

Long-term Follow-up (LTFU) of Patients Treated With Genome-edited Autologous Hematopoietic Stem and Progenitor Cells (HSPC)

Last Update: May 23, 2024

Long-term Follow-up (LTFU) of Patients Treated With Genome-edited Autologous Hematopoietic Stem and Progenitor Cells (HSPC)

ClinicalTrials.gov Identifier:

NCT06155500

Novartis Reference Number: CADPT03A12001

See if you Pre-qualify

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

CADPT03A12001 is a prospective, multi-center study that is designed to follow all enrolled patients who have received treatment with OTQ923 for long-term safety and efficacy. This study is monitoring patients treated with OTQ923, an investigational drug product of ex vivo genome-edited autologous hematopoietic stem and progenitor cells (HSPCs) that induces fetal hemoglobin (HbF) production, for a total of 15 years following infusion to monitor long-term safety and efficacy.

Condition

Sickle Cell Disease

Overall Status

Recruiting

Number of Participants

5

Start Date

Apr 16, 2024

Gender

All

Age(s)

18 Years - (Adult, Older Adult)

Interventions

Other

OTQ923

There is no treatment allocation. Patients administered were OTQ923 while enrolled on the treatment protocol CADPT03A12101 (NCT04443907)

Eligibility Criteria

Inclusion Criteria:

1. Accepted invitation to join based on prior treatment with gene therapy.
2. Patients must provide informed consent prior to their entry into this study.

Exclusion Criteria:

- 1\ Completion of less than 1 year of safety follow-up in the treatment protocol (CADPT03A12101)

United States

St Jude Childrens Rsrch Hospital

Recruiting

Memphis,Tennessee,38105-3678,United States

Akshay Sharma

Melissa Parrish

Email: Melissa.Parrish@STJUDE.ORG

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

Novartis Pharmaceuticals

Phone: [1-888-669-6682](tel:1-888-669-6682)

Email: novartis.email@novartis.com

Source URL: <https://prod1.novartis.com/clinicaltrials/study/nct06155500>

List of links present in page

1. <https://clinicaltrials.gov/ct2/show/NCT06155500>
2. [#trial-eligibility](#)
3. <mailto:Melissa.Parrish@STJUDE.ORG>
4. <tel:1-888-669-6682>
5. <mailto:novartis.email@novartis.com>