

PRESS RELEASE

NEVA SGR INVESTS IN TR1X, LEADING BIOTECH COMPANY IN RESEARCHING CURES FOR AUTOIMMUNE AND INFLAMMATORY DISEASES

- Tr1X builds on more than 20 years of successful research into regulatory cells and their role in the immune system by its founder, Professor Maria Grazia Roncarolo, one of the world's foremost experts in cell and gene therapy.
- Tr1X will begin the new drug approval process with the US Food & Drug Administration, with the aim of administering the first clinical trial dose in 2023.
- Mario Costantini: "Tr1X is an example of how Italian researchers, thanks to their preparation, can help revolutionise the pharmaceutical industry and change the future of our lives for the better. We are proud to participate in this great challenge, together with leading international life science investors, and to have Tr1X among our portfolio companies."
- Maria Grazia Roncarolo: "We are very excited about the presence of an Italian venture capital firm at Tr1x, which aims to develop new advanced therapies for patients with severe autoimmune and inflammatory diseases. Neva Sgr shares our vision and strong ambition to create a new frontier in medicine by using cutting-edge genetic engineering technologies to cure previously incurable diseases".

Turin, 14 September 2022 - Neva Sgr, an Intesa Sanpaolo Group company dedicated to venture capital wholly owned by Intesa Sanpaolo Innovation Center, has finalised, through its Neva First Fund, an investment in Tr1X, a US biotech company that studies and develops treatments for autoimmune and inflammatory diseases through the engineering of T cells.

Thanks to resources from the funding round in which **Neva Sgr and** other international venture capitalists participated, **Tr1X** will begin the new drug approval process with the **US Food & Drug Administration**, with the goal of administering the first clinical trial dose in 2023.

Many diseases of the immune system require treatment with immunosuppressive drugs, which, besides having harmful effects, are of limited efficacy. The physiological

regulation of the immune system depends on several regulatory cell populations, including type 1 (Tr1) regulatory T cells. Tr1s are present in the blood and are crucial for keeping the immune system in balance, but are difficult to isolate and produce as a drug. Tr1X has patented and is developing a system to generate Tr1 cells using state-of-the-art genetic engineering methods. The goal is to develop a single treatment that can eradicate autoimmune and inflammatory diseases by restoring the physiological balance of the patients' immune system.

Tr1X builds on more than 20 years of successful regulatory cell research by its founder, **Professor Maria Grazia Roncarolo**, one of the world's leading experts in cell and gene therapy.

"**Tr1X** is an example of how Italian researchers, thanks to their preparation, can help revolutionise the pharmaceutical industry and change the future of our lives for the better," commented **Mario Costantini, CEO and General Manager of Neva Sgr**. "We are proud to participate in this great challenge, together with leading international life science investors, and to have **Tr1X** among our portfolio companies." Since August 2020 we have invested in 26 highly innovative companies. We will continue to focus on life science – one of the sectors in which our country excels globally."

"We are very excited about the presence of an Italian venture capital firm at Tr1x, which aims to develop new advanced therapies for patients with severe autoimmune and inflammatory diseases," commented Maria Grazia Roncarolo, Founder of Tr1X. "Neva Sgr shares our vision and strong ambition to create a new frontier in medicine by using cutting-edge genetic engineering technologies to cure previously incurable diseases".

Maria Grazia Roncarolo is recognised worldwide for her leadership in translating scientific discoveries on immune-mediated diseases and regenerative medicine into new therapies for patients, including the world's first *ex vivo* gene therapy.

As the George D. Smith Professor in Stem Cell and Regenerative Medicine and as Professor of Pediatrics and of Medicine at Stanford University, Professor Roncarolo founded the Stanford Center for Definitive and Curative Medicine to treat patients with currently incurable diseases through the development of innovative cell- and gene-based therapies. A paediatric immunologist by training, she graduated in medicine and specialised in paediatrics from the **University of Turin**. Later, she specialised in Immunology at the University of Milan. She worked in Lyon, France where she developed new stem cell transplantation techniques. In the 1990s, she worked at the **DNAX Research Institute for Molecular and Cellular Biology in Palo Alto**, California, where she contributed to the discovery of new cytokines, cell-signalling molecules that are part of the immune response. Her work on interleukin-10 led to the discovery of a new class of T cells, called type 1 regulatory T cells. These cells help maintain immune system homeostasis by preventing autoimmune and inflammatory diseases and helping the immune system tolerate transplanted cells and organs. She completed the first clinical trials using type 1 regulatory T cells to prevent severe transplantation diseases against the host in leukaemia patients who received haematopoietic stem cell transplants.

During her previous tenure as Director of the **San RaffaeleTelethon Institute for Gene Therapy and** Scientific Director of the **San Raffaele Scientific Institute in Milan**, Professor Roncarolo developed new approaches in cell and gene therapy for complex genetic and acquired diseases. Her work led to the discovery of *ex vivo* gene therapies for genetic diseases of the immune system, including ADA-SCID and WASP, and metabolic diseases such as metachromatic leukodystrophy. The stem cell gene therapy treatment for ADA-SCID was the first in the world to be approved by the **European Medicines Agency (EMA)** in May 2016. She is also a co-founder of **Graphite Bio**, which is developing a new class of gene editing-based therapies to correct genetic defects in people with blood and immune system diseases.

Neva SGR

Neva SGR, part of the Intesa Sanpaolo Group and wholly owned by the Intesa Sanpaolo Innovation Center, plans and manages investment funds for professional investors interested in seizing diversification and high-yield opportunities offered by Venture Capital investments. Neva SGR can count on Intesa Sanpaolo Innovation Center's and Intesa Sanpaolo Group's strength, financial resources, know-how and network of relationships, a unique source of value on the market. Neva SGR can watch trends and markets from a privileged position, and takes action with the strength and the responsibility of Italy's leading banking group. Intesa Sanpaolo Innovation Center has invested in Neva First, the investment fund designed for excellent, high-tech, high-innovation start-ups, which take advantage of trends with exponential growth potential. The fund mainly focuses on FinTech and Italian companies with global growth plans or international companies that plan to develop projects with positive effects on industrial and production chains in Italy. To learn more visit <u>www.nevasgr.com</u>

Intesa Sanpaolo

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billion in impact lending by 2025 to communities and for the green transition, and €500 million in contributions to support people most in need, positioning Intesa Sanpaolo as a world leader in terms of social impact. Intesa Sanpaolo is committed to Net Zero by 2030 for its own emissions and by 2050 for its loan and investment portfolios. An engaged patron of Italian culture, Intesa Sanpaolo has created its own network of museums, the *Gallerie d'Italia*, to host the bank's artistic heritage and as a venue for prestigious cultural projects.

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