Small New World Laboratories *Using small things to make a big difference*

GMP-compliant EV-based biological therapeutics to combat surgery and implant-induced injury and fibrosis

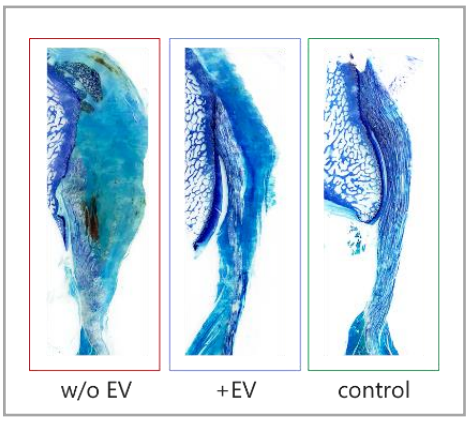
KEY WORDS: GMP-compliant, vesicles, fibrosis, regeneration, stromal cells, tendon, implant, cell-free cell therapy

INVENTION NOVELTY

Injuries, inflammation and tissue repair processes following surgical intervention or implant insertion are susceptible to foreign body reactions and fibrosis. Next generation biologics will eliminate the current shortcomings of stem cell therapies regarding personalization, dosing and side effects. Small New World Laboratories develops and manufactures GMP-compliant advanced next generation, extracellular vesicle (EV)-based biologics to improve and accelerate the endogenous healing process by suppressing inflammatory immunoreactivity and fibrosis.

VALUE PROPOSITION

Small New World Laboratories pioneer the GMP-compliant manufacturing of stromal cell-derived, EV-containing pharmaceutical preparations for ameliorating implantation- and surgery-related injuries, for improved and accelerated healing of bone fractures/defects and ruptured or inflamed tendon insertions as well as for neuroprotective intervention in the acute/subacute phase of traumatic spinal cord injuries. This allows for immediate clinical testing and evaluation.



Proof of Principle: A single injection with EVs significantly reduced fibrosis and improves tendon repair in a sheep model.

TECHNOLOGY DESCRIPTION

Fibrosis alters the normal architecture and function of the tissue and interferes with regeneration and repair. Our novel EV-based, cell-free therapeutic supports repair and regeneration via trophic support, and adenosine generation via active CD73. The proprietary EV-based biological product shows pronounced activity towards cytoprotection, immune cell modulation and the reduction of fibrosis. The product is ready for clinical testing in humans and is provided in a ready-to-use format for both direct liquid injection at the site of injury and implantation, or in combination with biodegradable supports. The manufacturing technology includes Eur. Pharm. tested MCB and WCB and a fully scalable single-step TFF pharmaceutical downstream process. This disruptive innovation has the potential to replace or augment established products, to alter current treatment modalities, and to reveal new markets.

COMMERCIAL OPPORTUNITY

The technology is available for co-development as well as for licensing.

DEVELOPMENT STATUS

The GMP-compliant off-the-shelf pharmaceutical EV preparation for immediate allogeneic application and clinical testing in patients was tested in non-clinical animal models as well as in human clinical applications. We have successfully established a pilot-scale GMP production and routinely obtain batches sufficient for successfully completing a phase II clinical trial.

PATENT SITUATION

A European patent was granted in January 2024.

FURTHER READING

Warnecke et al. (2021) J. Extracell. Vesicles | *DeLuca* et al. (2024) Stem Cell Res. Ther.

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