ATHERSYS - GLOBAL LEADER IN CELL THERAPY

About

Athersys is a clinical-stage biotech company developing MultiStem, a proprietary allogeneic cell therapy for critical health issues.

- Athersys holds approximately 400 patents covering the MultiStem technology composition of matter, disease indications, and large-scale manufacturing in key countries
- We retain global rights to our technology, excluding Japan, where we have a single partner with licensing rights for ischemic stroke and ARDS
- MultiStem has a unique, well characterized mechanism of action supported by more than 15 years of clinical and non clinical research with over 450 patients dosed and a well tolerated safety profile

Clinical Focus

We have an active phase 3 trial in ischemic stroke and phase 2 trial in Trauma. Our clinical focus is on acute critical care indications with high unmet need which cause a significant burden to patients, families and the broader health care system.

MultiStem is a platform technology that can be used to address a number of indications with minor adjustments to dosing levels and administration routes. We have an expansive portfolio of earlier-stage opportunities that are built on the same technology platform, including indications such as Graft vs Host Disease, Multiple Sclerosis, and Traumatic Brain Injury.

Ischemic Stroke

- Nearly 800,000 strokes per year in the US
- Leading cause of disability and third highest cause of death
- Over $55 billion cost to the health care system annually
- Current standard of care reaches only 30% of patients
- Phase 3 pivotal trial over 50% enrolled with anticipated commercial approval by the FDA in 2026 / 2027

Trauma

- Leading cause of death in people under 40 in the U.S
- 30 million emergency department visits in the U.S. annually
- Cost to the US health care system of $75 billion annually for car accidents, one subset of trauma
- MultiStem addresses complications that affect patients that survive the initial traumatic injury
- Phase 2 trial underway and sponsored by DoD, anticipate Phase 2 data read-out by 2025

ARDS

- 200,000 cases in the U.S. annually
- 30-50% mortality rate
- One of the leading causes of death in severe COVID-19 cases
- Notable burden to the health care system
- Few effective therapeutic modalities exist to ameliorate this deadly condition
- Completed Phase 1/2 MUST-ARDS trial in US and UK with positive results
- Healios completed open-label Phase 2 ONE-BRIDGE trial in Japan with positive results
- Healios planning a Phase 3 pivotal trial pending launch in Japan

Important Near Term Milestones

- Stroke: Interim analysis planned for September/October to determine if 300 patient size is sufficient to achieve statistical significance of the updated primary endpoint
- Trauma: Approval to initiate Cohort 3 of our Phase 2 trial, 140 patients with product utilizing our next generation bioreactor manufacturing process
- ARDS: Initiate Phase 3 trial in Japan pending PMDA approval on use of bioreactor clinical product; Decision from BARDA on application for Phase 2 trial support

Set up for Success

- New and experienced management team focused on execution and delivering results
- Lean operating structure dedicated to completing existing clinical trials and business development
- Actively pursuing development and commercialization partnerships to leverage non-core capabilities and secure non-dilutive capital

PLATFORM SUMMARY

MultiStem® Cell Therapy Platform: Ethical, Versatile & Favorable Tolerability
Adult bone marrow-derived stem cells

Off-The-Shelf Product
Allogenic, no tissue matching, IV administration of up to 1.2 billion cells per dose

Scalability, Stability & Consistent Product Quality
Single adult donor capable of generating hundreds of thousands of doses in proprietary process

Pivotal Ischemic Stroke Trial with RMAT, SPA and Fast-Track Regulatory Designations from FDA
Only ongoing Phase 3 cell therapy study in ischemic stroke, safety data in >450 patients

Platform Technology: Opportunities Across Multiple High Value Indications
Clinical, IND-ready, & development stage immune, neurological & cardiopulmonary programs

LEADERSHIP + KEY CONTACTS

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