Novadip Biosciences Receives Rare Paediatric Disease Priority Review and Orphan Disease Designation

- Dual designations granted for NVD-003 for the Treatment of Congenital Pseudarthrosis of the Tibia a serious and debilitating condition that primarily affects children
- Walloon Region Government to support the development of treatments at Novadip with €9.4 million of non-dilutive funding
- Walloon Region Minister Willy Borsus to visit Novadip Biosciences in Mont-Saint-Guibert today

Mont-Saint-Guibert, Dec 23 2020 (GlobeNewswire) - Novadip Biosciences ("Novadip"), a clinical stage company developing treatments to regenerate impaired tissues in patients with significant unmet medical needs, today announces that the U.S. Food and Drug Administration (FDA) has granted Rare Paediatric Disease designation and Orphan Drug designation for NVD-003, a cell therapy for the treatment of Congenital Pseudarthrosis of the Tibia ("CPT"), a rare but serious and debilitating condition, that primarily affects children with devastating consequences.

The Company also notes that the Walloon Region Government is providing €9.4 million of non-dilutive funding to support two programs: the next stages of development of NVD-003, the autologous program, for €5.7 million and €3.7 million to develop the allogenic program NVD-X3.

Product development of NVD-003, autologous program supported by Walloon Region for €5.7 million

With the support of the Walloon Region, Novadip will be able to extend and consolidate its product platform, including NVD-003 for CPT. The Orphan Status for NVD-003, which is now recognized by the FDA, will allow Novadip to benefit from incentives such as accelerated development, regulatory support, market exclusivity and reduced registration costs. It will also facilitate access to broader clinical indications that are attractive in terms of market potential.

Novadip has demonstrated the potential of its technology in CPT, including a case study in a five-year old boy who had failed prior treatments. After more than two years following implantation, a sufficient bone fusion was found that allowed the patient to walk without pain and to avoid amputation.

To fund the further development of NVD-003, an autologous therapy for CPT, the Directorate General for Economy, Employment and Research of the Walloon Region Government, will support the project with €5.7 million of non-dilutive funding to cover the phase I/IIa clinical development for congenital pseudarthrosis of the tibia (CPT) in pediatrics and the development of an optimized manufacturing process.

A clinical trial is expected to start in 2021 with all manufacturing, scientific expertise and operations to remain in Wallonia, Belgium.

Support of €3.7 million to reinforce the allogenic product, NVD-X3

Following the successful development of the Company's first autologous product already in the clinical phase with a strong characterization of its mode of action, Novadip is developing a new allogeneic product. This product is in a powder format (acellular matrix) that can be produced in large quantities and therefore proposed as a first line of treatment in large population of patients with high unmet medical need. The objective of the program is to make this product ready for clinical development.

Walloon Region Government Minister visit

To mark the occasion, the Directorate-General for Economy, Employment and Research of the Walloon Region Government, will be visiting the offices and manufacturing facilities in Mont-Saint-Guibert where these novel treatments are being produced that could potentially transform the lives of children that currently have not treatment options.

Denis Dufrane, M.D., PhD Chief Executive Officer at Novadip Biosciences, commented, "Our development program for NVD-003 reflects our recognition of the unmet medical need among all patients with CPT. We are gratified by these new designations as we continue to work towards our goal of providing the first cell therapy for the regeneration of bone tissue in children with CPT. This disease has always been amongst the most difficult to treat for orthopaedic specialists as even after several surgical treatments to fuse fractured bone, restoration of healthy bone tissue is hindered and the likelihood of a fracture occurring again is high, leading to severe problems with pain, mobility, and proper growth of the limb. We look forward to working with the FDA to determine next steps for the program in the coming months.

"The whole team at Novadip Biosciences is delighted to welcome the Minister Willy Borsus, the Directorate-General for Economy, Employment and Research of the Walloon Region Government, to our facilities in Mont-Saint-Guibert. We are honoured that he has chosen to visit our facilities and we are grateful to the Walloon Region for the non-dilutive funding they have provided us which will support growth in highly skilled employment and continue to further enhance Walloon's reputation for scientific expertise on a national and international level."

The Minister Willy Borsus said: "The biopharma sector is thriving in the Walloon region (Belgium), forming a key part of the local economy. There are around 170 companies within the sector that operate in the region with more than 15,000 jobs, including nearly 4000 in SMEs. These numbers have seen significant growth in recent years, highlighting continued momentum in the industry. It's great to see success stories, such as Novadip, emerging in this buoyant sector and we're pleased to support the development of this business, which has shown great promise for patients."

About NVD-003

NVD-003, Novadip's lead product candidate, is a clinical-stage investigational cell-based therapy and a new paradigm in regenerative medicine. Using its proprietary 3M^3 technology, stem cells from the patient obtained from only a few millilitres of fatty tissue are cultured in vitro to become a biomaterial consisting of bone forming cells embedded in their self-secreted extracellular matrix together with added hydroxyapatite particles, a mineral naturally present in bone to confer initial strength. For the physician, the product is in the form of a mouldable putty in quantities large enough to fill small as well as large bone defects (>20cm^3) using classical or minimally invasive surgery techniques without further complexities. Upon implantation, the bone-forming cells protected in their self-secreted matrix from the harsh pathological environment in the bone defect continue to mature and progressively transform the putty into normal, healthy bone.

About CPT

Congenital Pseudarthrosis of the Tibia (CPT) is a shin bone fracture that fails to heal properly on its own that is present at birth or manifests in early childhood when starting to walk. The underlying cause of CPT is not completely understood but it leads to abnormal structure of the bone tissue in the tibia, and sometimes fibula, combined with abnormal vascularization of the affected tissue. The natural history of the disease is extremely unfavourable. Despite various medical techniques to restore bone union and vasculature, the final prognosis of CPT remains poor and the risk of amputation cannot be eliminated.

About NVD-X3

NVD-X3 is a powder derived from the autologous product, NVD-003, and has been lyophilized and sterilized. This powder is intended to be used to fill small bone defects in complex environments as it contains biological factors and properties adapted to tissue regeneration in a poor environment.

About Novadip Biosciences

Novadip Biosciences is a clinical stage biopharmaceutical company leveraging its proprietary tissue regeneration technology platform 3M^3 to generate multiple product candidates to address hard and soft tissue reconstruction for patients who have limited or no treatment

options. The 3M^3 platform involves use of 3-dimensional extracellular matrix and adipose-derived stem cells to deliver highly specific growth factors and miRNAs to mimic the physiology of natural healing to create a range of products that address specific challenges in tissue regeneration. Novadip's initial focus is on reconstruction of critical size bone defects. The company is also applying its 3M^3 platform to develop truly novel off-the-shelf/allogeneic therapies addressing more prevalent tissue defects and miRNA/exosome products for broader indications. For more information, please visit www.novadip.com.

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