

Fortuna Fix Inc.

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Fortuna Fix: paradigm-shifting autologous cell therapies for neurodegenerative diseases

Fortuna Fix develops ethical, directly reprogrammed neural cell therapeutics manufactured on proprietary platform robotics allowing end-to-end manufacturing at high precision and scale.

Fortuna Fix Inc., a regenerative medicine company founded in 2015, develops ethical, next-generation technologies for neuronal repair and regeneration. The company's goal is to establish regenerative medicine as a modality that brings real solutions to neurological conditions—traumatic or degenerative—not curable with existing therapeutic approaches.

The introduction of reprogramming technologies (induced pluripotent stem cells and direct reprogramming) through the use of transcription factors allows a cell to switch from one type to another in vitro or in vivo. Direct cell reprogramming uniquely enables a patient's cells to be directly transformed into the desired multipotent or unipotent cells without involving a stage of pluripotency. These multipotent and unipotent cells are specialized cells—although not fully differentiated—and are tailored to regenerate or rebuild specific tissues following tissue degeneration or tissue loss after trauma.

Fortuna is a pioneer in this field, backed by a patented technology portfolio that includes the composition of matter for direct neural cell reprogramming. The process for manufacturing directly reprogrammed neural precursor cells (drNPCs; for which there are issued patents) is further optimized and currently fully automated for rapid scale-up and production.

Fortuna's industry-leading automated autologous cell manufacturing platform offers a significant competitive advantage

Philip Tagari, VP of research, Amgen

Unleashing the power of regeneration

Direct cell reprogramming enables the production of autologous neural precursor cells from almost any of the patient's cells (e.g. bone marrow, fat or blood) as a therapy for central nervous system diseases. Fortuna's proprietary reprogramming process, a fully enclosed ex vivo procedure, is carried out in a robotic manufacturing system over several weeks and includes the proliferation and predifferentiation of the cells. Cell reprogramming is achieved via the transient expression of reprogramming factors that are delivered to the cells using a synthetic plasmid—no animal components or viruses and genome integration

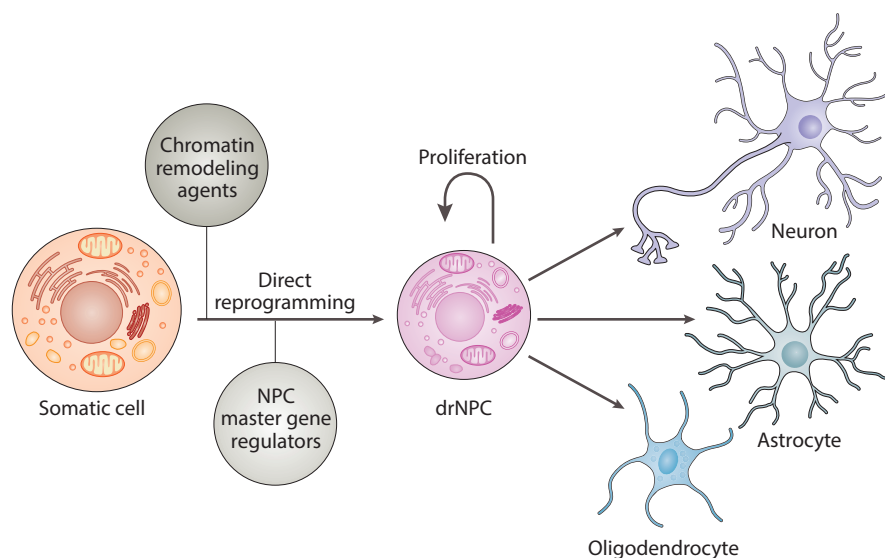


Fig. 1 | Central nervous system regeneration with direct reprogramming. Fortuna's proprietary process for rapid cell reprogramming of a patient-derived cell into any type of neural precursor cell. drNPC, directly reprogrammed neural precursor cell.

are involved. Each specific cell type to be produced, that is, for each clinical indication, has a unique set of transient transcription factors.

A key feature of Fortuna's reprogramming process is the ability of one of the reprogramming factors used in the process to relax the chromatin in the nucleosomes and thus expose the cell's DNA to the other reprogramming factors that drive the actual transformation of a somatic cell into the desired neural multipotent or unipotent cell (Fig. 1). This triggers the expression of master or regulatory genes that control the expression of a number of secondary genes that fully transform, that is, directly reprogram, the cell to the neural multipotent or unipotent cell of interest.

Stable expression of the master and secondary genes is achieved by allowing the chromatin to remodel and lock into the particular neural multipotent or unipotent epigenetic state. Once the cells have been reprogrammed, the new cells are incubated in proprietary animal origin-free reagents and media components chemically optimized for the growth of the specific neural cell of interest. Fortuna's pre-clinical pipeline of products includes autologous A9 dopaminergic neuronal precursor cells (drNPC-A9) for Parkinson's disease and oligodendroglia-biased drNPCs for spinal cord injury. "We have extensively tested the oligo-biased drNPCs in our preclinical spinal cord injury models," said Michael Fehlings, senior scientist at

Toronto's University Health Network and independent validator of Fortuna's technology. "We now are working through the last stages of translational work needed to reach clinical development," added Fehlings.

"Fortuna's industry-leading automated autologous cell manufacturing platform offers a significant competitive advantage, allowing highly reliable and reproducible production of therapeutically relevant transplantable cells," said Philip Tagari, VP of research at Amgen. "Once fully developed, their analytical technology and comprehensive final product characterization could help to enable efficient and definitive clinical development in a variety of neurological diseases."

Partnerships in cell therapy

Fortuna is looking to partner with companies and collaborators interested in direct neural cell reprogramming technologies and the automated manufacturing of cell therapies at high precision and scale.

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