

## Supplementary materials

### Supplementary Table 1. Other inclusion and exclusion criteria

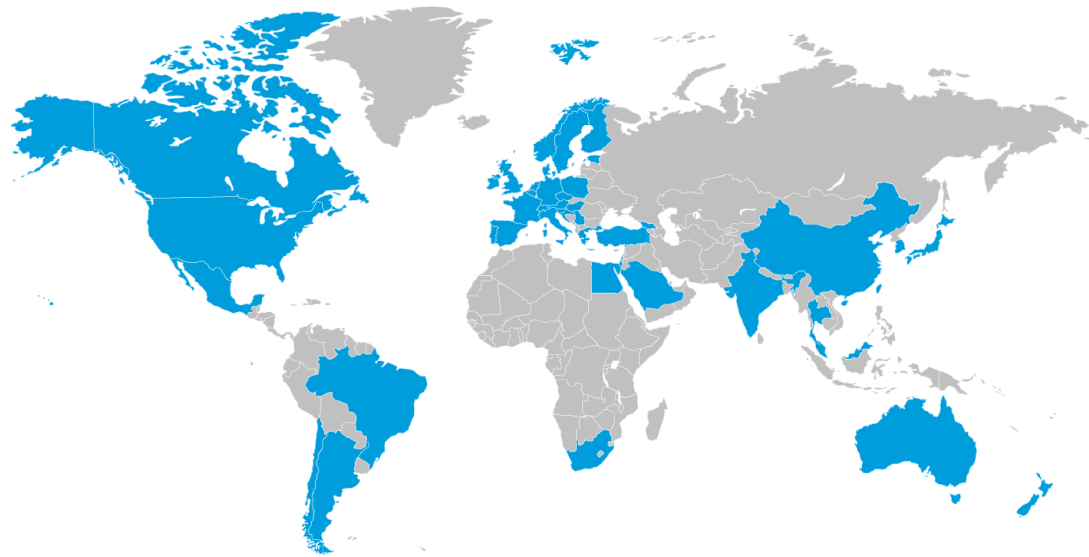
Inclusion criteria
<ul style="list-style-type: none"> <li>Adults aged <math>\geq 40</math> years</li> <li>Signed and dated written informed consent in accordance with ICH-GCP and local legislation prior to admission to the trial</li> <li>Women of childbearing potential must agree to use highly effective contraceptive methods</li> </ul>
Exclusion criteria
<ul style="list-style-type: none"> <li>Other clinically significant pulmonary abnormalities, in the opinion of the investigator</li> <li>Relevant chronic or acute infections including human immunodeficiency virus and viral hepatitis</li> <li>Major surgery (major according to the investigator's assessment) performed within 6 weeks prior to randomisation or planned during the trial period, eg, hip replacement; registration on lung transplantation list would not be considered as planned major surgery</li> <li>Any documented active or suspected malignancy or history of malignancy within 5 years prior to visit 1, except appropriately treated basal cell carcinoma of the skin, in situ squamous cell carcinoma of the skin or in situ carcinoma of uterine cervix</li> <li>Patients with underlying chronic liver disease (Child–Pugh A, B or C hepatic impairment)</li> <li>Cardiovascular diseases (severe hypertension, defined by uncontrolled/under treatment <math>\geq 160/100</math> mm Hg, on multiple occasions within 3 months of visit 1; myocardial infarction, stroke or transient ischaemic attack within 6 months of visit 1; unstable cardiac angina within 6 months of visit 1)</li> <li>Patients treated with immunomodulatory medications other than prednisone <math>\leq 15</math> mg/day or equivalent for respiratory or pulmonary reasons</li> <li>Patients who must or wish to continue the intake of restricted medications or any drug considered likely to interfere with the safe conduct of the trial</li> <li>Patients not expected to comply with the protocol requirements or not expected to complete the trial as scheduled (eg, chronic alcohol or drug abuse or any other condition that, in the investigator's opinion, makes the patient an unreliable trial participant)</li> <li>Inability to refrain from smoking on trial visit days</li> <li>History of allergy, hypersensitivity or contraindications to the class of drugs under study, including known hypersensitivity to the drug or its excipients</li> <li>Patients with a significant disease or condition other than the ILD under study, which, in the opinion of the investigator, may put the patient at risk because of participation, interference with study procedures or cause concern regarding the patient's ability to participate in the study</li> <li>Patients with positive tuberculosis test at visit 1 unless they have completed treatment for active or latent tuberculosis in line with local guidelines</li> <li>Previous randomisation in this trial or in the FIBRONEER-ILD trial</li> <li>Currently enrolled in another investigational device or drug trial, or less than 30 days since ending another investigational device or drug trial(s) or receiving other investigational treatment(s)</li> <li>Women who are pregnant, nursing or who plan to become pregnant while in the trial</li> </ul>

ICH-GCP, International Conference on Harmonisation-Good Clinical Practice; ILD, interstitial lung disease.

