

# Foot Ulcers

**Title:** A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose Range Finding Study to Evaluate the Efficacy and Safety of Intramuscular Injection of Human Placenta-Derived Cells (PDA-002) in Subjects Who Have Diabetic Foot Ulcer (DFU) With and Without Peripheral Arterial Disease (PAD).

**Purpose:** To investigate the efficacy and safety of the intramuscular (IM) injection of PDA-002 in subjects who have diabetic foot ulcer with peripheral arterial disease. The secondary objective is to evaluate potential clinical efficacy of the various doses of PDA-002 in effecting changes in assessed vascular parameters including ankle-brachial index (ABI)/toe-brachial index (TBI), transcutaneous oxygen (TcPO<sub>2</sub>) measurements, and pulse volume measurements.

**Eligibility:** Type 1 and Type 2 diabetic subjects who have DFU with PAD and an ulcer severity of Grade 1 (full thickness only) or Grade 2 on the Wagner Grading Scale (Appendix A) of greater than 1 month duration which has not adequately responded to conventional ulcer therapy.

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**Phase:** II