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FibroBiologics Completes Site Onboarding for Phase 1/2 Clinical Trial for CYWC628 for the Treatment of Refractory Diabetic Foot Ulcers

HOUSTON, March 05, 2026 (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 onboarding of the clinical sites has been completed for its Phase 1/2 clinical trial evaluating the safety and efficacy of CYWC628 for the treatment of refractory diabetic foot ulcers (DFUs).

The clinical trial is a prospective, multicenter, open label study designed to evaluate the safety, tolerability, and efficacy of FibroBiologics' investigational topically administered allogeneic fibroblast spheroid-based therapy, CYWC628, for the treatment of refractory DFUs. 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. FibroBiologics has completed site onboarding as outlined in the protocol for the clinical trial but will activate additional sites if needed to support recruitment objectives.

"This clinical trial will assess wound healing outcomes, durability of response, and safety parameters through regular clinical observation, testing, 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," said Hamid Khoja, Ph.D., Chief Scientific Officer of FibroBiologics.

"Successfully engaging all clinical trial sites is a critical step as we advance towards trial initiation to demonstrate the potential of fibroblast spheroid-based therapies as a major breakthrough in DFU treatment," said Pete O'Heeron, Founder and Chief Executive Officer of FibroBiologics. "With site onboarding complete, our human trial partners are in place and we are now focused on disciplined execution. We look forward to generating data that can clearly inform how this therapy fits into the future of chronic wound care."

[Southern Star Research](#), a leading full-service Australian CRO with APAC coverage, is managing all aspects of the CYWC628 trial from start to finish. "The CYWC628 program is an excellent fit for Australia's ecosystem and Southern Star Research's expertise in complex early-phase trials. We look forward to generating high-quality data to support FibroBiologics' innovative fibroblast spheroid therapy for patients with refractory diabetic foot ulcers," said Lloyd Prescott, CEO of Southern Star Research.

For more information, please visit FibroBiologics' [website](#), email FibroBiologics

at info@fibrobiologics.com or follow FibroBiologics on [LinkedIn](#), [YouTube](#), [Facebook](#) or [X](#).

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 the potential clinical benefits of fibroblasts and fibroblast-derived materials, including being a major breakthrough in DFU treatment. 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) the unpredictable relationship between R&D and preclinical results and clinical study results; (c) the ability of FibroBiologics to successfully prosecute its patent applications, (d) FibroBiologics' ability to manufacture its product candidates; and (e) 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 planning a prospective, multicenter, open-label 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.

About Southern Star Research

Southern Star Research is a full-service clinical research organization headquartered in Australia, guiding small and mid-sized biotech, pharmaceutical, and medical device companies to confidently navigate complex early-phase clinical development globally. With a strong focus on quality, collaboration, and scientific excellence, Southern Star Research supports trials across a range of therapeutic areas and phases. For more information, email: media@southernstarresearch.com

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