

The AIRTIVITY™ Study: A Study to Find Out Whether BI 1291583 Helps People With Bronchiectasis

NCT06872892

Status	RECRUITING
Phase	Phase 3
Sponsor	Boehringer Ingelheim
Enrollment	1,755 participants

Key Eligibility Criteria

Inclusion (11)

- Male or female participants. Woman of childbearing potential (WOCBP) must be ready and able to use highly effective methods of birth control per International Council of Harmonisation (ICH) M3 (R2) that result in a low failure rate of less than 1 % per year when used consistently and correctly, as well as one barrier method. A list of contraception methods meeting these criteria is provided in the participant information.
 - Signed and dated written informed consent and assent, if applicable, prior to admission to the study, in accordance with GCP and local legislation.
 - Age of participants when signing the informed consent/assent ≥12 years.
 - \-- Adolescents need to weigh at least 35 kg at Visit 1.
 - Clinical history consistent with bronchiectasis (e.g. cough, chronic sputum production, recurrent respiratory infections) and investigator confirmed diagnosis of bronchiectasis by CT scan where bronchiectasis has been documented by a radiologist.
- ... and 6 more (see full listing online)

Exclusion (10)

- Any new or newly diagnosed condition of primary or secondary immunodeficiency within 1 year before randomisation.
 - Allergic bronchopulmonary aspergillosis being treated or requiring treatment.
 - Tuberculosis or non-tuberculosis mycobacterial infection being treated or requiring treatment
 - Any findings in the medical examination and/or laboratory value assessed at Screening Visit 1 or during screening period, that in the opinion of the investigator may put the participant at risk by participating in the trial.
 - Any clinically relevant (at the discretion of the investigator) acute respiratory infection or ongoing pulmonary exacerbation at screening visit or during the screening unless recovered in the opinion of the investigator prior to Visit 2.
- ... and 5 more (see full listing online)

Locations (498 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States
Providence Medical Group Alaska, Anchorage, Alaska, United States
Dignity Health, St. Joseph's Hospital and Medical Center, Phoenix, Arizona, United States
... and 495 more locations

<https://clinicaltrials.gov/study/NCT06872892>

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