

## Media Release

# Limula and SR-Tiget partner to deploy a novel bioreactor towards closed and automated expansion of haematopoietic stem cells.

- The collaboration will leverage unique features of the award-winning solution for the production of highly personalised cell therapies, provided by Swiss company Limula.
- The San Raffaele Telethon Institute for Gene Therapy in Milan, Italy, is at the forefront of the development of therapies from haematopoietic stem cells.
- The goal is to develop automated and scalable *ex vivo* haematopoietic stem cell expansion protocols based on those developed by Prof. Bernhard Gentner and his team.
- The collaboration has been established under the EIC Pathfinder Cell and Gene Therapy Sub Portfolio “Advancing cell therapy manufacturing and products to a clinical stage”.

Lausanne, 15 March 2024 – Limula SA, a Life Science Tools company based in Lausanne, Switzerland, and San Raffaele Telethon Institute for Gene Therapy (SR-Tiget), an institute in Milan, Italy, announce they have entered into a partnership agreement to explore the potential of a novel bioreactor design for the expansion of haematopoietic stem cells (HSC).

## Cell & Gene Therapies: making curative treatments accessible

Over the past decade, HSC-based gene therapy medicinal products have proved successful in curing severe genetic diseases that previously had no treatment available. Several products have received regulatory approval in the USA and in Europe for the treatment of rare inherited conditions – including Strimvelis and Libmeldy, both developed at SR-Tiget – and many more are in development.

Prof. Bernhard Gentner and colleagues at SR-Tiget, a world-recognized centre of excellence for research and clinical translation of Cell and Gene Therapy, have pioneered the use of HSC-based gene therapy as an effective treatment for several primary immunodeficiencies. However, providing broad access of these life-saving medicines to patients will still require significant technological and regulatory innovations.

Prof. Bernhard Gentner says “we believe the solution Limula is advancing can support our current process development activities and later enable the manufacturing of these cell products at scale. We also see its potential in improving the status quo in Cell & Gene Therapy manufacturing in general, and in the field of haematopoietic stem cell transplantation in particular.”

## **A device to automate cell processing steps across scales.**

To address the problem of manufacturing capacity, Limula is developing a unique technology that has the potential to support every step of the complex process, in a single self-contained device, with minimal operator intervention. This solution decreases the need for large clean room facilities that are costly to build and maintain. It also prevents errors and contamination stemming from human manipulations.

In line with SR-Tiget strategic goal of advancing HSC gene therapy to standard-of-care for rare genetic diseases, researchers in Milan aim to leverage the unique design developed by Limula, and in particular the ability to perform multiple process unit operations – including cell expansion – on a small number of cells, all the way to a therapeutic dose. This represents incredible value when limited cell material is available and needs to be handled gently and efficiently.

Over the past 3 years, Limula has already collaborated with several academic and industrial partners to advance the development of a versatile solution suitable for cell processing across different applications. After a successful proof of concept demonstrating the capacity of the technology to perform key steps in the production of an anti-CD19 CAR T cell product, this new collaboration will expand Limula's application scope to the manufacturing of gene therapies based on *ex vivo* manipulations of HSC.

## **About SR-Tiget**

The San Raffaele Telethon Institute for Gene Therapy (SR-Tiget) was created in 1996 as a joint venture between the Fondazione Telethon and Ospedale San Raffaele, with the mission to perform cutting-edge research, towards the discovery of novel gene and cell therapy platforms and their development from preclinical models to first-in-human testing.

## **About Limula**

Limula SA is a Life Science Tools company based in Lausanne, Switzerland, looking to disrupt the status quo in the manufacturing of Cell & Gene Therapies, supporting rapid and cost-effective introduction of new advanced therapy products to the market. The company develops a unique cell processing technology enabling 'one-pot' end-to-end production of cell therapies at scale, through automation and standardisation.

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