

Nasal Polyps

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

Trial Status
Completed

Trial Runs In
14 Countries

Trial Identifier
NCT03478930 2017-003450-16
WA40169

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

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
Sponsor

Phase 3
Phase

NCT03478930 2017-003450-16 WA40169
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
≥ 18 Years & ≤ 75 Years

Healthy Volunteers
No