

Italian gene therapy start-up Genenta banks \$7M in series A round

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DUBLIN – Italian gene therapy pioneer Luigi Naldini is one of the co-founders of a new start-up, [Genenta Science](#) SpA, a spinout from the San Raffaele Hospital in Milan, which aims to exploit his deep experience in lentiviral vectors in the development of ex vivo engineered autologous cell therapies for cancer.

Milan-based Genenta has raised €6.2 million (US\$7 million) in a first closing of its series A round. Co-

founder and company chairman and CEO Pierluigi Paracchi told *BioWorld Today* that it has received commitments that will take the total to €10 million in the coming weeks.

Paracchi, a venture capital investor, was associated with a recent Italian biotech success, the sale of Ethical Oncology Science SpA (EOS) to Clovis Oncology Inc., of Boulder, CO, in a deal worth \$200 million up front and as much as \$420 million eventually. (See *BioWorld Today*, Nov. 21, 2013).

The third member of the founding team, Bernhard Gentner, is a physician scientist, who, like Naldini, is also based at the San Raffaele Hospital. He also holds a position at the San Raffaele-Telethon Institute for Gene Therapy, of which Naldini is director.

The cash injection will enable the company to complete ongoing preclinical development work and to initiate phase I trials in patients. "Also, during the preclinical development period we will prepare and organize our manufacturing activities," Paracchi said. "Our idea is to enter the clinical phase between the end of 2016 and the beginning of 2017."

Genenta is recasting an old idea in a modern guise. It aims to arm tumor-infiltrating lymphocytes with interferon-alpha (IFN-alpha), a cytokine involved in host defense against viral pathogens, which also has antitumor activity. Until recently a cornerstone of therapy for hepatitis C virus infection, IFN-alpha has not been widely used in cancer therapy because of the levels of toxicity associated with an effective dose.

Naldini and colleagues previously identified a Trojan horse – a population of monocytes that expresses a tunica interna endothelial 2 (TIE2) receptor tyrosine kinase, which binds angiopoietin growth factor and helps to regulate the maturation and stabilization of blood vessels. Expression of the TIE2 gene is sharply up-regulated once those cells infiltrate tumors, and it leads to both pro-angiogenic and immunosuppressive effects.

Genenta's approach is based on turning those monocytes into carriers of a gene encoding IFN-alpha. To minimize any potential systemic effects, the gene is placed under the transcriptional control of the TIE2 promoter and also under the post-transcriptional control of a microRNA species. That ensures that expression is conditional and largely confined to the tumor microenvironment.

Genenta's lead indication will be multiple myeloma patients undergoing bone marrow transplant. "It's crucial for us to work with hematopoietic stem cells," Paracchi said.

The basic approach is described in a paper, which was published online on April 29, 2014, in *Oncoimmunology*, under the title "Engineered tumor-infiltrating macrophages as gene delivery vehicles for interferon- α activates (sic) immunity and inhibits (sic) breast cancer progression."

The company is building on Naldini's two decades of involvement at the forefront of gene therapy. During the

mid-1990s, he pioneered the development of lentiviral vectors in nonreplicating cells while working with Inder Verma at the Salk Institute, of La Jolla, Calif. More recently, he has harnessed those to correct the hematopoietic stem cell genotypes of patients with rare genetic conditions such as metachromatic leukodystrophy and Wiskott Aldrich syndrome.

A syndicate of private investors, family offices and high net worth individuals have backed the company. Its board includes Roger Abravanel, also a director of Teva Pharmaceutical Industries Ltd., of Petach Tikva, Israel, and EOS co-founder Gabriella Camboni, who is also on the investment team of Ares Life Sciences, the investment arm of the Bertarelli family.

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