ForPatients
by Roche

Bacterial Infection

A study to look at how safe different doses of a new medicine called “DSTA4637S” were for patients – and how this medicine was processed through the body

Study to Investigate the Safety, Tolerability, and Pharmacokinetics of DSTA4637S in Participants With Staphylococcus Aureus Bacteremia Receiving Standard-of-Care (SOC) Antibiotics

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT03162250 2016-001880-35 GV39131

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:

A Phase IB, Randomized, Double-Blind, Placebo-Controlled, Multiple-Ascending Dose Study to Investigate the Safety, Tolerability, and Pharmacokinetics of DSTA4637S in Patients With Staphylococcus Aureus Bacteremia Receiving Standard-of-Care Antibiotics

Trial Summary:

This is a Phase Ib, randomized double-blind, placebo-controlled multiple-ascending dose study to investigate the safety, tolerability, and pharmacokinetics of multiple doses of DSTA4637S when given in addition to anti-staphylococcal SOC antibiotics to participants with methicillin-resistant staphylococcus aureus (MRSA) and methicillin-sensitive staphylococcus aureus (MSSA) bacteremia requiring at least 4 weeks of anti-staphylococcal SOC antibiotics.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT03162250 2016-001880-35 GV39131
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 80 Years	No

This clinical trial was done to study a new medicine called, “DSTA4637S”, for the treatment of patients with infections caused by bacteria named Staphylococcus aureus. This study investigated the side effects caused by this medicine. Researchers were also interested to find out what happens to the medicine inside the body of patients. Twenty-five patients with S. aureus infection took part in the study at 17 study centers in 3 countries.

Inclusion Criteria:

- Body mass index greater than or equal (>/=) 18 to less than or equal to (</=) 40 kg/m^2
- At randomization, participants must have >/=1 blood culture or molecular diagnostic that is positive for Staphylococcal aureus (S. aureus) collected in the previous 120 hours
- In the investigator's judgment, an expected treatment duration for S. aureus intravenous infection with anti-staphylococcal SOC antibiotics >/= 4 weeks

Exclusion Criteria:

- The presence of an intravascular catheter that is not planned to be removed within 96 hours of study randomization
- S. aureus bacteremia associated with an intracardiac device and/or intravascular prosthetic material (including hemodialysis access graft)
- In the investigator's judgement, S. aureus bacteremia involving infection of a prosthetic joint or vertebral hardware
- In participants with cirrhosis, a Child-Pugh Score of Class B or C
- Known rifampicin-resistant S. aureus
- Anticipated receipt of a rifamycin class (excluding rifaxamin) antibiotic from Day 1 to study completion/ discontinuation
- In the investigator's judgment, the need for emergent valve surgery at the time of randomization or a high likelihood of cardiac surgery within 3 days after randomization
- Polymicrobial bacteremia
- Participants with significant immune suppression
- Participants with evidence of liver disease
- History or presence of an abnormal electrocardiogram (ECG)
- Exposure to any biological therapy or investigational biological agent within 90 days prior to the screening evaluation or have received any other investigational treatment 30 days prior to the screening evaluation