

Supplemental Table S1 – Inclusion/Exclusion Criteria

Inclusion criteria - A subject was enrolled in this study if he/she met the following criteria:

Male or female aged 18 years and older

Female subjects were post-menopausal or surgically sterilized

Females of child-bearing potential must have had a negative pregnancy test at screening and agree to use hormonal contraceptive or intra-uterine device or diaphragm with spermicide or condom with spermicide or abstinence throughout the study

Diabetes mellitus (type I or II) with HbA_{1c} < 10%

Diagnosis of neuropathic foot ulcer

Cutaneous, full thickness (University of Texas grade A1), below ankle surface ulcer between 0.5 cm² and 40 cm² post debridement

A viable, granulating wound as per Investigator's discretion

Ulcer Present for at least 4 weeks prior to Screening

Ankle brachial pressure index (ABPI) between 0.7 and 1.3 measured at Screening

Signed informed consent form

Exclusion criteria - A subject was not considered eligible for the study if he/she met any of the following criteria:

Decrease or increase in the ulcer size by 30% or more during the 7 day screening period

Cannot tolerate the off-loading method or comply with SOC

An ulcer which showed signs of severe clinical infection

The ulcer to be treated required operative debridement

An ulcer positive for β -hemolytic streptococcus upon culture

Requirement for total contact casts

The ulcer had more than 50% slough, significant necrotic tissue, bone, tendon, or capsule exposure

Highly exuding wounds (wounds that require a daily dressing change)

Ankle brachial pressure index (ABPI) <0.7 or >1.3 or ankle systolic pressure < 70 mm Hg

Subjects with active systemic infections

Met one of the following (only 1 out of 3 tests was required)

- On Doppler waveform analysis on the dorsalis pedis and posterior tibial arteries a monophasic or biphasic flow (with loss of reverse flow) in either foot artery
- A toe: brachial index <0.7 or >1.3
- Transcutaneous oxygen pressure <40 mm Hg

Presence of an active systemic or local cancer or tumor of any kind (with the exception of non-melanoma skin cancer)

Subjects with congestive heart failure; New York Heart Association class II – IV or coronary heart disease with ST segment elevation, myocardial infarction, or coronary artery bypass graft or percutaneous transluminal coronary angioplasty within the last 6 months

Subjects with active osteomyelitis of the study foot

Subjects with active connective tissue disease

Subjects with acute Charcot's neuro-arthropathy as determined by clinical and/or radiographic examination

Subjects with active treatment with systemic corticosteroids

Previous or current radiation therapy to the distal lower extremity or likelihood to receive this therapy during study participation

Pregnant or nursing subjects

Subjects with uncontrolled anemia (Hb < 10 g/dL in females and < 12 g/dL in males)

Subjects with estimated glomerular filtration rate (eGFR) < 25 mL/min

Subjects with poor nutritional status defined as albumin < 25 g/L

Subjects with significant peripheral edema as per Investigator's discretion

Known prior inability or unavailability to complete required study visits during study participation

A psychiatric condition (e.g., suicidal ideation) or chronic alcohol or drug abuse problem, determined from the subject's medical history, which, in the opinion of the Investigator, may pose a threat to subject compliance

Use of a platelet derived growth factor within the 28 days prior to Screening

Use of any investigational drug or therapy within the 28 days prior to Screening

Any other factor which may have, in the opinion of the Investigator, compromised participation and follow-up in this study