

## Supplementary Material

**Supplementary Table 1.** Patients receiving restricted immunosuppressive medication added after baseline over 52 weeks in the Japanese population (Treated Set).

<b>Immunosuppressive agent (<i>n</i> [%])</b>	<b>Nintedanib (<i>N</i> = 34)</b>	<b>Placebo (<i>N</i> = 36)</b>
Mycophenolate	1 (2.9)	0 (0.0)
Methotrexate	0 (0.0)	0 (0.0)
Rescue treatment		
Cyclophosphamide	3 (8.8)	0 (0.0)
Azathioprine	0 (0.0)	1 (2.8)
Tacrolimus	2 (5.9)	2 (5.6)

**Supplementary Table 2.** Patients with serious adverse events reported in the Japanese population (Treated Set).

<b>Serious adverse event (<i>n</i> [%])</b>	<b>Nintedanib (<i>N</i> = 34)</b>	<b>Placebo (<i>N</i> = 36)</b>
<b>Patients with at least one serious adverse event</b>	<b>9 (26.5)</b>	<b>5 (13.9)</b>
<b>Respiratory, thoracic and mediastinal disorders</b>	<b>4 (11.8)</b>	<b>1 (2.8)</b>
Interstitial lung disease	2 (5.9)	0 (0.0)
Acute lung injury	1 (2.9)	0 (0.0)
Pneumonia aspiration	1 (2.9)	0 (0.0)
Pulmonary hypertension	1 (2.9)	0 (0.0)
Dyspnoea	0 (0.0)	1 (2.8)
<b>Hepatobiliary disorders</b>	<b>3 (8.8)</b>	<b>1 (2.8)</b>
Bile duct stone	1 (2.9)	0 (0.0)
Drug-induced liver injury	1 (2.9)	1 (2.8)
Liver disorder	1 (2.9)	0 (0.0)
<b>Infections and infestations</b>	<b>3 (8.8)</b>	<b>1 (2.8)</b>
Influenza	1 (2.9)	0 (0.0)
Lower respiratory tract infection	1 (2.9)	0 (0.0)
Pneumonia	1 (2.9)	0 (0.0)
Pyelonephritis	1 (2.9)	0 (0.0)
Cellulitis	0 (0.0)	1 (2.8)
<b>Cardiac disorders</b>	<b>1 (2.9)</b>	<b>1 (2.8)</b>
Atrial fibrillation	1 (2.9)	0 (0.0)
Atrial flutter	0 (0.0)	1 (2.8)
<b>Eye disorders</b>	<b>1 (2.9)</b>	<b>1 (2.8)</b>
Glaucoma	1 (2.9)	0 (0.0)
Rhegmatogenous retinal detachment	0 (0.0)	1 (2.8)
<b>Gastrointestinal disorders</b>	<b>1 (2.9)</b>	<b>0 (0.0)</b>
Intestinal pseudo-obstruction	1 (2.9)	0 (0.0)
<b>General disorders and administration site conditions</b>	<b>1 (2.9)</b>	<b>0 (0.0)</b>
Multiple organ dysfunction syndrome	1 (2.9)	0 (0.0)
Systemic inflammatory response syndrome	1 (2.9)	0 (0.0)
<b>Injury, poisoning and procedural complications</b>	<b>1 (2.9)</b>	<b>0 (0.0)</b>
Postoperative ileus	1 (2.9)	0 (0.0)
<b>Investigations</b>	<b>1 (2.9)</b>	<b>0 (0.0)</b>
Neutrophil count decreased	1 (2.9)	0 (0.0)
White blood cell count decreased	1 (2.9)	0 (0.0)
<b>Nervous system disorders</b>	<b>1 (2.9)</b>	<b>0 (0.0)</b>
Depressed level of consciousness	1 (2.9)	0 (0.0)
<b>Psychiatric disorders</b>	<b>1 (2.9)</b>	<b>0 (0.0)</b>
Delirium	1 (2.9)	0 (0.0)
<b>Vascular disorders</b>	<b>1 (2.9)</b>	<b>0 (0.0)</b>
Deep vein thrombosis	1 (2.9)	0 (0.0)