Novadip's NVDX3 reaches key milestones leading to IND approval from FDA to start phase 2b/3 study in cervical spine fusion

Built upon robust preclinical and clinical datasets, NVDX3 has potential to replace existing allogenic bone grafting materials - providing patients with complex comorbidities better bone fusion success

Phase 2b/3 expected to begin enrollment in H2 2025 in the US

Mont Saint-Guibert, Belgium, November 20, 2024 – Novadip Biosciences, a clinical stage biotechnology company specializing in regenerative medicine, today announces approval from the US Food and Drug Administration (FDA) for its allogenic bone grafting material NVDX3 to enter an investigational new drug study (IND).

NVDX3 is an allogenic bone grafting material forming 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. The osteogenic properties of NVDX3 make it uniquely suited to compromised bone environments in patients with a risk of fusion failure or settings with decreased bone healing capacity; it therefore has the potential to provide higher healing success rates than current treatments (as demonstrated in previous animal and human studies).

The FDA-approved IND study is a phase 2b/3 trial assessing the efficacy of NVDX3 compared to standard-of-care treatments in level two cervical spine fusion. The trial aims to enroll 106 participants across up to ten sites in the US. The participants for the study will have symptomatic cervical disc disease and be candidates for spinal fusion at two adjacent levels. Patients will be randomized to receive either NVDX3 or a standard-of-care bone graft material and will not be excluded based on comorbidities.

"We are thrilled to have received FDA approval for an IND trial for NVDX3 in spinal fusion. Our robust clinical data behind NVDX3 demonstrates its potential to replace the allogenic bone grafts currently in use, decreasing the risk of disease transmission, reactions due to histocompatibility and delayed union or fusion in patients at high risk of nonunion. The trial will accelerate our capability to bring NVDX3 to patients with complex needs, providing them with a better chance of healing compared to standard-of-care treatments. These strategic steps enable us to take NVDX3 to the next level," said Denis Dufrane, MD, PhD, CEO of Novadip Biosciences.

"This study will be a good test to see how well NVDX3 performs compared with current products," said Dr. Alexander Ropper, Associate Professor and Director of Spinal Neurosurgery, Baylor College of Medicine, Houston, Texas. "The promising pre-clinical results will hopefully translate into improved fusion rates for spine surgery patients."

Each year, over 130,000 people in the US undergo cervical spine surgery using the anterior cervical discectomy and fusion (ACDF) procedure. Allogenic bone grafts that are currently used in ACDF are associated with a fusion success rate of less than 95% in single-level procedures, with the success rate falling to 76% when two contiguous levels are treated. Therefore, NVDX3 could be positioned as a single treatment cure.

This phase 2b/3 trial is designed with an interim analysis to allow for a seamless conversion into phase 3, thus accelerating its path to market.

A product backed by compelling preclinical and clinical data

NVDX3 for spinal fusion is backed by compelling preclinical and clinical data demonstrating the safety and efficacy of the product:

- Recent six-month results from a phase 1b/2a proof-of-concept single-arm clinical trial in lumbar intervertebral spine fusion on one-level found that there was an improvement in function compared with pre-surgery status, as measured with the Oswestry Disability Index. CT scans at the four-month mark showed progression toward bone union as appropriate for this stage. The trial was carried out on five adult patients aged 57-74 at a single site in Europe, where all participants received NVDX3
- Ovine model of spinal fusion: the goal of this preclinical study was to assess the safety and efficacy of NVDX3 for spinal fusion in an ovine posterolateral lumbar fusion (PLF) model. An ovine model was used for this study because of the comparable anatomy and physiology between the ovine and human lumbar spines. A total of 18 sheep underwent bilevel posterior lumbar fusion using standard hardware (pedicle screws and connecting rods), test items were distributed along the right and left lateral regions of vertebral bodies of L2-L3 and L4-L5 based on the treatment group. It allowed the implantation of the maximal dose of NVDX3 planned to be administered in human. The NVDX3 treatment and bone autograft control were equivalent in efficacy when examined at 26 weeks. These methods both contribute to spinal fusion, bone bridging and tissue incorporation in a similar fashion

Novadip now has a US allogeneic and a European adipose stem cell bank, to cover clinical studies and commercial development on both continents.

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 three-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.

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