Long-term Follow-up of Patients With Spinal Muscular Atrophy Treated With OAV101 in Clinical Trials

Last Update: Dec 10, 2024
Long-term Follow-up of Patients With Spinal Muscular Atrophy Treated With OAV101 IT or OAV101 IV in Clinical Trials
ClinicalTrials.gov Identifier:
NCT05335876
Novartis Reference Number:COAV101A12308
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 a global, prospective, multi-center study that is designed to assess the long-term safety and efficacy of OAV101 in patients who participated in an OAV101 clinical trial. The assessments of safety and efficacy in Study COAV101A12308 will continue for 5 years after enrollment in this study. The study is comprised of a Baseline Visit and 2 Follow-up Periods. For Follow-up Periods 1 and 2, which includes Baseline through Year 5 visits, assessments will be performed at the Investigational site. For the first 2 years (Follow-up Period 1), visits will occur every 6 months. For Years 3 to 5 (Follow-up Period 2) follow-up visits will be conducted annually. All patients will enter the study at the baseline visit and continue for 5 years.

Condition
Spinal Muscular Atrophy (SMA)
Phase
Phase3
Overall Status
Recruiting
Number of Participants
175
Start Date
Dec 19, 2022
Completion Date
Jun 26, 2030
Gender
All
Age(s)
0 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Biological

onasemnogene abeparvovec

Onasemnogene abeparvovec is a non-replicating recombinant adeno-associated virus serotype 9 containing the human survival motor neuron gene under the control of the ytomegalovirus enhancer/chicken β-actin-hybrid promoter. Onasemnogene abeparvovec is administered as a one-time intravenous (IV) infusion or intrathecal (IT) injection. Dosage determined by participant weight.

Eligibility Criteria

Inclusion Criteria:

1. Participated in an OAV101 clinical trial.
2. Written informed consent must be obtained before any assessment is performed.
3. Patient/Parent/legal guardian willing and able to comply with study procedures.

Exclusion Criteria:

There are no exclusion criteria for this study.

Australia

Novartis Investigative Site

Recruiting

Randwick,New South Wales,2031,Australia

Belgium

Novartis Investigative Site

Recruiting

Leuven,3000,Belgium

Canada

Novartis Investigative Site

Recruiting

Montreal,Quebec,H4a 3j1,Canada

China

Novartis Investigative Site

Recruiting

Chongqing,Chongqing,400010,China

Novartis Investigative Site

Recruiting

Guangzhou,Guangdong,510623,China

Novartis Investigative Site

Recruiting

Chengdu,Sichuan,610041,China

Novartis Investigative Site

Recruiting

Beijing,100069,China

Novartis Investigative Site

Recruiting

Beijing,100034,China

Denmark

Novartis Investigative Site

Recruiting

Copenhagen,2100 o,Denmark

France

Novartis Investigative Site

Recruiting

Bron Cedex,69677,France

Novartis Investigative Site

Recruiting

Toulouse Cedex,31059,France

Novartis Investigative Site

Recruiting

Garches,92380,France

Novartis Investigative Site

Recruiting

Strasbourg,67000,France

Italy

Novartis Investigative Site

Recruiting

Roma,RM,00168,Italy

Japan

Novartis Investigative Site

Recruiting

Kurume city,Fukuoka,830-0011,Japan

Novartis Investigative Site

Recruiting

Shinjuku ku,Tokyo,162 8666,Japan

Malaysia

Novartis Investigative Site

Recruiting

Kuala Lumpur,59100,Malaysia

Novartis Investigative Site

Recruiting

Kuala Lumpur,50300,Malaysia

Netherlands

Novartis Investigative Site

Recruiting

Utrecht,3584cx,Netherlands

Saudi Arabia

Novartis Investigative Site

Recruiting

Riyadh,11211,Saudi Arabia

Singapore

Novartis Investigative Site

Recruiting

Singapore,119074,Singapore

Spain

Novartis Investigative Site

Recruiting

Barcelona,Catalunya,08035,Spain

Taiwan

Novartis Investigative Site

Recruiting

Taipei,10002,Taiwan

Novartis Investigative Site

Recruiting

Kaohsiung,80756,Taiwan

Thailand

Novartis Investigative Site

Recruiting

Bangkok,10700,Thailand

United Kingdom

Novartis Investigative Site

Recruiting

London,Wc1n 3jh,United Kingdom

Novartis Investigative Site

Recruiting

Newcastle Upon Tyne,Ne1 4lp,United Kingdom

United States

Child Hosp Of The Kings Daughters

Recruiting

Norfolk,Virginia,23507,United States

Crystal Proud

Erin Smith

Phone: 757-668-9026
Email: erin.smith@chkd.org

Vietnam

Novartis Investigative Site

Recruiting

Hanoi,100000,Vietnam

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
Email: medinfo.gtx@novartis.com

Novartis Pharmaceuticals

Phone: +41613241111
Email: medinfoemea.gtx@novartis.com

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