Kesimpta (Ofatumumab) Pregnancy Registry

Last Update: Jan 14, 2025
Post-Authorization Safety Study for Assessment of Pregnancy and Infant Outcomes in Patients Treated With Kesimpta (Ofatumumab) Using OTIS Observational Pregnancy Surveillance Program and DMSKW Registry
ClinicalTrials.gov Identifier:
NCT05634967
Novartis Reference Number:COMB157G2403
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

The Kesimpta Pregnancy Registry is an observational, exposure cohort designed study to examine pregnancy and infant outcomes in women and infants who are exposed to Kesimpta (ofatumumab) during pregnancy to treat MS. The study is expected to enroll for approximately 7 years and follow the pregnant women and their infant(s) over a maximum of 21 months.

The study will be conducted as two sub-studies leveraging independent ongoing pregnancy registries:

* The Organization of Teratology Information Specialists (OTIS) Research Group, University of California, San Diego, USA (referred to as "OTIS") will serve as data source for the Kesimpta-OTIS sub-study;
* The German MS and pregnancy registry - Deutschsprachigen Multiple Sklerose und Kinderwunsch Register (DMSKW) at Katholisches Klinikum Bochum gGmbH, St Josef Hospital, Bochum, Germany (referred to as "DMSKW") will serve as data source for the Kesimpta- DMSKW sub-study.

Both registries will independently collect and assess data related to the pregnancy and infant outcomes of interest and provide aggregate data which will be further combined (metaanalyses) by Novartis (referred to as the Sponsor) or a designated contract research organization (CRO).

Condition
Multiple Sclerosis, Pregnancy
Overall Status
Recruiting
Number of Participants
725
Start Date
Jan 05, 2023
Completion Date
Feb 28, 2033
Gender
All
Age(s)

18 Years - 100 Years (Adult, Older Adult)

Interventions

Other

Kesimpta

Prospective non-interventional study. There is no treatment allocation. Patients participating in from the two independent sub-studies, namely the Kesimpta-OTIS sub-study and Kesimpta-DMSKW sub-study, of identical design, conducted in parallel, enrolling pregnant women (MS and non-MS) residing in US or Canada and pregnant women (MS only) from Germany respectively are eligible for enrolling to this study.

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: Kesimpta-Exposed Cohort

1. Pregnant women
2. Diagnosed with MS, with the indication validated by medical records when possible
3. Administered Kesimpta for the treatment of MS at any time from 166 days prior to the first day of the LMP, or 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 (OTIS specific), and validated developmental performance questionnaire 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 (OTIS specific), and validated developmental performance questionnaire in live born children

Cohort 3: Healthy Comparison Cohort (Comparison Group 2):Kesimpta-OTIS sub-study specific

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 validated developmental performance questionnaire in live born children

Exclusion Criteria:

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

Cohort 1: Kesimpta-Exposed Cohort

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

* Other anti-CD20 monoclonal antibody: same class as Kesimpta
* S1P modulators: same class as Mayzent
* Cladribine (Mavenclad): Based on the US label, animal studies indicate that there is positive evidence of teratogenicity for Cladribine
* Teriflunomide (Aubagio): The teratogenecity of teriflunomide is unknown and currently under investigation.
* New medications (marketed after 2021) 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 diagnostic test(s) that 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. Administered Kesimpta 166 days before the first day of LMP or anytime during pregnancy
2. Women with exposure to any of the following medications within 5 half-lives (or pharmacodynamic effect when relevant) of conception:

* Anti CD-20 monoclonal antibody
* Cladribine (Mavenclad)
* S1P modulators
* Teriflunomide (Aubagio) New medications (marketed after 2021) indicated for the treatment of MS will be evaluated for inclusion/exclusion criteria as the study progresses.

3. Women who have enrolled in the Kesimpta cohort or BAF312A2403 Mayzent 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 diagnostic test(s) that 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): Only applicable to Kesimpta-OTIS sub-study

1. Administered Kesimpta 166 days before or Mayzent 4 days after the first day of LMP or anytime during pregnancy
2. Women who have a diagnosis of a MS
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 treated with Mayzent or Kesimpta for non-MS indication
6. Retrospective enrollment after the outcome of pregnancy is known (i.e. the pregnancy has ended prior to enrollment)
7. Results of diagnostic test(s) that 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.

8. Women exposed to a known human teratogenic drugs during pregnancy

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