Long-term Safety, Tolerability and Effectiveness Study of Ofatumumab in Patients With Relapsing MS

Last Update: Nov 20, 2024

An Open-label, Single Arm, Multi-center Extension Study Evaluating Long-term Safety, Tolerability and Effectiveness of Ofatumumab in Subjects With Relapsing Multiple Sclerosis

ClinicalTrials.gov Identifier:

NCT03650114

Novartis Reference Number:COMB157G2399

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 purpose of this study is to collect long-term safety, tolerability, effectiveness and health outcomes data in eligible subjects who have participated in a Novartis ofatumumab clinical MS study.

Vaccination sub-study The purpose of this research sub-study is to find out the effects of ofatumumab on the development of antibody responses to selected vaccines and keyhole limpet hemocyanin (KLH) neo-antigen in subjects with relapsing multiple sclerosis (RMS).

COVID-19 sub-study:

The purpose of this research sub-study is to explore the immune response following Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccination in a subset of subjects on long-term ofatumumab 20 mg sc. Note: Novartis is not supplying the SARS-CoV-2 vaccine.

Condition

Relapsing Multiple Sclerosis

Phase

Phase3

Overall Status

Recruiting

Number of Participants

2060

Start Date

Dec 28, 2018

Completion Date

Sep 30, 2028

Gender

All

Age(s)

18 Years - 100 Years (Adult, Older Adult)

Interventions

Biological

13-valent pneumococcal conjugate vaccine (13-PCV)

0.5mL Vial/Syringe
Biological

23-valent pneumococcal polysaccharide vaccine (23-PPV)

0.5mL Vial/Syringe
Biological

Keyhole limpet hemocyanin (KLH) neo-antigen

1mg Vial
Biological

Ofatumumab

subcutaneous injection of 20 mg ofatumumab every 4 weeks
Biological

Seasonal Quadrivalent influenza vaccine

Seasonal 2020-2021 0.5mL Vial/Syringe (trivalent may be used where quadrivalent is not available)
Biological

Tetanus toxoid (TT) containing vaccine (Td, Tdap)

0.5mL Vial/Syringe Containing 5 limit of flocculation (LF) tetanus toxoid

Eligibility Criteria

Inclusion Criteria:

1. Must have completed a selected Novartis MS study which dosed ofatumumab 20 mg sc every 4 weeks
2. Written informed consent

Exclusion Criteria:

* Emergence of any clinically significant condition/disease during the previous ofatumumab study in which study participation might result in safety risk for the subject
* Subjects with active systemic bacterial, viral or fingal infections, or chronic infection (e.g. AIDS)
* Subjects taking medications prohibited by the protocol
* Pregnant or nursing (lactating) women Other protocol-defined inclusion/exclusion criteria may apply

Vaccination sub-study:

Inclusion criteria

1. Informed consent
2. Actively enrolled in the COMB157G2399 Study
3. 12 weeks of continuous treatment within the COMB157G2399 Study
4. prior vaccination history as per protocol-defined

Exclusion criteria

* known hypersensitivity or history of systemic allergic, neurologic or other reactions to vaccines
* allergies to egg or shellfish
* any safety findings including low IgG/IgM requiring ofatumumab interruption within 12 weeks prior to vaccination sub-study start
* any major episode of infection requiring hospitalization or treatment with intravenous antibiotics within 2 weeks of the first vaccination sub-study visit

