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FibroBiologics Announces First Patients Dosed in Phase 1/2 Clinical Trial Evaluating CYWC628 for the Treatment of Diabetic Foot Ulcers

HOUSTON, June 03, 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 the first patients have been enrolled and dosed in the Company's Phase 1/2 clinical trial evaluating CYWC628 for the treatment of diabetic foot ulcers (DFUs).

A Media Snippet accompanying this announcement is available by clicking on this link.

The prospective, multicenter, randomized study is being conducted across multiple sites in Australia following receipt of both public and private Human Research Ethics Committee (HREC) approvals and completion of the required Therapeutics Goods Administration (TGA) filing. The trial is designed to enroll up to 120 patients and will evaluate the safety, tolerability, and efficacy of CYWC628, FibroBiologics' investigational topically administered allogeneic fibroblast-spheroid cell-based therapy, compared to standard of care (SoC) alone. Participants will receive up to 12 weeks of treatment using either SoC plus a low or high dose of CYWC628, or SoC alone.

"With the first patients enrolled and dosed, FibroBiologics has reached a significant milestone in advancing CYWC628 into the clinic," said Pete O'Heeron, Founder and Chief

Executive Officer of FibroBiologics. “Most chronic wound therapies are designed to manage symptoms of chronic wounds rather than actively restore the underlying biology required for repair. Our approach is different – CYWC628 is built on the idea that fibroblasts play a central role in the wound healing process, and we believe their therapeutic potential has been largely overlooked in chronic wound care. Dosing the first patients is an important step in evaluating how our platform can shift the approach to care for patients living with diabetic foot ulcers.”

“This trial represents a meaningful opportunity to demonstrate what fibroblast-spheroid-based therapies can do for patients with some of the most difficult-to-treat chronic wounds,” said Hamid Khoja, Ph.D., Chief Scientific Officer of FibroBiologics. “The data we generate from this study will be foundational, not only for CYWC628, but for our broader understanding of how fibroblast-spheroid cell therapy can be applied across chronic disease indications.”

The trial will assess wound healing outcomes and safety parameters through regular clinical and imaging evaluations. An interim analysis will be conducted after participants complete six weeks of treatment to assess primary safety and efficacy endpoints. In addition to confirming safety and therapeutic potential, the study is expected to generate key clinical data supporting CYWC628 as a novel cell therapy addressing a significant unmet need in chronic wound management.

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 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.

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