Novadip Biosciences
www.novadip.com

Restoring the physiology of natural healing

Novadip is designing new treatment options for critical size defects, complex small size defects and surgically inaccessible tissue with its patented 3D tissue regeneration technology platform to transform the lives of patients with unmet medical needs.

Belgian company Novadip is focused on healing damaged bone and skin tissues by restoring their natural physiology. The company already has three new classes of products based on its proprietary 3M³ microRNA (miRNA) delivery platform, which utilizes adipose-derived stem cells and their 3D extracellular matrix (ECM).

The most advanced candidate is an autologous product designed to restore critical size bone defects. When tested in two young children with congenital pseudarthrosis of the tibia (CPT) it was shown to restore normal quality of life and avoid the need for amputation (Fig. 1). "Using Novadip's technology, we were able to develop a sufficient amount (20 cm^3) of autologous product to repair the affected bone and achieve direct continuity between the tibia and the fibula, enabling the child to walk without pain," said Denis Dufrane, CEO and founder of Novadip.

Founded in 2013 as a spin-out from the Catholic University of Louvain and St Luc University Hospital, Novadip is led by a reputed management team and supported by an international Scientific Advisory Board. The company has two clinical trials underway, a pipeline of seven products and a strong IP portfolio. To date, Novadip has successfully raised €50 million in equity and debt finance since 2015.

Three product classes

The 3M³ miRNA delivery platform is based on the virtuous cycle between adipose stem cells and ECM. "Our technology is designed to improve the release of specific miRNA from differentiated stem cells, which are integrated in a complex ECM in a 3D manner—it's really the interactions between the cells and the matrix that is the key," said Denis Dufrane.

By varying the culture conditions and type of particle used, Novadip can also control the profile of miRNA release and create various 3D scaffold-free products, such as bone, skin, cartilage and skeletal muscle products (Fig. 2). The autologous cell products comprise cells, ECM, growth factors and miRNAs, and are designed to restore large tissue defects (>15 cm^3). The product is implanted directly in the affected tissue for critical size bone or skin reconstruction, in order to restore continuity with viable tissue.

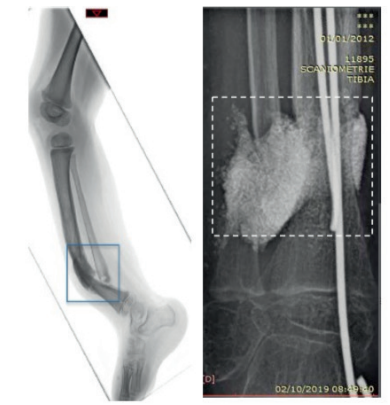

Fig. 1 | Novadip's candidate autologous product. The candidate product has restored normal quality of life in a child with congenital pseudoarthrosis of the tibia (CPT). Before treatment (left) the child was unable to walk. Complete bone fusion between the tibia and new bone formations was achieved at 24 months after implantation (right).

An off-the-shelf allogeneic product line is being developed to treat defects in smaller but more complex environments such as multi-level spinal fusion, maxillofacial fractures, diabetic skin wounds and osteomyelitis. These products contain enriched ECM with the highly specific growth factors and miRNA preserved. They are in the form of a powder with biological activity and can be stored at room temperature. Novadip has demonstrated in vivo that its product candidates can promote tissue healing of bone and skin, with low immunogenicity for an allogeneic product.

Novadip is also working on a line of exosomal miRNA-based therapeutics for systemic tissue and other diseases, which is currently at an early stage of development. These products are being developed for local in situ or intravascular injection to address various potential indications, including systemic tissue diseases, such as osteoporosis and osteoarthritis, and certain solid tumors, such as osteosarcoma and melanoma. The company has isolated specific miRNAs from its autologous products and upregulated them with its 3M³ technology platform. "We have demonstrated in vitro that we can synthesize a specific pattern of miRNA into the exosome for specific cellular targets, so the next step will be in vivo proof-of-concept," said Denis Dufrane.

Positioned for growth

To date, Novadip's product candidates have been used to treat 44 patients for bone reconstructions (up to 8 years of safety and full bone restoration in the context of tumor resection) and 6 for skin reconstructions (with a complete wound closure of a critical skin size defect >250 cm^2). Novadip owns a certified good manufacturing practice (GMP) facility in Belgium and is preparing for marketing scale-out.

NVD-003 is the most advanced program with a clinical proof-of-concept (POC) trial in CPT patients due to start in 2020 and first sales in this indication expected by 2025. NVD-003 is also being tested in adults with bone non-union in an ongoing phase 1/2a trial. Finally, a clinical trial is planned for NVD-002, which has demonstrated preclinical POC for critical size skin reconstruction.

Novadip is currently seeking further capital as part of a Series B to advance its clinical programs and R&D pipeline. This will include progressing clinical development of the autologous products for bone and skin indications, clinical POC of two off-the-shelf products and further preclinical development of cell-free exosomal miRNA-based products.

The market potential across all three product lines range could be worth in excess of $10 billion with future opportunities for partnering and licensing.

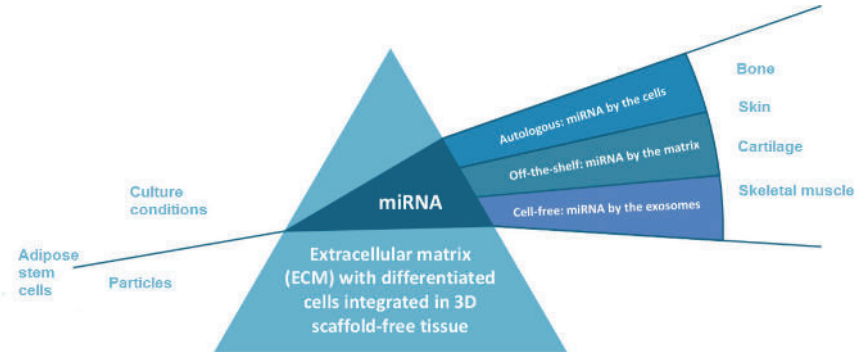

Fig. 2 | 3M³ miRNA delivery platform. By varying the culture conditions and particles, Novadip controls the profile of miRNA release through a 3D extracellular matrix. ECM, extracellular matrix; miRNA, micro RNA.

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