Novadip and Cliniques universitaires Saint-Luc report positive results for compassionate use of NVD003 on four pediatric patients

- **NVD003 is a bone grafting material developed to surgically treat patients with Congenital Pseudarthrosis of the Tibia, a rare and difficult-to-treat pediatric disease**
- **Four young patients were treated at Cliniques universitaires Saint-Luc under compassionate use programs managed by Belgian medicines agency, AFMPS**
- **All patients treated with NVD003 had complete healing of their fractures with no recurrent fractures after four to seven years of follow-up**

Mont Saint-Guibert and Brussels, Belgium, June 30, 2025 – Novadip Biosciences, a late-stage clinical biotechnology company specializing in regenerative medicine, and the Cliniques universitaires Saint-Luc today announce the successful treatment of four pediatric patients with Congenital Pseudarthrosis of the Tibia (CPT) using NVD003, an autologous therapy developed by Novadip for the reconstruction of bone tissue.

CPT is a very rare, debilitating and devastating condition, with an incidence between 1:140,000 to 1:250,000 live births. Treatment of CPT is difficult; children with CPT can endure impaired mobility, severe pain and years of corrective surgeries. Undergoing amputation of an affected limb is not uncommon.

Four pediatric patients with CPT underwent surgical treatment with NVD003 between January 2018 and March 2021, as part of the AFMPS (Belgian Authority for Medicines and Health Products) compassionate use programs. Subsequent four to seven years of clinical follow-ups showed that each of the four patients had successful outcomes, achieving bone repair with no subsequent refracture. No safety events related to the NVD003 graft have been reported.

Under the specific provisions of the Belgian legislation programs: 'Urgent Medical Need' and 'Hospital Exemption', and at his request, the treating physician, Professor Pierre-Louis Docquier, pediatric orthopedic surgeon at the Cliniques universitaires Saint-Luc (Belgium), implanted NVD003 in the four pediatric patients to treat their non-healing fractures.

"Critical size and non-healing bone defects are among the most difficult conditions to treat in orthopedic surgery, sometimes leaving physicians with no alternative than to amputate," said Professor Docquier. "The results after several years of this innovative regenerative therapy in these young patients are simply exceptional."

NVD003 is an autologous, ready-to-use, scaffold-free, tissue-engineered osteogenic implant for use during elective bone reconstructive procedures. The graft, which could be compared to a type of plasticine, is implanted directly into the non-healing fracture. Novadip designed and manufactured the implant based on the specific characteristics of the four young children, enabling the regeneration of the lost bone volume.

Clinical trials to confirm the therapeutic potential of NVD003

Earlier this year Novadip reported 12-month interim data from its phase 1b/2a pilot trial in four pediatric patients with CPT (NCT05693558). The first patient recently completed a 24-month follow-up visit and continues to do well.

"As the inventor of this technology, I am extremely happy to confirm that NVD003 has restored function and prevented amputation in these children. We are working hard to bring this product to the market as quickly as we can, to be able to help as many children with CPT as possible. We warmly thank the team at the Cliniques universitaires Saint-Luc who made it possible to obtain these very encouraging results," said Dr. Denis Dufrane, founder and CEO of Novadip.

Based on the encouraging combined data from the total of eight patients treated with NVD003 to date, Novadip is planning a phase 3 clinical trial in CPT, with enrolment opening in June 2025. Prof. Docquier will be the coordinating investigator for this pivotal trial.

About NVD003
NVD003 is a three-dimensional (3D) osteogenic graft derived from autologous adipose derived mesenchymal stem cells (ASCs) combined with hydroxyapatite/beta-tricalcium phosphate (HA/TCP) particles. NVD003 was specifically developed to improve bone healing in severe pathophysiological conditions (e.g. hypoxia, lack of mineralized callus formation, bone resorption and low osteogenicity) as found in congenital pseudarthosis, bone tumors (after an extensive surgical resection), osteolytic syndromes like Gorham-Stout disease, genetic bone resorption syndromes with osteoporosis as found in Hajdu-Cheney syndrome and following severe trauma (casualties of war).
Novadip aims to put NVD003 on the market in 2027.

About the Cliniques universitaires Saint-Luc
UCLouvain's academic hospital, the Cliniques universitaires Saint-Luc, and its partners provide patients with reliable local, cutting-edge, high-quality care. Together, they constitute a Belgian and international reference center for certain complex pathologies, particularly in orthopedic surgery, while guaranteeing excellence in carrying out their academic missions of research, innovation, teaching and service to society, which they share with UCLouvain.
www.saintluc.be

About Novadip Biosciences
Novadip is a late-stage clinical biotech company aiming at advancing the standard of care for patients undergoing bone and tissue regenerative treatment.
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 3M³ tissue regeneration technology platform, designed to create a new class of regenerative tissue products that accelerate the healing of large bone defects, bone non-union 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 non-union, 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 (€13.06bn).
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