

Press Release

Sanofi and Orano join forces to develop next-generation radioligand medicines

Paris, October 17, 2024. Sanofi and Orano Med, a subsidiary of the Orano Group and a pioneer in the development of targeted alphatherapies in oncology, have entered into an agreement to combine their expertise in the fight against rare cancers and further accelerate the development of next-generation radioligand medicines.

Building on the expertise and radioligand pipeline of Orano Med, Sanofi and Orano will invest in a new entity, operating under the Orano Med brand, and focusing on the discovery, design, and clinical development of next-generation radioligand therapies (RLTs) based on lead-212 (²¹²Pb) alpha-emitting isotopes. This agreement follows Sanofi's announcement of an exclusive licensing agreement with Orano Med and RadioMedix to advance RLTs in rare cancers with a focus on one late-stage project, AlphaMedix™.

Targeted alpha therapy relies on a simple concept: combining the ability of biological vectors to target cancer cells with the short-range and highly energetic cell-killing capabilities of alpha-emitting radioisotopes. The vector directs the radioisotope to the target cancer cells expressing the specific marker, even when they have spread throughout the body. This unique mechanism of action aims to damage or destroy target cancer cells, while limiting impact on nearby healthy cells. This novel precision medicine approach aims at changing the standard of care in some rare cancers to extend patients' lives and improve their quality of life.

Paul Hudson

CEO, Sanofi

"We are excited to partner with Orano in establishing a French pioneer that unites our respective expertise in biopharma and nuclear technology to drive groundbreaking progress in the fight against cancer. As a French biopharmaceutical company, we are deeply committed to fostering and enabling innovation in our home country. This collaboration is part of a broader effort to strengthen our ties within the scientific community, both in France and globally, with the goal of advancing the development of cutting-edge treatments for patients."

Nicolas Maes

CEO, Orano Group

"The success of Orano Med is an example of our group's ability to diversify beyond our core nuclear business. By applying our expertise in nuclear materials to fields like targeted alpha therapies, we are demonstrating that nuclear technology can have a positive societal impact, not just for energy and climate, but also for human health. This innovation reflects Orano's commitment to exploring new opportunities and taking bold steps to address some of the world's most pressing challenges."

Sanofi's investment will further strengthen Orano Med and allow the company to accelerate the development of its pipeline, leveraging its unique capabilities in the discovery and development of lead-212 based therapies. Orano Med has also developed a highly differentiating global industrial platform, which, thanks to its vast stock of raw materials and patented manufacturing process, will ensure an independent, reliable, and scalable supply of lead-212 based therapies to patients worldwide.

Houman Ashraffian

Executive Vice President, Head of Research and Development, Sanofi

"We are thrilled to invest in the promising field of radioligand therapies, a modality that holds potential for patients suffering from rare cancers. We see opportunity in the innovative lead-212 based technologies being developed by Orano Med, which align with our commitment to advancing transformative therapies for unmet medical needs."

Julien Dodet

President of the Governing Board, Orano Med

"Sanofi's partnership with Orano Med is a strong recognition of the potential of lead-212 based radioligand therapies to advance the treatment of cancers. This validates our strategy, having developed this expertise over the past 15 years, and reinforces our position as a leader in targeted alpha therapies. We look forward to combining Sanofi's expertise with our R&D and world-class radiopharmaceutical capabilities to advance the development of potentially transformative therapies like AlphaMedix and make them available to patients in need as quickly as possible."

In striving to become a leading immunoscience company globally, Sanofi remains committed to advancing oncology innovation. The pipeline is being reshaped and prioritized, leveraging expertise in immunoscience to drive progress. Efforts are centered on difficult-to-treat cancers such as select hematologic malignancies and solid tumors with critical unmet needs, including rare cancers such as multiple myeloma, acute myeloid leukemia, and certain types of lymphomas, as well as gastrointestinal and lung cancers.

Sanofi and Orano Med are members of the Paris Saclay Cancer Cluster and look forward to contributing to the ambitious agenda of the France 2030 plan to accelerate innovation in oncology.

This agreement is subject to standard regulatory approvals required for transactions of this nature.

Financial considerations

Under the terms of the agreement, Sanofi will make an equity investment of €300 million, approximately 16% equity stake in the new entity valued at €1.9bn.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across the world, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions. Sanofi is listed on Euronext: SAN and NASDAQ: SNY

About Orano Med

Orano Med, a subsidiary of the Orano Group, is a clinical-stage biotechnology company that develops a new generation of targeted therapies against cancer using the unique properties of lead-212 (^{212}Pb), an alpha-emitting radioisotope and one of the more potent therapeutic payloads against cancer cells known as Targeted Alpha-Emitter Therapy (TAT). The company is developing several treatments using ^{212}Pb combined with various targeting agents. Orano Med has ^{212}Pb manufacturing facilities, laboratories, and R&D centers in France and in the US and is currently investing to further expand its GMP-manufacturing capacities for ^{212}Pb radiolabeled pharmaceuticals in North America and Europe.

As a recognized international operator in the field of nuclear materials, Orano Group delivers solutions to address present and future global energy and health challenges. Its expertise and mastery of cutting-edge technologies enable Orano to offer its customers high value-added products and services throughout the entire fuel cycle. Every day, the Orano group's 17,500 employees draw on their skills, unwavering dedication to safety and constant quest for innovation, with the commitment to develop know-how in the transformation and control of nuclear materials, for the climate and for a healthy and resource-efficient world, now and tomorrow.

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Sanofi forward-looking statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions, and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi's ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that pandemics or other global crises may have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2023. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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