Novadip shares positive 12-month results from phase 1b/2a trial with NVDX3 in trauma

At 12 months, 100% of participants with distal radius fractures treated in trial with NVDX3, an allogenic stem-cell derived bone graft material, demonstrated durable bone union

No adverse events related to NVDX3 observed

A phase 2b/3 trial in 2-level cervical spine fusion to begin in November 2025

Mont Saint-Guibert, Belgium, February 20, 2025 – Novadip Biosciences, a clinical stage biotechnology company specializing in regenerative medicine, today announces the promising 12-month results of its first-in-human proof-of-concept study of NVDX3 in distal radius fractures in adults, following the interim results unveiled in October 2024.

NVDX3-CLN01 (NCT05987033) was a single-arm, open-label clinical trial aimed at evaluating the safety and preliminary efficacy of NVDX3, an allogeneic bone grafting material created from human osteogenic adipose tissue-derived mesenchymal stem cells (ASCs). This trial focused on adults with distal radius fractures involving the wrist joint with multiple bone fragments.

The participants, aged 28-84 years old, were treated with NVDX3 with follow-ups conducted at 3, 6 and 12 months. At the 12-month follow-up visit, 100% of patients had bone union of their fractures, regardless of age and complexity of fractures treated, with the majority of patients achieving this by the six-month visit. No adverse events were deemed by the investigator to be related to NVDX3.

"These are the promising results I was expecting, given the compelling non-clinical data and the well-understood mechanism of action of NVDX3," said Philipp Leucht, MD, PhD, Vice Chair of Research, Department of Orthopedic Surgery at NYU Grossman School of Medicine. "I'm looking forward to seeing how NVDX3 performs in larger, randomized clinical trials compared with standard of care bone graft materials. Surgeons urgently need more effective options, especially for patients with comorbidities that can negatively impact bone healing."

"I'm very excited by these results, as they strongly indicate that NVDX3 has the potential to address the high unmet needs of patients with bone defects who, due to comorbidity factors (e.g., smoking, age), experience delayed bone formation, or nonunion. Currently, no on-label osteobiologic can prevent or cure bone nonunion (up to 30%). With NVDX3, we are addressing a potential market of up to $12B," said Denis Dufrane, MD, PhD, CEO of Novadip Biosciences.

"These strong results not only support the efficacy of NVDX3 in patients who are at risk of nonunion, they also help answer concerns around the safety of using an allogeneic cell-derived product like NVDX3 that retains biologic activity," added Judy Ashworth, MD, chief medical officer of Novadip Biosciences. "Importantly, we observed no signs of immunogenicity or

ectopic bone formation, reinforcing the safety profile of NVDX3 and its potential as a transformative therapeutic option."

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

In November 2024, the company also launched an Investigational New Drug (IND) study for NVDX3 and is currently in the start-up stage of a phase 2b/3 trial in the US in 2-level cervical spine fusion. Novadip aims to begin patient enrollment in November 2025.

About NVDX3

Originating from Novadip's $3M^3$ 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 comorbidities (ageing, diabetes, obesity, smoking and other conditions) and medication use.

About Novadip Biosciences

Novadip is a clinical stage biotech company aiming at advancing the standard of care for patients undergoing bone and tissue regenerative medicine.

Based on the scientific discoveries of founder Prof. Dr. Denis Dufrane, MD, PhD, and research from UCLouvain and St. Luc University Hospital, the company is developing its unique $3M^3$ tissue regeneration technology platform, designed to create a new class of regenerative tissue products that accelerate the healing of large bone defects, bone nonunion and spine fusion in a single treatment, for patients with limited or no treatment options.

Novadip's pipeline includes two lead products: NVD003, an autologous cell-based therapy currently in phase 1b/2a clinical trials in adults with bone nonunion, and pediatric congenital pseudarthrosis of the tibia; and NVDX3, an allogenic bone grafting material currently in phase 1b/2a trials in trauma surgery and lumbar intervertebral spine fusion. Novadip is ready to start two phase 3 trials for NVD003 in the US and EU, and the FDA has granted approval to start a phase 2b/3 IND (Investigational New Drug) trial with NVDX3 in level two cervical spine fusion.

Founded in 2013 in Belgium, Novadip employs 45 staff. Since inception, it has raised €88 million in equity and non-dilutive funding. The company targets a total addressable market of $13.5 billion (€13.06B).

www.novadip.com

Media and analyst contact
Andrew Lloyd & Associates
Celine Gonzalez – Saffiyah Khalique
UK: +44 1273 952 481 / US: +1 203 724 5950