

Long-term Efficacy, Safety and Tolerability of Iptacopan in C3G or IC-MPGN

Last Update: Aug 11, 2025

An Open-label, Non-randomized Extension Study to Evaluate the Long-term Efficacy, Safety and Tolerability of Iptacopan (LNP023) in C3 Glomerulopathy or Idiopathic Immune-complex-membranoproliferative Glomerulonephritis

ClinicalTrials.gov Identifier:

[NCT03955445](#)

Novartis Reference Number:CLNP023B12001B

[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

This is an open-label extension study to evaluate the long-term efficacy, safety and tolerability of iptacopan in subjects with C3 glomerulopathy or idiopathic immune-complex-membranoproliferative glomerulonephritis. The primary purpose of this extension study is to collect long-term efficacy, safety and tolerability data in eligible participants receiving open-label iptacopan after completing treatment in the C3G Phase 2 proof of concept study CLNP023X2202.

The primary (at 9 months) and longer-term (>9 months) efficacy and safety data of iptacopan collected from CLNP023X2202 participants will be used to support health authority submissions.

This umbrella protocol will also allow:

- * continued access to iptacopan to patients enrolled in the ongoing Phase 3 programs (C3G and IC-MPGN)
- * C3G study (CLNP023B12301): adults and adolescents
- * IC-MPGN study (CLNP023B12302): adults and adolescents
- * provision of additional efficacy and safety information following longer-term treatment in C3G and IC-MPGN populations to support health authority submissions.

Efficacy and safety assessments at the 9 month visit of this extension study in combination with data from CLNP023X2202 (baseline plus 3 months of treatment) allowed evaluation of the effects of iptacopan on potential endpoint(s) at 12 months of iptacopan treatment in C3G participants. The enrollment of C3G and IC-MPGN participants (adults and adolescents) from Phase 3 studies, CLNP023B12301 and CLNP023B12302, permits longer-term evaluation of the persistence of effects observed after iptacopan treatment. These longer term efficacy and safety assessments may be compared to historical/concurrent control data available from relevant real world databases in C3G or IC-MPGN patients and used as supportive information for registration purposes.

This extension study is expected to continue until the drug product becomes commercially available and accessible (anticipated to be up to approximately 168 months from the first patient first visit date), or the

benefit-risk profile is no longer positive, or the program is discontinued for business or strategic reasons.

"Baseline" refers to the Day 1 visit (pre-dose) of CLNP023X2202, CLNP023B12301 or CLNP023B12302, whereas the Day 1 visit for this C3G/IC-MPGN extension study (CLNP023B12001B) is identified as "Extension Day 1".

Condition

C3 Glomerulopathy, Immune-complex-membranoproliferative Glomerulonephritis

Phase

Phase3

Overall Status

Recruiting

Number of Participants

225

Start Date

Oct 03, 2019

Completion Date

May 30, 2036

Gender

All

Age(s)

12 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Drug

LNP023

LNP023 capsules

Eligibility Criteria

Inclusion Criteria:

- Patients must have completed the treatment period of the CLNP023X2202, CLNP023B12301 or CLNP023B12302 study on study drug

Exclusion Criteria:

* Severe concurrent co-morbidities, e.g. advanced cardiac disease (NYHA class IV), severe pulmonary arterial hypertension (WHO class IV), or any illness or medical condition that in the opinion of the investigator and sponsor is likely to prevent the patient from safely tolerating LNP023 or complying with the requirements of the study

* Participants with an active systemic bacterial, viral or fungal infection within 14 days prior to screening, or the presence of fever $\geq 38^{\circ}\text{C}$ (100.4°F) within 7 days prior to screening.