Other protocol-defined inclusion/exclusion criteria may apply

United States

The Neuromedical Center

Recruiting

Baton Rouge,Louisiana,70810,United States

Danielle Bryant

Phone: 608-848-8900
Email: dbryant@delricht.com

Jon Olson

University of Tennessee Medical Center

Recruiting

Knoxville,Tennessee,37920,United States

Randall Trudell

Patricia Pryor

Phone: 865-305-9100
Email: patricia.pryor@amrllc.com

University of Kansas Hospital

Recruiting

Kansas City,Kansas,66160,United States

Lisa Schmidt

Phone: 913-588-0614
Email: lschmidt@kumc.edu

Sharon Lynch

Billings Clinic

Recruiting

Billings,Montana,59101,United States

Sarah Hall

Phone: 406-435-7459
Email: shall6@billingsclinic.org

Sara Qureshi

Evergreen Health Multiple Sclerosis Center

Recruiting

Kirkland,Washington,98034,United States

Amenah Al Khafaji

Phone: 425-899-0555
Email: AAAlKhafaji@evergreenhealthcare.org

Theodore Brown

Neurology Offices of South Florida PLLC

Recruiting

Delray Beach,Florida,33445,United States

Phone: 561-482-1027

Brian Costell

Neurology and Sleep Center

Recruiting

Lubbock,Texas,79410,United States

Bhupesh Dihenia

Zenaida Hernandez

<!-- THEME DEBUG -->
<!-- THEME HOOK: 'printable_pdf_header' -->
<!-- BEGIN TEMPLATE OUTPUT from 'themes/custom/polaris/templates/print/printable-header.html.twig' -->
<!-- END TEMPLATE OUTPUT from 'themes/custom/polaris/templates/print/printable-header.html.twig' -->
<!-- THEME DEBUG -->
<!-- THEME HOOK: 'printable_pdf_footer' -->
<!-- BEGIN OUTPUT from 'modules/contrib/printable/modules/printable_pdf/templates/printable-footer.html.tw
<!-- END OUTPUT from 'modules/contrib/printable/modules/printable_pdf/templates/printable-footer.html.tw

Phone: 806-722-3500
Email: zenaida.hernandez806@outlook.com

<!-- THEME DEBUG -->
<!-- THEME HOOK: 'printable_pdf_header' -->
OM TEMPLATE OUTPUT from 'themes/custom/polaris/templates/print/printable-header.html.twig' -->

University of Alabama at Birmingham

OM TEMPLATE OUTPUT from 'themes/custom/polaris/templates/print/printable-header.html.twig' -->

Recruiting

Birmingham,Alabama,35233-0271,United States

Jennifer Mahaffey

Phone: 205-502-9967
Email: jdmahaffey@uabmc.edu

Khurram Bashir

Cleveland Clinic Foundation

Recruiting

Cleveland,Ohio,44195,United States

Jeffrey Cohen

Tammy Skaramagas

Phone: 216-445-2572
Email: skaramt1@ccf.org

Wayne State University Multiple Sclerosis Clinic

Recruiting

Detroit,Michigan,48201,United States

Carla Santiago

Phone: 313-745-4220
Email: csantiago@med.wayne.edu

Jacob Rube

College Park Family Care Center

Recruiting

Overland Park,Kansas,66210,United States

<!-- THEME DEBUG -->
<!-- THEME HOOK: 'printable_pdf_footer' -->
GIN OUTPUT from 'modules/contrib/printable/modules/printable_pdf/templates/printable-footer.html.t

Jeffrey Kaplan

Kristen Giese

ND OUTPUT from 'modules/contrib/printable/modules/printable_pdf/templates/printable-footer.html.tw

Phone: 913-469-9887
Email: Kristen.giese@hcahealthcare.com

<!-- THEME DEBUG -->
<!-- THEME HOOK: 'printable_pdf_header' -->
<!-- BEGIN TEMPLATE OUTPUT from 'themes/custom/polaris/templates/print/printable-header.html.twig' -->

Rush University Medical Center

<!-- END TEMPLATE OUTPUT from 'themes/custom/polaris/templates/print/printable-header.html.twig' -->

Recruiting

Chicago,Illinois,60612,United States

Christian Holt

Phone: 312-942-8011
Email: Christian_Holt@rush.edu

Thomas Shoemaker

Hope Neurology

Recruiting

Knoxville,Tennessee,37922,United States

Sarah Waters

Phone: 865-218-6222
Email: swaters@hopeneuro.com

Sibyl Wray

North Central Neurology Associates PC

Recruiting

Cullman,Alabama,35058,United States

Christopher LaGanke

Magan Bender

Phone: 256-739-1210
Email: mbender@prn-inc.net

Lonestar Neurology of San Antonio

Recruiting

San Antonio,Texas,78258,United States

<!-- THEME DEBUG -->
<!-- THEME HOOK: 'printable_pdf_footer' -->
<!-- BEGIN OUTPUT from 'modules/contrib/printable/modules/printable_pdf/templates/printable-footer.html.tw

