A double-blind, randomized, placebo-controlled, parallel group, Phase IIa trial to evaluate safety, tolerability, pharmacokinetics, and pharmacodynamics and efficacy of BI 765423 administered intravenously on top of standard of care in patients with idiopathic pulmonary fibrosis

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- at least 40 years old - diagnosis of idiopathic pulmonary fibrosis (IPF) - women can only be included if they are unable to become pregnant i.e. post hysterectomy, bilateral salpingectomy and/or bilateral oophorectomy, or post menopausal - men who have woman of childbearing potential (WOCBP) sexual partners must use contraception - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- acute exacerbation of IPF within at least 12 weeks prior - significant cardiovascular disease such as severe hypertension, myocardial infarction, stroke, TIA - significant pulmonary hypertension - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Conditions:
Rare Diseases, Respiratory System
Keywords:
Clinics and Surgery Center (CSC), IPF, Pulmonary Fibrosis

More Information

Description: The purpose of this study is to find out if a study drug called BI 765423 can improve lung function in people with idiopathic pulmonary fibrosis (IPF). This study compares BI 765423 with a placebo to see if there is a difference in lung function or blood test results related to lung health after 3 month. The placebo looks like BI 765423 but does not contain any active drug.
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Phase: PHASE2
IRB Number: STUDY00026265

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