nervous system (CNS) disorders and oncology, with eight compounds currently in development. Utilizing target-based drug discovery, high-throughput organic screening/high content screening, computer-aided drug design, and combinatorial chemistry, the companies drive R&D efforts in biology/discovery, medicinal chemistry, pharmacology, and clinical development. For more information, visit www.SKLifeScienceInc.com.

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