Post-Authorization Safety Study for Assessment of Pregnancy Outcomes in Patients Treated With Mayzent

Last Update: May 16, 2024
Post-Authorization Safety Study for Assessment of Pregnancy Outcomes in Patients Treated With Mayzent (Siponimod): An OTIS Observational Pregnancy Surveillance Study
ClinicalTrials.gov Identifier:
NCT04933552
Novartis Reference Number:CBAF312A2403
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 study will utilize a prospective, observational, exposure cohort design to examine pregnancy and infant outcomes in women and infants who are exposed to siponimod during pregnancy to treat MS. The prevalence of each outcome in women exposed to siponimod and their infants will be compared to those observed in two unexposed comparator groups: a disease-matched comparison group of women who have not used siponimod during pregnancy but have been diagnosed with MS (disease-matched unexposed comparison group), and a comparison group of healthy women who do not have diagnosis of MS, have not had exposure to a known human teratogen, and have not taken siponimod in pregnancy (healthy comparison group). Pregnant women exposed to siponimod who do not meet the prospective cohort criteria will also be followed as part of an exposure series. All participants will be recruited via voluntary participant registration following informed consent by the pregnant woman for her participation. Participants may withdraw from the study at any time.

Condition
Multiple Sclerosis
Overall Status
Recruiting
Number of Participants
867
Start Date
Dec 15, 2021
Completion Date
May 31, 2032
Gender
Female
Age(s)
- (Child, Adult, Older Adult)

Interventions

Other

Siponimod

Prospective observational cohort study. There is no treatment allocation. Patients administered siponimod, that have started before inclusion of the patient into the study will be enrolled.

Eligibility Criteria

Inclusion Criteria:

Participants must meet all the criteria listed under the respective cohorts to enroll in that particular cohort of the registry:

Cohort 1: Siponimod-Exposed Cohort

1. Pregnant women
2. Diagnosed with MS, with the indication validated by medical records when possible
3. Exposure to siponimod for the treatment of MS, for any number of days, at any dose, and at any time from the 4th day post the first day of LMP prior to conception up to and including the end of pregnancy
4. Agree to the conditions and requirements of the study including the interview schedule, release of medical records, the dysmorphology examination of live born infants, and the Ages and Stages Questionnaire (ASQ) in live born children

Cohort 2: Disease-Matched Comparison Cohort (Comparison Group 1)

1. Pregnant women
2. Diagnosed with MS, with the indication validated by medical records when possible
3. May or may not have taken another medication for MS in the current pregnancy
4. Agree to the conditions and requirements of the study including the interview schedule, release of medical records, the dysmorphology examination of live born infants, and the ASQ in live born children

Cohort 3: Healthy Comparison Cohort (Comparison Group 2):

1. Pregnant women
2. Agree to the conditions and requirements of the study including the interview schedule, release of medical records, the dysmorphology examination of live born infants, and the ASQ in live born children

Exclusion Criteria:

Women meeting any of the following criteria will be excluded from the cohort study:

Cohort 1: Siponimod-Exposed Cohort

1. Women who have enrolled in the siponimod cohort study with a previous pregnancy
2. Women who have used siponimod for an indication other than a currently approved indication
3. Women with exposure to any of the following medications within 5 half-lives prior to conception:

* Cladribine (Mavenclad)

* Based on the US label, animal studies indicate that there is positive evidence of teratogenicity for Cladribine
* All other S1P modulators including fingolimod (Gilenya), ozanimod, etc.
* S1P modulatros are in the same class of drug as siponimod
* Teriflunomide (Aubagio)
* The teratogenicity of teriflunomide is unknown and currently under investigation
* Other anti-CD20 monoclonal antibody: same class as Kesimpta
* New medications (marketed after 2020) indicated for the treatment of MS will be evaluated for inclusion/exclusion criteria as the study progresses.
4. Retrospective enrollment after the outcome of pregnancy is known (i.e. the pregnancy has ended prior to enrollment)
5. Results of a diagnostic test are positive for a major structural defect prior to enrollment. However, women who have had any normal or abnormal prenatal screening or diagnostic test prior to enrollment are eligible as long as the test result does not indicate a major structural defect.

Cohort 2: Disease-Matched Comparison Cohort (Comparison Group 1):

1. Exposure to siponimod any time from the 4th day post the first day of LMP prior to conception up to and including end of pregnancy
2. Women with exposure to any of the following medications within 5 half-lives of conception:

* Cladribine (Mavenclad)
* S1P modulators
* Teriflunomide (Aubagio)
* Anti CD-20 monoclonal antibody New medications (marketed after 2020) indicated for the treatment of MS will be evaluated for inclusion/exclusion criteria as the study progresses.
3. Women who have enrolled in the siponimod cohort or OMB157G2403 Kesimpta cohort with a previous pregnancy
4. Retrospective enrollment after the outcome of pregnancy is known (i.e. the pregnancy has ended prior to enrollment)
5. Results of a diagnostic test are positive for a major structural defect prior to enrollment. However, women who have had any normal or abnormal prenatal screening or diagnostic test prior to enrollment are eligible as long as the test result does not indicate a major structural defect.

Cohort 3: Healthy Comparison Cohort (Comparison Group 2):

1. Exposure to Kesimpta 166 days before or to siponimod any time from the 4th day post first day of LMP prior to conception to and including end of pregnancy
2. Women who have a diagnosis of a MS or a siponimod approved indication
3. Women who have a current diagnosis of any autoimmune disease
4. Women who have first contact with the project after prenatal diagnosis of any major structural defect
5. Women who have enrolled in the siponimod cohort or Kesimpta cohort study with a previous pregnancy
6. Women treated with Mayzent or Kesimpta for non-MS indication
7. Retrospective enrollment after the outcome of pregnancy is known (i.e. the pregnancy has ended prior to enrollment)
8. Results of a diagnostic test are positive for a major structural defect prior to enrollment. However, women who have had any normal or abnormal prenatal screening or diagnostic test prior to enrollment are eligible as long as the test result does not indicate a major structural defect.
9. Women exposed to a known human teratogen during pregnancy as confirmed by the OTIS Research Center

United States

Novartis Investigative Site

Recruiting

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Worldwide Contacts

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

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct04933552*

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