ForPatients
by Roche

Healthy Volunteers

A study to look at how safe different doses of a new medicine (GDC-5780) were

A Phase I, Randomized, Double-Blind,#Single Ascending Dose Study#to Evaluate#the#Safety#and Pharmacokinetics#of#GDC-5780#in Healthy Subjects

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	GV43221

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

Trial Summary:

This clinical trial was done to study a new medicine called, “GDC-5780,” for the treatment of patients with “complicated urinary tract infection.” Researchers wanted to find out if it was safe to give GDC-5780 to people. Healthy people joined different dose groups. Some people in each dose group got a “placebo” treatment – with no medicine. Side effects were recorded for each dose group – for people who got GDC-5780 for those who got placebo. This was a randomized, double-blind, single ascending dose study conducted at one study center in the USA.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland) Sponsor	**Phase 1** Phase

GV43221
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	18 to 65 years	Yes

Healthy volunteers were enrolled at one study sites in the USA to evaluate the safety and tolerability of GDC-5780, an antibiotic for multidrug-resistant bacteria. Fifty-six participants joined the study and comprised the safety-evaluable population. This was a randomized, double-blind, single-ascending-dose study conducted at one study center in the USA. Results showed several people got side effects that were thought to be caused by the study medicine but were not serious. Dosing was stopped (discontinued) due to side

effects for one person who stayed in the study and completed follow-up visits. All side effects in the study went away (resolved) by the time the study ended. Other studies are planned for GDC-5780.

The purpose of this first-in-human study is: -

1. To find out how safe GDC-5780 is when given as a single dose

2. To find out how GDC-5780 will be distributed and eliminated from the body

GDC-5780 is an experimental drug, which means health authorities have not approved GDC-5780 for the treatment of any disease, and it has not been tested in people before this study.

Who can participate?

Healthy participants aged between 18 to 65 years.

What does the study involve?

Participants may be asked to be in the study for up to#40 days. This includes:

- A Screening Period of up to 28 days before the start of the study where tests will be done to check if the participants are eligible to take part in the study.
- Treatment Period where participants will#have to check in to the clinic 2 days before receiving the study treatment and will have to stay in the clinic for 5 nights and receive single#dose#of GDC-5780#or placebo (drug without an active substance).
- Follow-up Period where participants#will have#to#report#to the clinic#for a check-up#2 times,#with the last visit taking place#about 14 days after the dose of study drug.

#The first 8 participants will get a single dose of GDC-5780 or placebo as intravenous (IV) infusion (through the vein) over 2 hours. The dose for new participants joining the study will be adjusted according to the test results of previous participants. Participants joining the study at later stages will get higher doses of the study drug. All participants will be closely monitored throughout the study to ensure that the study drug is safe and tolerable. After the dose of study treatment, the study doctor will follow-up participants for 14 days.

#**What are the possible benefits and risks of participating?**

Participants will not receive any benefit from participating in this study, but the information that is learned may help people with Urinary Tract Infection in the future.#No clinical information is available for GDC-5780 to date, as this is a first-in-human#study. The expected risks for GDC-5780, determined according to the

mechanism of action and results from nonclinical studies (laboratory studies on animals) are listed below:

- Reaction during or following the drug infusion that may mimic an allergic reaction and could include symptoms such as fever, chills, rash, low blood pressure, and difficulty breathing
- Sudden decrease in kidney function
- Transient loss of muscle coordination; awkward, uncoordinated walking; or unsteadiness when walking

There may be a risk in exposing an unborn child to the study drug, and all risks are not known at this time.# Participants must take precautions to avoid exposing an unborn child to study drug.#Participants#who#are pregnant, become pregnant, or are currently#breastfeeding, cannot#take part in this study.