RHEGEN
瑞吉生物

Government of South Australia

Health
Central Adelaide
Local Health Network

Participant Recruitment Advertisement

Protocol Title: A Randomised, Double Blind, Placebo-Controlled, Single and Multiple Ascending Dose, First-in-Human Study Evaluating the Safety Tolerability, Efficacy and Pharmacokinetics of RH116 Administered Intra-Articularly in Patients with knee Osteoarthritis not Requiring Surgery

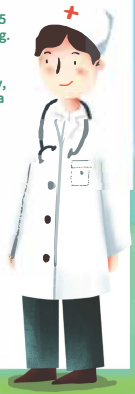
Protocol No.: RH116-RG001A-1

We are looking for adult participants aged 40-85 years who will participate in a clinical trial to evaluate the Safety, Tolerability, Efficacy and Pharmacokinetics of RH116.

RH116 is mRNA based DMOAD encoding the fibroblast growth factor 18 (FGF18) gene, it can reduce pain and has the potential to promote cartilage growth and repair and to be a therapeutic option for patients with OA. The nonclinical pharmacology study has demonstrated that RH116 could reduce pain and increase cartilage thickness, and the toxicity study shows that RH116 is well tolerated and it is safe for use. The study has been approved by Central Adelaide Local Health Network Human Research Ethics Committee(CALHN HREC).

Basic requirements for you to participate in this study:

1. No major knee surgery (e.g., partial or total knee replacement, interventional arthroscopy) in the target knee planned for at least 12 months after first injection of the study drug.
2. Primary femorotibial OA according to American College of Rheumatology (ACR) clinical and radiographic criteria (radiography which to confirm OA diagnosis must be within 6 months prior to Screening).
3. Radiologically grading of 2 or 3 and a minimum joint space width (JSW) of ⩾ 2.5 mm in the medial compartment in the target knee, obtained during Screening.



If you meet the above requirements and are voluntarily participating in this study, you can contact the study doctor below for details. Your doctor will give you a detailed explanation and assessment.

Hospital _____

Doctor name : _____

Clinic time : _____

worktime telephone: _____