ADMIRE-CD II Clinical Trial

University of California, Irvine | UCLA-UCI Alpha Stem Cell Clinic

**Study Title:** A phase III, randomized, double blind, parallel group, placebo controlled, international, multicentre study to assess efficacy and safety of Cx601, adult allogeneic expanded adipose-derived stem cells (eASC), for the treatment of complex perianal fistula(s) in patients with Crohn’s disease over a period of 24 weeks and a follow-up period up to 52 weeks. ADMIRE-CD II study.

**Lead Investigator:** Nimisha K. Parekh, MD

**Study Sponsor:** TIGENIX, S.A.U., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited.

What is the study?

The purpose of this study is to confirm how well Cx601 works compared to a placebo, and how safe and tolerable Cx601 is compared to placebo for the treatment of complex perianal fistula(s) in subjects with Crohn’s disease.

How long will my participation last?

Study participation will last approximately 15 months from the screening period.

How can I take part in this trial?

Approximately 554 subjects will participate across all sites. UC Irvine will enroll up to 10 subjects.

*Please note this may not be a complete list of eligibility criteria.*

**Main Inclusion Criteria**

* Adults between the ages of 18 and 75 years of age
* Subjects with Crohn’s disease diagnose at least 6 months prior to screening.
* Presence of complex perianal fistula(s)

**Main Exclusion Criteria**

* Active, uncontrolled infection requiring parenteral antibiotics.
* Any prior invasive malignancy diagnosed within the last 5 years prior to Screening visit.
* Unable to undergo MRI
* Pregnant or breastfeeding

How does it work?

Cx601 is a solution containing human expanded adipose-derived stem cells (eASC) obtained from healthy donors. The study drug has shown the potential to aid the immune system in some non clinical studies.

Where is the study conducted?

At the University of California, Irvine Medical Center located in Orange, CA.

Will I be compensated?

Participants will not be compensated.

For more information, please contact:

**UC Irvine Alpha Stem Cell Clinic**

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