Novadip reports promising interim results from its first-in-human proof-of-concept trial with NVDX3, a new game changer in the bone field

At six months post-grafting surgery with NVDX3, x-rays demonstrate that 90% of patients have reached, or are steadily progressing towards, complete bone healing

Derived from Novadip's 3M³ stem cell platform, NVDX3, a unique 'off-the-shelf allogeneic matrix product to cure common but challenging orthopedic conditions, has potential to replace existing allogeneic bone substitutes to heal fractures

Mont Saint-Guibert, Belgium, October 17, 2024 – Novadip Biosciences, a clinical stage biotechnology company specializing in regenerative medicine, today announces positive interim results from its first-in-human clinical trial, NVDX3-CLN01, assessing the safety and efficacy of NVDX3 to heal distal radius fractures in adults.

Originating from Novadip's 3M³ platform, NVDX3 is an allogeneic bone grafting material created from human osteogenic adipose tissue-derived mesenchymal stem cells (ASCs). It is formulated as a lyophilized powder intended to be used as an 'off-the-shelf' implant to induce bone formation between two bone segments in both orthotopic and heterotopic environments.

NVDX3 is a new class of regenerative tissue products that accelerates bone healing in a single treatment for patients at high risk of nonunion due to co-morbidities (ageing, diabetes, obesity, smoking and other conditions) and medication use.

NVDX3-CLN01 (NCT05987033) is a single-arm, open-label clinical trial designed to assess the safety and preliminary efficacy of NVDX3 in adults with distal radius fractures, involving the wrist joint with multiple bone fragments. Ten participants, aged 28 to 84 years old, were treated.

Radiologically, 90% of patients have achieved, or are on-track to achieve, complete bone healing. All but one are progressing as expected clinically. There is no apparent impact of age or sex on the efficacy of NVDX3, despite the complexity of fractures treated. There have also been no safety concerns arising from this study.

"The interim results of this first clinical trial mirror the safety and efficacy of NVDX3 demonstrated in our nonclinical program. NVDX3 is the first and only bone graft product following a Biologics License Application (BLA) pathway. Based on these preliminary data, NVDX3 has the potential to address the high unmet needs of patients with bone defects who, due to co-morbidity factors, experience delayed bone formation or nonunion," said Denis Dufrane, MD, PhD, CEO of Novadip Biosciences. "We will share the results of this trauma study with the US FDA as part of our IND submission to support the further clinical development of NVDX3 as we explore its potential for the treatment of complex cervical spine fusion."

"We need more options to improve outcomes in bone healing, particularly for patients with co-morbidities like advanced age, diabetes and smoking," said Philipp Leucht, MD, PhD, Vice Chair of Research, Department of Orthopedic Surgery at NYU Grossman School of

Medicine. "These interim results suggest that NVDX3 may have the potential to address this unmet need."

The 12-month results of NVDX3-CLN01 are expected at the end of 2024.

In parallel to NVDX3-CLN01, Novadip is investigating the safety and preliminary efficacy of NVDX3 as a bone graft to achieve spine fusion in the lumbar spine in trial NVDX3-CL02 (NCT05961956). One-year results from this trial are expected in March 2025.

In addition to its allogeneic program with NVDX3, the clinical development of the company's lead autologous program, NVD003, will soon be entering phase 3 for the treatment of congenital pseudarthrosis of the tibia, a rare pediatric disease that often leads to amputation. Planning for a pivotal phase 3 trial and BLA submission is underway.

About Novadip's 3M³ platform

The 3M³ platform drives multiple classes of product candidates, with an initial focus on autologous cell therapies for critical size tissue reconstruction and allogeneic therapeutics in development for prevalent bone grafting procedures and solid tumors.
The platform consists of a 3-dimensional, scaffold-free, extracellular matrix (ECM) utilizing differentiated adipose-derived stem cells (ASCs), to generate highly specific growth factors and miRNAs to restore the physiology of natural healing. The components of the 3M³ include a matrix with ASCs to deliver growth factors/miRNA, the mature implant mimicking the physiology of natural healing.

About Novadip Biosciences

Novadip is a Belgium-based clinical stage biotech company aiming at advancing the standard of care in bone and tissue regenerative medicine. Based on the scientific discoveries of founder Prof. Dr. Denis Dufrane, MD, PhD, the company is developing its unique 3M³ tissue regeneration technology platform, which has the potential to generate an array of candidates that utilize adipose-derived stem cells to mimic the physiology of natural tissue healing, and hard and soft tissue reconstruction, for patients with limited or no treatment options.
Novadip is a spin-off company from the Université Catholique de Louvain (UCLouvain) and St. Luc University Hospital.
www.novadip.com

Media and analyst contact
Andrew Lloyd & Associates
Celine Gonzalez – Saffiyah Khalique
celine@ala.associates – saffiyah@ala.associates
UK/US: +44 1273 952 481