



Press Release

Sanofi, RadioMedix, and Orano Med announce licensing agreement on next-generation radioligand medicine for rare cancers

Paris, France, and Houston, Texas, September 12, 2024. As part of its effort to develop innovative treatments for people living with rare cancers, Sanofi has entered into an exclusive licensing agreement with RadioMedix, Inc., a US clinical-stage biotechnology company developing radiopharmaceuticals for PET imaging and targeted alpha therapy (TAT) against unmet medical needs in cancer, and Orano Med, a French clinical-stage biotechnology company, subsidiary of the Orano Group, developing lead-212 (^{212}Pb) radioligand therapies (RLTs) against cancer.

This collaboration between Sanofi, RadioMedix and Orano Med focuses specifically on the late-stage project, AlphaMedix™ (^{212}Pb -DOTAMTATE), which currently is being evaluated for the treatment of adult patients with unresectable or metastatic, progressive somatostatin-receptor expressing neuroendocrine tumors (NETs), a rare cancer. AlphaMedix™ is a TAT which consists of a somatostatin receptor-targeting peptide complex radiolabeled with lead-212 (^{212}Pb) that serves as an in vivo generator of alpha particles.

Dietmar Berger

Chief Medical Officer, Global Head of Development, Sanofi

“We are excited to develop a leading-edge project in the rapidly evolving field of radioligand therapies in rare cancers. Early results for ^{212}Pb have demonstrated its differentiated biophysical and clinical profile, reinforcing its potential to be a transformative radioligand therapeutic for patients across multiple difficult-to-treat rare cancers. This agreement underscores our efforts to explore innovative collaborations that leverage novel technologies to address the needs of people living with cancer.”

AlphaMedix™ has recently been granted Breakthrough Therapy Designation in gastroenteropancreatic neuroendocrine tumors (GEP-NETs) from the US Food and Drug Administration (FDA) for patients who are naïve to peptide-receptor radionuclide therapy. The FDA’s decision was based on findings from phase 1ⁱ and 2 clinical studies, which found that AlphaMedix™ was well tolerated and provided substantial reduction in tumor burden, with a durable response rate (ORR according to RECIST 1.1) of 62.5%.ⁱ AlphaMedix™ is currently completing phase 2 clinical development, and the data is being discussed with the FDA for potential regulatory filing and approval.

Ebrahim S. Delpassand

Chairman and CEO, RadioMedix

“The Breakthrough Therapy Designation of AlphaMedix is a testament of its success in validating targeted alpha therapies. We see this as a potential for the future of nuclear oncology in general, and today it is pioneering next-generation treatment for patients with neuroendocrine tumors. In our research, we have seen that significantly higher energy delivery over much shorter path lengths in the tissue of alpha emitters can overcome the limitations of currently available beta emitter radioligand therapies. We believe ^{212}Pb is an ideal alpha emitter with highly desirable physical and supply characteristics in comparison to other alpha emitters. RadioMedix has been one of the pioneers in the field of radioligand therapy in the U.S and, through this licensing agreement with Sanofi, our goal is to bring this potentially life-saving therapy to as many patients as possible.”

Julien Dodet

President and CEO, Orano Med

“At Orano Med, we are at the forefront of innovation in radioligand therapy and are developing a global industrial platform for the manufacture and distribution of our ²¹²Pb-conjugated drugs. This marks a pivotal moment to expedite the development of this new therapy and in our fight against cancer. Through this agreement, we aim to lead the charge in advancing radioligand therapies with the ambition to revolutionize cancer therapeutics.”

Under the licensing agreement, Sanofi will be responsible for the global commercialization of AlphaMedix™, while Orano Med will be responsible for the manufacturing of AlphaMedix™ through its global industrial platform currently under development. Under the terms of the agreement, RadioMedix and Orano Med will receive an upfront payment of €100 million and up to €220 million in sales milestones and be eligible for tiered royalties. This agreement is subject to standard regulatory approvals required for transactions of this nature.

In striving to become the number one immunoscience company globally, Sanofi remains committed to advancing oncology innovation. Through focused strategic decisions the company has reshaped and prioritized its pipeline, leveraging its 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 multiple myeloma, acute myeloid leukemia, certain types of lymphomas, as well as gastrointestinal and lung cancers.

About neuroendocrine tumors

Neuroendocrine tumors (NETs) are a heterogeneous group of rare cancers that originate from neuroendocrine cells. These cancers occur mostly in the gastrointestinal tract and pancreas but can also occur in other tissues including the thymus, lung, and other uncommon sites such as ovaries, heart, and prostate. Most NETs strongly express somatostatin receptors. In the United States, around 12,000 patients annually are expected to be diagnosed with neuroendocrine tumors, with an average 5-year survival rate of 60% at a metastatic stage. Despite the global prevalence of NETs increasing each year, it is considered a rare cancer that is estimated to affect approximately 35/100,000 individuals worldwide.

About RadioMedix

RadioMedix, Inc. is a clinical-stage biotechnology company, based in Houston and Humble, Texas. The company is focused on innovative targeted radiopharmaceuticals for diagnosis, monitoring, and therapy of cancer. RadioMedix is developing radiopharmaceuticals for PET imaging and therapy (alpha- and beta-labeled agents). The company established contract service facilities for academic and industrial partners, including a cGMP and analytical suite for Phase I-II-III clinical trials and commercial launch. To learn more, visit www.radiomedix.com and [LinkedIn](#). For more information about this press release, please contact: radiomedix@knbcomm.com.

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 (²¹²Pb), 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 ²¹²Pb combined with various targeting agents. Orano Med has ²¹²Pb 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 ²¹²Pb 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.

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

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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.

All trademarks mentioned in this press release are the property of the Sanofi group with the exception of AlphaMedix.

ⁱ Delpassand ES, Tworowska I, Esfandiari R, et al. Targeted α -Emitter Therapy with ^{212}Pb -DOTAMTATE for the Treatment of Metastatic SSTR-Expressing Neuroendocrine Tumors: First-in-Humans Dose-Escalation Clinical Trial. *J Nucl Med*. 2022;63(9):1326-1333. doi:10.2967/jnumed.121.263230.