Nutech Mediworld
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ReoStem
A new paradigm in allogenic stem cells

Looking for allogenic cell-based therapies?

Nutech Mediworld is addressing unmet medical needs including central nervous system disorders and dermatology indications with clinically validated allogenic stem cell therapy.

Nutech Mediworld is a clinical-stage company delivering allogenic cell-based therapeutic treatments with ready-to-use products, SCT-N and SCT-NX, based on its proprietary stem cell platform, ReoStem. While ReoStem products have been used to treat an extensive range of indications, particularly in the central nervous system field, an initial focus is likely to be the treatment of burns and/or nonhealing wounds, such as diabetic foot ulcers and bed sores. Nutech Mediworld is now looking for strategic partnerships with licensees to commercialize these products globally.

Cell therapy is increasingly seen as a viable solution to treat complex and/or unmet medical needs. As the etiology of various diseases is more deeply understood, it is apparent that intervention with traditional pharmaceuticals and the new waves of biological drugs, whilst highly targeted, will not be able to provide comprehensive medical solutions in many cases. However, while cell therapy approaches account for approximately two-thirds of regenerative medicine trials, they are not without challenges.

Indeed, although chimeric antigen receptor T cell technology has already yielded the first approved single-administration treatments—Kymriah from Novartis and Yescarta from Kite Pharma (now owned by Amgen)—they are both expensive, costing in the region of $400,000 per patient, homogenic in nature, and are potent stimulators of the immune system that could trigger life-threatening events.

Much effort has been made to utilize stem cells as potential treatments but again there are technical risks and uncertainties associated with some of the approaches currently in development. Conventional human embryonic stem cells (hESCs), derived from the inner cell mass of blastocysts, show evidence of epigenetic imprinting, such as DNA methylation, require immunosuppression and have been shown to give rise to teratomas and tumors in animal models. The epigenetic history and the molecular reprogramming involved in the production of induced pluripotent stem cells (iPSCs), dedifferentiated from adult somatic cells and genetically manipulated to trigger pluripotency, also raise concerns about their long-term safety in clinical practice. Mesenchymal stem cells (MSCs) appear to have limited stem-cell-like phenotypes, which are largely constrained to their tissue of origin, raising doubts about their widespread adoption as genuine stem cell therapies.

Targeting premorula stem cells

By focusing on human premorula stem cells (PMSCs), Nutech Mediworld believes it has developed an approach that tackles many of the challenges faced by other stem cell approaches. "PMSCs are essentially devoid of epigenetic imprinting, possess an immune-privileged phenotype, demonstrate genetic stability following the equivalent of more than 6,000 expansions from a single source, and manifest a truly elastic pluripotency," explained Geeta Shroff, the company's founder and medical director.

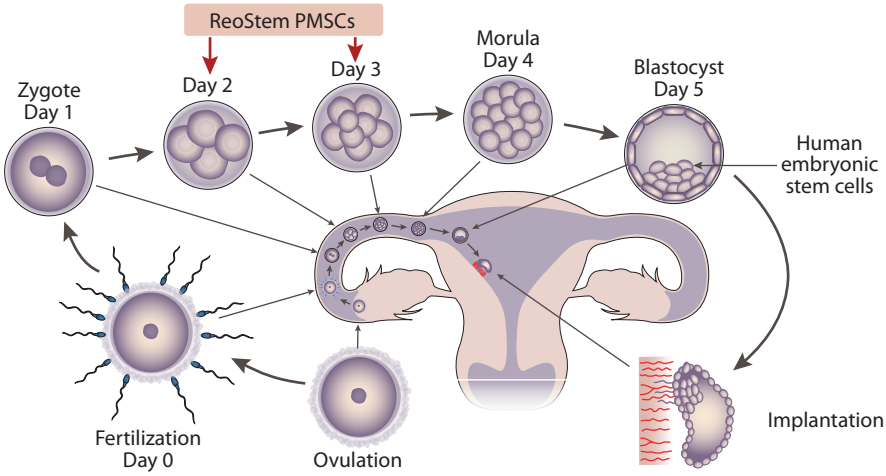

Fig. 1 | Premorula stem cells are isolated prior to the formation of the morula and the blastocyst. Clinical use of the PMSCs indicates a highly plastic regenerative phenotype consistent with their early stage of development. Source: image adapted from invitra.com (www.invitra.com/embryo-implantation-symptoms)

The ReoStem platform involves the derivation of PMSCs from a 2–3-day-stage fertilized ovum, isolated before the formation of the morula. "PMSCs are distinct from every other class of human stem cell currently in development, having been isolated at such an early stage of development. ReoStem products are universally applicable since they do not require tissue matching or the coadministration of immunosuppressive drugs. Moreover, they are safe and show no evidence of triggering teratomas, tumors, or immune reactions in recipients following longitudinal studies in more than 15 years of clinical practice," she added.

The company has developed two ready-to-use products: SCT-N, which is a preparation of ReoStem stem cells enriched for neuronal progenitor stem cells, and SCT-NX, a preparation enriched for non-neuronal progenitor stem cells. "These ready-to-use products have a shelf-life of up to 10 years. Due to the proprietary methods of expanding ReoStem PMSCs, the properties of the products represent a compelling option for allogenic cell-based treatments. Their unique profile, ease of manufacture and universal product status support a business model of global distribution and/or their storage at multiple locations and outlets. They could be used like vaccines or potentially as self-medication products such as insulin," added Shroff.

Treating a wide spectrum of indications

Nutech Mediworld was established in 1996 and has been developing the ReoStem-based treatments since 1999–2000. To date, PMSCs have been used clinically to treat more than 1,500 patients, principally for conditions such as spinal cord injury (294), neurodegenerative disorders (237), cerebral palsy (159), chronic Lyme disease (119), brain injuries including stroke (111), diabetes mellitus (110), muscular dystrophies (106), osteoarthritis of the knees (60), and vision disorders (50). However, whilst the company sees neurological conditions as a major target for PMSCs, Shroff believes they have high potential as near-term treatments of skin disorders and nonhealing wounds.

"We propose to license rights to ReoStem-derived products initially for the treatment of burns and nonhealing wounds. Clinical trials in skin conditions offer not only a straightforward trial design but also represent a significant group of unmet medical needs. The global market for diabetic foot ulcers and skin replacement products is worth some $850 million and there is a clear gold standard—Allergan's Alloderm regenerative tissue matrix represents 35% of the market—to target," she added.

contact
Geeta Shroff, Founder and Medical Director
Nutech Mediworld
New Delhi, India
Tel: +91-9811031012
Email: geeta.shroff@ntmw.net