ForPatients
by Roche

Nasal Polyps

An Extension Study of Omalizumab in Participants With Chronic Rhinosinusitis With Nasal Polyps

Trial Status	Trial Runs In	Trial Identifier
Completed	14 Countries	NCT03478930 2017-003450-16 WA40169

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

Open-Label Extension Study of Omalizumab in Patients With Chronic Rhinosinusitis With Nasal Polyps

Trial Summary:

The overall purpose of this study is to evaluate the safety, efficacy, and durability of response of omalizumab in an open-label setting in adult participants with chronic rhinosinusitis with nasal polyps who completed the double-blind, placebo-controlled, Phase III studies GA39688 (NCT03280550) or GA39855 (NCT03280537). Participants will be eligible for enrollment in the study at, or within 28 days after, the Week 24 visit of Studies GA39688/GA39855. After enrollment into this open-label extension (OLE) study, participants will receive 28 weeks of dosing of omalizumab before entering a 24-week off-treatment observation phase of the study. Baseline in this OLE study is defined as the last pre-treatment measurement prior to randomization in Studies GA39688/GA39855 (i.e., baseline of Studies GA39688/GA39855). The data that will be reported from baseline to Week 24 inclusive will come from Studies GA39688/GA39855.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 75 Years	No

Inclusion Criteria:

- Ability to comply with the study protocol, in the investigator's judgment
- Participation in Study GA39688 or GA39855, including completion of endoscopy and other assessments at Week 24, without discontinuation of study drug
- Completion of eDiary daily assessments for at least 4 out of 7 days in the week prior to the Week 24 visit of Study GA39688 or GA39855
- For women of childbearing potential: agreement to remain abstinent or use acceptable contraceptive methods during the treatment period and for 60 days after the last dose of study drug

Exclusion Criteria:

- Anaphylaxis/hypersensitivity related to study drug in Study GA39688 or GA39855
- Serious adverse events related to study drug in Study GA39688 or GA39855 that the investigator or Sponsor determines may jeopardize the patient's safety if he or she continues in the study
- Uncontrolled epistaxis within Study GA39688 or GA39855
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 60 days after the last dose of omalizumab
- Any serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study