

AlphaMedix™ (²¹²Pb-DOTAMTATE) achieved all primary efficacy endpoints in phase 2 study, demonstrating clinically meaningful benefits in patients with gastroenteropancreatic neuroendocrine tumors

- AlphaMedix™ showed prolonged and clinically meaningful benefits across PRRT-naïve and PRRT-exposed patients with unresectable or metastatic GEP-NETs, highlighting the potential of Targeted Alpha Therapy with lead-212 as a new treatment option
- Results will form the basis of future discussions with health authorities

Paris, October 8, 2025. Positive results from the ALPHAMEDIX-02 phase 2 study (clinical study identifier: [NCT05153772](https://clinicaltrials.gov/ct2/show/study/NCT05153772)) showed AlphaMedix™ (²¹²Pb-DOTAMTATE), an investigational somatostatin receptor (SSTR)-Targeted Alpha Therapy using the lead-212 isotope, met all primary efficacy endpoints and showed clinically meaningful overall response rates (ORR) and prolonged clinical benefits in both peptide receptor radionuclide therapy (PRRT)-naïve and PRRT-exposed patients with unresectable or metastatic SSTR positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Benefits in key secondary endpoints, including progression-free survival (PFS) and overall survival (OS), were also observed across both cohorts. AlphaMedix™ had a manageable safety profile that was similar across both cohorts.

*"The positive results from the ALPHAMEDIX-02 study represent a pivotal movement for the Orano Med ²¹²Pb-based platform and underscore the profound potential of lead-212-based radiopharmaceuticals in addressing critical unmet needs for patients with GEP-NETs. We are very encouraged by AlphaMedix™'s consistent and clinically meaningful activity across both peptide receptor radionuclide therapy (PRRT)-naïve and PRRT-exposed patients," said **Volker Wagner**, MD, PhD, Chief Medical Officer at Orano Med. "These data reinforce our belief that delivering highly potent alpha-emitters directly to cancer cells could potentially offer a meaningful new treatment option for people living with GEP-NETs."*

Alpha-emitters are being studied to determine their relative potency and targeted tumor activity compared to current approved therapies. It is believed they could potentially reduce exposure of surrounding healthy tissue due to the short range of alpha particles. In February 2024, AlphaMedix™ was granted Breakthrough Therapy Designation by the US Food and Drug Administration (FDA) for treatment of PRRT-naïve patients with unresectable or metastatic, progressive SSTR-expressing GEP-NETs, recognizing the potential clinical benefits and potential of this lead-212-based therapy.

*"The promising ALPHAMEDIX-02 results represent a significant step forward, reinforcing the potential of targeted alpha therapy to deliver precise treatment for GEP-NETs," said **Christopher Corsico**, MD, Global Head of Development at Sanofi. "These data, demonstrating clinically meaningful activity and a manageable safety profile, underscore our unrelenting commitment to developing innovative therapies for patients with difficult-to-treat cancers. We look forward to advancing AlphaMedix™ and working with Orano Med and regulators to bring this important treatment to the GEP-NET community as soon as possible."*

The study is ongoing, and the full results will be presented at the 2025 European Society for Medical Oncology (ESMO) Congress. The results will also form the basis of discussions with health authorities. AlphaMedix™ has not been approved by any regulatory authority.

About the ALPHAMEDIX-02 study

ALPHAMEDIX-02 is a phase 2, open-label, multicenter study evaluating the efficacy and safety of AlphaMedix™ (²¹²Pb-DOTAMTATE) in patients with histologically confirmed unresectable or metastatic GEP-NETs, positive somatostatin analogue imaging and at least one site of measurable disease. The study included two cohorts evaluating PRRT-naïve (n=35) and PRRT-exposed (n=26) patients. PRRT-exposed patients had progressive disease after receiving up to four doses of ¹⁷⁷Lu-DOTATATE and received their last dose at least six months prior to Day 1. In both cohorts, AlphaMedix™ was administered at 67.6 µCi/kg every eight weeks for up to four cycles (6 mCi maximum per cycle). Primary endpoints included ORR per RECIST1.1 and safety. Secondary endpoints included PFS and OS.

About NETs

NETs are a heterogeneous group of 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 the ovaries, heart, and prostate. Most NETs strongly express somatostatin receptors. 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. In the United States, around 12,000 patients annually are expected to be diagnosed with neuroendocrine tumors, with an average five-year survival rate of 60% at a metastatic stage.

About Orano Med

Orano Med is a subsidiary of the Orano Group. Orano Med 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 Therapy (TAT). Leveraging its unique and secured access to ²¹²Pb, 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 expanding its GMP-manufacturing capacities for ²¹²Pb radiolabeled pharmaceuticals in North America and Europe.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.

Sanofi is listed on Euronext: SAN and NASDAQ: SNY

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