Novo Biosciences

Unlocking Our Regenerative Power™

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Company: Novo Biosciences is a late-stage, preclinical drug discovery and development company changing the paradigm in regenerative medicine. We develop first-in-class small molecule therapies that reactivate intrinsic tissue regenerative capacity to treat age-related degenerative changes, rare degenerative diseases and traumatic injuries.

Biology Problem: The genetic pathways required for repairing and regenerating complex tissues and organs injured by disease and trauma are encoded in our genomes. Regeneration fails because this regenerative capacity declines rapidly during postnatal development and aging.

Technology Problem: Effective tissue and organ regeneration requires the coordinated function and regulation of multiple cellular processes including immune system responses, metabolism, cell proliferation and cell differentiation. Stem cell transplants bypass these coordinated processes and have failed as a therapeutic approach despite over 20 years of intensive R&D.

Solution: Novo Biosciences' proprietary scientific platform employs an integrative understanding of regenerative biological processes and has identified multiple new therapeutic targets and associated IP. Our lead drug candidate, MSI-1436, slows and reverses chronic degenerative changes and stimulates regeneration of heart, skeletal muscle, skin, bone, nerve, connective and vascular tissues following acute injury.

Mechanism: MSI-1436 targets a master regulator of signaling networks that control multiple regenerative cellular processes. Inhibition of this target activates these networks and the intrinsic tissue regeneration mechanisms they control.

Multiple Indications: MSI-1436 has implications for the treatment of multiple injury types and age-related and rare degenerative diseases. It reverses acute ischemic heart injury (a $130B U.S. market) in mice and slows and reverses degeneration of heart and skeletal muscle in a mouse Duchenne muscular dystrophy (DMD) model.

Initial Indication: Novo Biosciences is initially pursuing MSI-1436 to reverse heart and skeletal muscle degeneration in DMD, a rare genetic disease characterized by progressive muscle degeneration and greatly shortened lifespan. Effective treatment options are limited to steroid therapy. Most patients lose the ability to walk by their early teens and die from heart or respiratory failure as young adults.

Market: DMD is designated as an orphan disease. Annual U.S. healthcare costs for treating DMD are >$500M. The global DMD drug market size is expected to reach $4 billion by 2023 with a CAGR of 41.3%.

Study Results: MSI-1436 has demonstrated safety in previous human Phase 1 clinical trials. It activates tissue regeneration at doses 50-times lower than the maximum well-tolerated human dose. In a mouse DMD model, MSI-1436 prevents and reverses chronic heart and skeletal muscle injury caused by dystrophin mutations. Per the FDA, these and other efficacy data are sufficient to support a DMD IND application.

Development Stage: Previously demonstrated safety in adult humans, preclinical efficacy in mouse models and a successful FDA pre-IND review are complete. Dosing regimen studies for Phase 1 trials in DMD patients are underway. Efficacy studies replicating heart attack and recovery in a pig ischemia/reperfusion model are ongoing with early promising results.

Competition: Development of small molecule drug therapies represents <5% of ongoing regenerative medicine R&D efforts. MSI-1436 is the only small molecule shown to reverse heart damage in acute and chronic injury settings.

Intellectual Property: Protected by U.S., European, and Japanese patents. Additional patent applications are pending.

Business Profile

URL: www.novobiosciences.com
Industry: Regenerative Medicine/ Small Molecule Therapeutics
Employees: 3
Founded: 2013

Contact

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Financial Information

Development Stage: Late preclinical
Capital Raised: $2.5M
Funding Stage: Seeking Series A
Capital Seeking: $8-9M

Founders and Management

- **Kevin Strange, Ph.D.**, CEO, cofounder, coinventor
- **Voot Yin, Ph.D.**, CSO, cofounder, coinventor

Advisory Board

- **Jean-Michel Brunel, Ph.D.**, Prof. of Integrative Structural & Chemical Biology, Aix Marseille Université
- **Richard Lee, M.D.**, Prof. of Stem Cell & Regenerative Biology, Harvard
- **Tom Rando, M.D.**, Ph.D., Prof. of Neurology, Stanford
- **David Jolly, Esq.**, General Counsel, former U.S. congressman

Strategic Partners

Cascade Chemistry – CMC development, CGMP synthesis and manufacturing
Cure Duchenne and **TREAT-NMD TACT** - Drug development and clinical trials expertise

Funding

NIGMS, NHLBI, NIDDK, DoD, foundations, and private investment

Referral

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