February 20, 2024

FibroBiologics to Present Preclinical and Clinical Data at the 2024 Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum

HOUSTON, Feb. 20, 2024 /PRNewswire/ -- FibroBiologics (Nasdaq: FBLG) ("FibroBiologics") is a clinical-stage biotechnology company with 150+ patents issued and pending with a focus on the development of therapeutics and potential cures for chronic diseases using fibroblasts and fibroblast-derived materials. FibroBiologics will present in vitro and in vivo preclinical data using allogeneic human dermal fibroblasts (HDFs) and HDF spheroids as well as primary safety phase 0/1 clinical trial data for the single-dose infusion of HDFs during the poster sessions at the upcoming Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2024 on Thursday, February 29, at the Palm Beach County Convention Center and the Hilton West Palm Beach in West Palm Beach, Florida.

The National Institutes of Health describes multiple sclerosis (MS) as a T-cell-mediated autoimmune disorder in which the immune system targets and destroys the myelin sheath of axons in the central nervous system, leading to severe and progressive cognitive impairment, sensory deprivation, and weakened coordination. FibroBiologics is investigating the therapeutic potential of using HDFs as a treatment for MS through immune modulation and stimulation of myelin expression by oligodendrocytes to rebuild the damaged myelin sheath.

Extensive preclinical studies were conducted using allogeneic HDFs in the experimental autoimmune encephalomyelitis (EAE) animal model of MS. In vivo results indicated that HDFs significantly suppressed Th17 cell activation, stimulated T regulatory (Treg) cell expansion, inhibited dendritic cell maturation, reduced microglial activation, and stimulated oligodendrocyte expansion and remyelination. The results also demonstrated that administration of HDFs in the EAE model significantly enhanced Treg-dependent disease inhibition in a manner superior to adipose or bone marrow-derived MSCs.

The phase 0/1 primary-safety clinical trial studied a single-dose infusion of allogeneic HDFs into four relapsing-remitting and one secondary progressive MS patients. The primary

outcome of the safety clinical trial indicated a strong correlation for CBC, blood chemistry, and electrocardiogram data for all patients compared with pre-infusion test results, and no adverse events were reported.

"Our in vivo animal studies provided evidence that allogeneic HDFs are capable of suppressing pathogenic T cell activation, stimulating T regulatory (Treg) cell expansion, inhibiting dendritic cell maturation, and stimulating oligodendrocyte expansion and myelin protein expression," said Dr. Hamid Khoja, Chief Scientific Officer at FibroBiologics. "Based on our results to date, we are enthusiastic about the promise of HDFs for the treatment of MS, although we understand that further study is required. In pursuit of that goal, FibroBiologics is designing a phase II clinical trial to study the safety and efficacy profile of various concentrations of HDF spheroids and the effect of multiple-dose treatments over an eighteen-month study period."

Abstract Information:
Title: The Potential of Using Allogeneic Human Dermal Fibroblast Spheroids as a Biological Extended-Release Therapy for the Treatment of Multiple Sclerosis: Preclinical and Phase 0/1 Clinical Trial Results
Authors: H. Khoja, B. Jiang, P. O'Heeron
Session Title: PS1-Poster Session 1
Session Date and Time: February 29, 2024, 6:00 PM - 7:30 PM
Poster Number: P341

For more information, please visit FibroBiologics' website or email FibroBiologics at: info@fibrobiologics.com.

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voting proxy given to the Board of Directors. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and FibroBiologics assumes no obligation and, except as required by law, does not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise. FibroBiologics gives no assurance that it will achieve its expectations.

About FibroBiologics

Based in Houston, FibroBiologics is a cell therapy, regenerative medicine company developing a pipeline of treatments and potential cures for chronic diseases using fibroblast cells and fibroblast-derived materials. FibroBiologics holds 150+ US and internationally issued patents/patents pending across various clinical pathways, including disc degeneration, orthopedics, multiple sclerosis, psoriasis, wound healing, reversing organ involution, and cancer. FibroBiologics represents the next generation of medical advancement in cell therapy. For more information, visit www.FibroBiologics.com.

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