A Follow-up Study to Test Long-term Treatment With Nerandomilast in People With Pulmonary Fibrosis Who Took Part in a Previous Study With Nerandomilast

NCT06238622

Status	RECRUITING
Phase	Phase 3
Sponsor	Boehringer Ingelheim
Enrollment	1,700 participants

Key Eligibility Criteria

Inclusion (3)

- Patients who completed treatment in the parent trials (1305-0014, 1305-0023, or 1305-0035) without prematurely discontinuing treatment permanently according to protocol (i.e. completed treatment with or without temporary treatment interruption)
- Signed and dated written informed consent in accordance with ICH-GCP and local legislation prior to admission to the trial
- Women of childbearing potential (WOCBP) must be ready and able to use highly effective methods of birth control per ICH M3 (R2) that result in a low failure rate of less than 1% per year when used consistently and correctly. WOCBP taking oral contraceptives (OCs) also have to ensure the use of one barrier method during sexual intercourse with their partner, e.g., condom to account for the risk of potentially reduced efficacy of the OCs in the event of severe vomiting and diarrhoea. For France, fertile males must be ready and able to use acceptable methods of birth control

Exclusion (10)

- Any disease that may put the patient at risk when participating in this trial at investigator's discretion.
- Patient exhibits suicidality, in the clinical judgment of the investigator or according to the following criteria at Visit 1:
- any suicidal behaviour (i.e. actual attempt, interrupted attempt, aborted attempt, or preparatory acts or behaviour)
- any suicidal ideation of type 4 or 5 in the Columbia-Suicide Severity Rating Scale (C-SSRS) (i.e. active suicidal thought with intent but without specific plan, or active suicidal thought with plan and intent)
- Patients with clinically relevant severe depression at investigator's discretion or a Hospital Anxiety and Depression Scale (HADS) subscore \>14 at Visit 1.

... and 5 more (see full listing online)

Locations (372 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States
University of Arizona, Tucson, Arizona, United States
University of Southern California, Los Angeles, California, United States
... and 369 more locations