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FibroBiologics completes third cGMP batch for fibroblast therapy trial

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The CYWC628 drug product will support the companyâ??s Phase 1/2 trial in refractory diabetic foot ulcers.

FibroBiologics has completed manufacturing of the third batch of CYWC628 drug product for its ongoing Phase 1/2 clinical trial in patients with diabetic foot ulcers.

The batch was manufactured under cGMP standards and is undergoing required safety and quality testing before release for clinical use. Once released, FibroBiologics expects to have enough CYWC628 supply to complete the diabetic foot ulcer trial.

This is relevant because diabetic foot ulcers remain a major complication of diabetes and can lead to infection, hospitalisation, amputation and long-term disability. Patients with refractory wounds often have limited treatment options, and therapies that can accelerate or improve wound closure remain a significant clinical need.

CYWC628 is an investigational, topically administered allogeneic fibroblast cell-based therapy for wound healing. FibroBiologics is evaluating the candidate in a prospective, multicentre, randomised clinical trial assessing safety, tolerability and efficacy in refractory diabetic foot ulcers.

The study includes up to 12 weeks of treatment using standard of care plus either a low or high dose of CYWC628, compared with standard of care alone. This design is intended to clarify whether the allogeneic fibroblast therapy can improve outcomes beyond current wound management approaches.

The manufacturing milestone is important because cell therapies depend heavily on reliable production, quality testing and supply planning. Completing enough cGMP drug product in three batches could reduce the need for additional manufacturing runs, lowering short-term cash requirements and supporting trial continuity.

The company said an early healing trend observed in the trial positions it to have surplus doses available for future research and development initiatives. FibroBiologics also anticipates reporting statistically significant interim data in the third quarter of 2026.