* History or current diagnosis of ECG abnormalities indicating significant risk of safety for subjects

* History of HIV or any other immunodeficiency disease

Other protocol-defined inclusion/exclusion criteria may apply

Argentina

Novartis Investigative Site

Recruiting

Buenos Aires,W3400abh,Argentina

Brazil

Novartis Investigative Site

Recruiting

Botucatu,Sao Paulo,3880-1001,Brazil

Novartis Investigative Site

Recruiting

Belo Horizonte,MG,30150-221,Brazil

Novartis Investigative Site

Recruiting

Sao Paulo,SP,04038-002,Brazil

Novartis Investigative Site

Recruiting

Porto Alegre,RS,90035-074,Brazil

China

Novartis Investigative Site

Recruiting

Beijing,100034,China

Novartis Investigative Site

Recruiting

Shanghai,200040,China

France

Novartis Investigative Site

Recruiting

Montpellier 5,34295,France

Novartis Investigative Site

Recruiting

Paris,75015,France

Novartis Investigative Site

Recruiting

Toulouse,31054,France

Germany

Novartis Investigative Site

Recruiting

Mainz,55131,Germany

Novartis Investigative Site

Recruiting

Essen,45147,Germany

Novartis Investigative Site

Recruiting

Hamburg,20246,Germany

Greece

Novartis Investigative Site

Recruiting

Heraklion Crete,71110,Greece

Israel

Novartis Investigative Site

Recruiting

Petach Tikva,4941492,Israel

Novartis Investigative Site

Recruiting

Petach-Tikva,4920235,Israel

Italy

Novartis Investigative Site

Recruiting

Ranica,BG,24020,Italy

Novartis Investigative Site

Recruiting

Roma,RM,00165,Italy

Japan

Novartis Investigative Site

Recruiting

Ohtsu,Shiga,520-2192,Japan

Netherlands

Novartis Investigative Site

Recruiting

Leiden,Zuid Holland,2333,Netherlands

Spain

Novartis Investigative Site

Recruiting

Pamplona,Navarra,31008,Spain

Novartis Investigative Site

Recruiting

Sevilla,Andalucia,41009,Spain

Novartis Investigative Site

Recruiting

Madrid,28040,Spain

Novartis Investigative Site

Recruiting

Madrid,28041,Spain

Switzerland

Novartis Investigative Site

Recruiting

Bern,3010,Switzerland

Turkey

Novartis Investigative Site

Recruiting

Ankara,06500,Turkey

Novartis Investigative Site

Recruiting

Kocaeli,41380,Turkey

Novartis Investigative Site

Recruiting

Talas Kayseri,38039,Turkey

United Kingdom

Novartis Investigative Site

Recruiting

London,W12 0hs,United Kingdom

Novartis Investigative Site

Recruiting

Newcastle upon Tyne,Ne7 7dn,United Kingdom

United States

Childrens Hospital Colorado

Recruiting

Aurora,Colorado,80045,United States

Bradley Dixon

Claire Giachino

Phone: [+1 720 777 6895](tel:+17207776895)

Email: claire.giachino@childrenscolorado.org

Georgia Nephrology Research Inst

Recruiting

Lawrenceville, Georgia, 30046, United States

James A Tumlin

Julie Scoggin

Phone: [+1 404 645 7850#3024](tel:+14046457850#3024)

Email: jscoggin@nephronet.com

University of Iowa Health Care

Recruiting

Iowa City, Iowa, 52242-1091, United States

Phone: [+1 319 335 7555](tel:+13193357555)

Carla Nester

Col Uni Med Center New York Presby

Recruiting

New York, New York, 10032, United States

Andrew S Bomback

Brianna Ortiz

Phone: [+1 212 304 5684](tel:+12123045684)

Email: bo2323@cumc.columbia.edu

Worldwide Contacts

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

Novartis Pharmaceuticals

Phone: [+41613241111](tel:+41613241111)

Email:

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/nct03955445>

List of links present in page

1. <https://clinicaltrials.gov/ct2/show/NCT03955445>
2. [#trial-eligibility](#)
3. [tel:+1 720 777 6895](tel:+17207776895)
4. <mailto:claire.giachino@childrenscolorado.org>
5. [tel:+1 404 645 7850#3024](tel:+14046457850#3024)
6. <mailto:jscoggin@nephronet.com>
7. [tel:+1 319 335 7555](tel:+13193357555)
8. [tel:+1 212 304 5684](tel:+12123045684)
9. <mailto:bo2323@cumc.columbia.edu>
10. <tel:+41613241111>
11. <mailto:>
12. <tel:1-888-669-6682>
13. <mailto:novartis.email@novartis.com>