

Healthy Volunteers Asthma

A study to find out if a new medicine, GDC-0214, is safe in healthy people and in patients with asthma

A Phase 1 study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of inhaled GDC-0214 conducted in three parts: a single-ascending dose study in healthy volunteers, a multiple-ascending dose study in healthy volunteers, and a proof-of-activity study in patients with mild asthma.

Trial Status
Completed

Trial Runs In
1 Countries

Trial Identifier

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

Trial Summary:

Healthy volunteers for Parts A ($n=34$) and B ($n=32$), and asthma patients for Part C ($n=36$) were enrolled at 2 study sites in New Zealand to evaluate the safety and tolerability of GDC-0214, a small molecule inhibitor of JAK1. All 102 participants completed the study and comprised the safety-evaluable population. Part A was a single-ascending dose study (0.15-15 mg of GDC-0214). Parts B and C were multiple-ascending dose studies (1-10 mg QD and 15 mg BID for Part B; 1-15 mg QD and 15 mg BID for Part C). Results showed GDC-0214 to be similarly tolerated in active and placebo dose groups in Parts A-C at doses of up to 15 mg BID; all adverse events (AEs) that occurred in #2 participants were all of grades 1-2. There were no deaths or serious AEs, and no discontinuations or modifications of the study treatment. The observed safety, pharmacokinetics, and pharmacodynamics data support continued development of GDC-0214 in asthma indication.

Genentech, Inc.
Sponsor

Phase 1
Phase

Trial Identifiers

Eligibility Criteria:

Gender
All

Age
 ≥ 18 years

Healthy Volunteers
Yes

ForPatients

by Roche

GDC-0214 is a new medicine intended for the treatment of patients with “Type 2 asthma”. This study investigated the effects of GDC-0214 when taken by healthy people and patients with mild asthma. Some participants got the study medicine while others got a placebo (no medicine) to compare side effects of the treatment with and without the medicine.