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FibroBiologics Receives HREC Approval for Phase 1/2 Clinical Trial for CYWC628 for the Treatment of Refractory Diabetic Foot Ulcers

HOUSTON, Nov. 20, 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 that it has received both public and private Human Research Ethics Committee (HREC) approvals in Australia for a Phase 1/2 clinical trial evaluating CYWC628 for the Treatment of Refractory Diabetic Foot Ulcers (DFU). This approval enables enrollment of 120 patients at 10 sites across Australia. With the HREC approval and Therapeutics Goods Administration (TGA) filing now complete, FibroBiologics has secured all necessary regulatory approvals and submitted all required filings to proceed with the clinical trial.

Southern Star Research, a leading full-service Australian CRO with APAC coverage, will manage all aspects of the CYWC628 trial from start to finish. "We are honored to continue our partnership with FibroBiologics whose leadership in cell therapy and regenerative medicine truly inspires us." said Lloyd Prescott, CEO of Southern Star Research.

The approved clinical trial is a prospective, multicenter, randomized study designed to evaluate the safety, tolerability, and efficacy of FibroBiologics' investigational topically administered allogeneic fibroblast cell-based therapy, CYWC628, for the treatment of refractory DFU. Participants will receive up to 12 weeks of treatment using either standard of care (SoC) plus a low or high dose of CYWC628, or SoC alone.

The trial will assess wound healing outcomes, efficacy of response, and safety parameters through regular clinical and imaging evaluations. An interim analysis will be conducted after a predefined number of participants complete six weeks of treatment to assess primary safety and efficacy endpoints.

"We're excited to receive HREC approvals for our Phase 1/2 trial in refractory diabetic foot ulcers," said Pete O'Heeron, Founder and CEO of FibroBiologics. "This is an important milestone. It moves our fibroblast-based platform into real-world clinical testing. What we learn from this study could potentially help unlock a new class of cell therapies for chronic wounds—an area where patients have been underserved for far too long. This is exactly the kind of long-term, high-impact work that drives our mission."

In addition to confirming safety and therapeutic potential, the study is expected to provide key clinical data supporting CYWC628 as a novel, fibroblast-based cell therapy aimed at addressing a significant unmet need in chronic wound management.

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 plans for, and the anticipated timing of the initiation of and results from, FibroBiologics' clinical trials and research and development programs, and the potential clinical benefits of fibroblasts and fibroblast-derived materials. 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.

About CYWC628
CYWC628 is an investigational topically administered allogeneic fibroblast cell-based therapy for wound healing. Preclinical data suggest CYWC628 may significantly accelerate wound healing compared to currently available treatments.

FibroBiologics is conducting a prospective, multicenter, randomized clinical trial evaluating the safety, tolerability, and efficacy of CYWC628 in treating refractory diabetic foot ulcers with up to 12 weeks of treatment using either standard of care plus a low or high-dose of CYWC628, or standard of care only.

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.

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

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