

Supplementary Table S7. Summary of adverse events (CTCAE v3.0) during the phase II portion

Characteristic	Treatment Group	
	Nintedanib, 200 mg bid (n = 62), n (%)	Sorafenib, 400 mg bid (n = 31), n (%)
Patients with any AE	62 (100)	31 (100.0)
Patients with investigator defined drug-related AEs	54 (87.1)	30 (96.8)
Patients with AEs leading to dose reduction of trial drug	12 (19.4)	13 (41.9)
Patients with AEs leading to discontinuation of trial drug	28 (45.2)	7 (22.6)
Patients with serious AEs	34 (54.8)	14 (45.2)
Fatal	9 (14.5)	3 (9.7)
Immediately life-threatening	2 (3.2)	0 (0.0)
Disability/incapacitating	0 (0.0)	1 (3.2)
Required hospitalization	31 (50.0)	14 (45.2)
Prolonged hospitalization	1 (1.6)	0 (0.0)
Congenital anomaly	0 (0.0)	0 (0.0)
Other	1 (1.6)	0 (0.0)
Worst CTCAE grade of AEs		
Grade 1	8 (12.9)	1 (3.2)
Grade 2	12 (19.4)	2 (6.5)
Grade 3	26 (41.9)	24 (77.4)
Grade 4	7 (11.3)	1 (3.2)
Grade 5	9 (14.5)	3 (9.7)

Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events.
NOTE. A patient may be counted in more than one seriousness criterion. Percentages are calculated using total number of patients per treatment as the denominator. MedDRA v17.0 was used for reporting.