

# ForPatients

by Roche

## 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](https://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**  
 $\geq 18$  years

**Healthy Volunteers**  
Yes

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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.