Ann Bass

Virginia Vazquez

<!-- END OUTPUT from 'modules/contrib/printable/modules/printable_pdf/templates/printable-footer.html.tw

Phone: +1 210 490 0016#23
Email: Virginia@lonestarneurology.net

Wesley Neurology Clinic

TOM TEMPLATE OUTPUT from 'themes/custom/polaris/templates/print/printable-header.html.twig' -->

Recruiting

Cordova,Tennessee,38018,United States

Phone: 901-866-9252

Kendrick K Henderson

Henry Ford Hospital

Recruiting

Detroit,Michigan,48202 2689,United States

Phone: 313-556-8186

Mirela Cerghet

Neuro Medical Clinic of Cenla LLC

Recruiting

Alexandria,Louisiana,71301,United States

Ariel Antezana-Antezana

Mary Rabalais

Phone: 318-443-0490
Email: mary.rabalais@intrafusion.com

Josephson Wallack Munshower Neurology P.C

Recruiting

Indianapolis,Indiana,46256,United States

Phone: +1 (317) 537-6060

Craig Edward Herrman

Jem Research Institute

ND OUTPUT from 'modules/contrib/printable/modules/printable_pdf/templates/printable-footer.html.tw

Recruiting

Atlantis,Florida,33462-6608,United States

Phone: +1 561 968 2933 302

Mark Allen Goldstein

Texas Institute for Neurological Disorders

Recruiting

Sherman,Texas,75092,United States

Phone: +1 903 893 5141#4334

Bharathy E. Sundaram

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
Email:

Novartis Pharmaceuticals

Phone: 1-888-669-6682
Email: Novartis.email@novartis.com

Source URL: *https://dev.arctic.novartis.com/clinicaltrials/study/nct03650114*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT03650114
2. #trial-eligibility
3. tel:608-848-8900
4. mailto:dbryant@delricht.com
5. tel:865-305-9100
6. mailto:patricia.pryor@amrllc.com
7. tel:913-588-0614
8. mailto:lschmidt@kumc.edu
9. tel:406-435-7459
10. mailto:shall6@billingsclinic.org
11. tel:425-899-0555
12. mailto:AAAlKhafaji@evergreenhealthcare.org
13. tel:561-482-1027
14. tel:806-722-3500
15. mailto:zenaida.hernandez806@outlook.com
16. tel:205-502-9967
17. mailto:jdmahaffey@uabmc.edu
18. tel:216-445-2572
19. mailto:skaramt1@ccf.org
20. tel:313-745-4220
21. mailto:csantiago@med.wayne.edu
22. tel:913-469-9887

23. mailto:Kristen.giese@hcahealthcare.com
24. tel:312-942-8011
25. mailto:Christian_Holt@rush.edu
26. tel:865-218-6222
27. mailto:swaters@hopeneuro.com
28. tel:256-739-1210
29. mailto:mbender@prn-inc.net
30. tel:+1 210 490 0016#23
31. mailto:Virginia@lonestarneurology.net
32. tel:901-866-9252
33. tel:313-556-8186
34. tel:318-443-0490
35. mailto:mary.rabalais@intrafusion.com
36. tel:+1 (317) 537-6060
37. tel:+1 561 968 2933 302
38. tel:+1 903 893 5141#4334
39. tel:+41613241111
40. mailto:
41. tel:1-888-669-6682
42. mailto:Novartis.email@novartis.com

<!-- THEME DEBUG -->
<!-- THEME HOOK: 'printable_pdf_header' -->
GM TEMPLATE OUTPUT from 'themes/custom/polaris/templates/print/printable-header.html.twig' -->
GM TEMPLATE OUTPUT from 'themes/custom/polaris/templates/print/printable-header.html.twig' -->

<!-- THEME DEBUG -->
<!-- THEME HOOK: 'printable_pdf_footer' -->
GIN OUTPUT from 'modules/contrib/printable/modules/printable_pdf/templates/printable-footer.html.t

ND OUTPUT from 'modules/contrib/printable/modules/printable_pdf/templates/printable-footer.html.tw