### Supplementary Table 2. Further endpoints

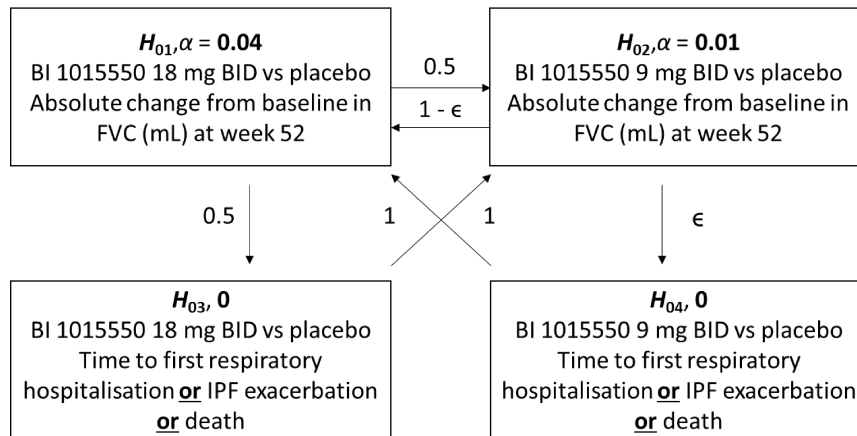
Further endpoints
<ul style="list-style-type: none"><li>• Time to first acute IPF exacerbation over the duration of the trial</li><li>• Time to absolute decline from baseline in FVC (% predicted) &gt;10% from baseline over the duration of the trial</li><li>• Time to hospitalisation for respiratory cause over the duration of the trial</li><li>• Annual rate of decline in FVC (mL/year) as measured over 52 weeks</li><li>• Absolute change from baseline in FVC% predicted at week 26</li><li>• Absolute change from baseline in FVC (mL) at week 26</li><li>• Absolute change from baseline in DLco% predicted at week 26</li><li>• Time to a relative decline from baseline in FVC% predicted &gt;10% or death over the duration of the trial</li><li>• Time to absolute decline from baseline in FVC% predicted &gt;5% or death over the duration of the trial</li><li>• Time to a relative decline from baseline in FVC% predicted &gt;5% or death over the duration of the trial</li><li>• Absolute change from baseline in L-PF Impact score at week 52</li><li>• Absolute change from baseline in L-PF Symptoms total score at week 52</li><li>• Absolute change from baseline in L-PF total score at week 52</li><li>• Change from baseline in SpO<sub>2</sub> (oxygen saturation, expressed in %) at rest at week 52</li><li>• Time to first non-elective hospitalisation for any cause or death over the duration of the study</li><li>• Time to first use of antifibrotic (rescue) therapy over the duration of the study (non-antifibrotic group)</li><li>• Annualised rate of hospitalisation for respiratory cause</li></ul>

DLco, diffusing capacity of the lung for carbon monoxide; FVC, forced vital capacity; IPF, idiopathic pulmonary fibrosis; L-PF, Living with Pulmonary Fibrosis; SpO<sub>2</sub>, blood oxygen saturation.

**Supplementary Figure 1. Countries where patient enrolment will take place**

This study will take place in Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Croatia, Czech Republic, Denmark, Egypt, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, India, Ireland, Israel, Italy, Japan, Malaysia, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Saudi Arabia, Serbia, Singapore, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, United Kingdom and United States.

**Supplementary Figure 2. Graphical testing procedure for hypothesis testing strategy of the two doses of BI 1015550 versus placebo**



$\epsilon$  is set to a negligible amount of 0.0001 at the start.

BID, two times per day; H, hypothesis; FVC, forced vital capacity; IPF, idiopathic pulmonary fibrosis.