December 31, 2025

FibroBiologics Files IND Application with the U.S. FDA to Advance Clinical Development of CYPS317 in Patients with Psoriasis

HOUSTON, Dec. 31, 2025 (GLOBE NEWSWIRE) -- FibroBiologics, Inc. (Nasdaq: FBLG) ("FibroBiologics"), a clinical-stage biotechnology company with 270+ patents issued and pending with a focus on the development of therapeutics and potential cures for chronic diseases using fibroblasts and fibroblast-derived materials, today announced the filing of a Phase 1/2 Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) seeking regulatory clearance to initiate clinical trials of CYPS317, an investigational allogeneic fibroblast spheroid-based therapy for the treatment of moderate to severe psoriasis.

This IND filing represents a major advancement for FibroBiologics' chronic inflammatory disease pipeline and follows a series of positive IND-enabling preclinical results demonstrating the potential of fibroblast spheroids to significantly reduce psoriasis disease severity and relapse in preclinical models. In animal studies, a single dose of CYPS317 matched or exceeded the therapeutic effects of multiple doses of anti-IL-23 monoclonal antibodies and yielded significant reductions in disease recurrence, underscoring both the durability and immunomodulatory capacity of this approach.

FibroBiologics is pursuing a development program for CYPS317 with the goal of advancing first-in-human clinical trials following FDA review of the IND filing. The IND submission includes comprehensive preclinical pharmacology, safety, and manufacturing data supporting the therapeutic's mechanism of action, durability of effect, and safety profile.

Psoriasis is an autoimmune skin disease that affects over eight million adults in the United States alone and can significantly impair quality of life and productivity. Despite advances in biologic treatments, unmet needs remain, particularly in achieving durable responses with favorable safety profiles.

"Filing this IND application with the FDA marks a pivotal transition from preclinical research to clinical development for CYPS317 and advances our goal of achieving IND clearance for all four of our product candidates in 2026," said Pete O'Heeron, Founder and Chief Executive Officer of FibroBiologics. "Psoriasis affects millions of patients who continue to face challenges with existing therapies. We believe allogeneic fibroblast spheroid-based therapeutics have the potential not only to improve disease outcomes, but also to redefine how chronic inflammatory disorders are treated. This filing underscores our commitment to innovation, clinical rigor, and delivering real impact for patients and clinicians."

Hamid Khoja, Ph.D., Chief Scientific Officer of FibroBiologics, added: "Our preclinical data

suggest that CYPS317 harnesses unique, multi-faceted biological activity, combining extracellular matrix signaling with localized and systemic immunomodulation, which may help restore normal tissue homeostasis in chronic inflammatory conditions such as psoriasis. We are excited to work closely with the FDA as we progress this promising program toward clinical evaluation."

FibroBiologics continues to develop additional fibroblast-based therapies across a range of chronic disease indications, leveraging its differentiated platform of engineered organoids and native fibroblast spheroids and a broad intellectual property estate.

About FibroBiologics
Based in Houston, FibroBiologics is a clinical-stage biotechnology company developing a pipeline of treatments and seeking potential cures for chronic diseases using fibroblast cells and fibroblast-derived materials. FibroBiologics holds 270+ US and internationally issued patents/patents pending across various clinical pathways, including wound healing, multiple sclerosis, disc degeneration, psoriasis, orthopedics, human longevity, and cancer. FibroBiologics represents the next generation of medical advancement in cell therapy and tissue regeneration. For more information, visit www.FibroBiologics.com. For more information, please visit FibroBiologics' website or email FibroBiologics at: info@fibrobiologics.com.

Cautionary Statement Regarding Forward-Looking Statements
This communication contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements include information concerning the scope and strength of the Company's intellectual property portfolio, the potential indications for FibroBiologics' programs, the potential clinical benefits of fibroblasts and fibroblast-derived materials, plans for, and the anticipated timing of the initiation and completion of, FibroBiologics' current and future preclinical studies, clinical trials, and research and development programs, the robustness, progress, and momentum of FibroBiologics' research and development program, and plans for, and the timing of, regulatory filings. These forward-looking statements are based on FibroBiologics' management's current expectations, estimates, projections and beliefs, as well as a number of assumptions concerning future events. These forward-looking statements are not guarantees of future performance, conditions or results, and involve a number of known and unknown risks, uncertainties, assumptions and other important factors, many of which are outside FibroBiologics' management's control, that could cause actual results to differ materially from the results discussed in the forward-looking statements, including those set forth under the caption "Risk Factors" and elsewhere in FibroBiologics' annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the SEC and any subsequent public filings. Copies are available on the SEC's website, www.sec.gov. These risks, uncertainties, assumptions and other important factors include, but are not limited to: (a) risks related to FibroBiologics' liquidity and its ability to maintain capital resources sufficient to conduct its business; (b) expectations regarding the initiation, progress and expected results of FibroBiologics' R&D efforts and preclinical studies; (c) the unpredictable relationship between R&D and preclinical results and clinical study results; (d) the ability of FibroBiologics to successfully prosecute its patent applications, (e) FibroBiologics' ability to manufacture its product candidates; and (f) FibroBiologics' ability to conduct clinical trials. 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.

General Inquiries:
info@fibrobiologics.com

Investor Relations:
Nic Johnson
Russo Partners
(212) 845-4242
fibrobiologicsIR@russopr.com

Media Contact:
Liz Phillips
Russo Partners
(347) 956-7697
Elizabeth.phillips@russopartnersllc.com

Source: FibroBiologics, Inc.