

**Real-World Safety and Tolerability of Nintedanib in Patients with Idiopathic Pulmonary
Fibrosis: Interim Report of a Japanese Post-Marketing Surveillance Study**

Supplementary Material

Authors: Takashi Ogura¹, Yoshikazu Inoue², Arata Azuma³, Sakae Homma⁴, Yasuhiro Kondoh⁵,
Katsumi Tanaka⁶, Kaori Ochiai⁷, Yukihiro Sugiyama⁸, Toshihiro Nukiwa⁹

Affiliations: ¹Department of Respiratory Medicine, Kanagawa Cardiovascular and Respiratory Center, Kanagawa, Japan; ²Clinical Research Center, National Hospital Organization Kinki-Chuo Chest Medical Center, Osaka, Japan; ³Nippon Medical School Graduate School of Medicine, Tokyo, Japan; ⁴Department of Respiratory Medicine, School of Medicine, Toho University, Tokyo, Japan; ⁵Department of Respiratory Medicine and Allergy, Tosei General Hospital, Aichi, Japan; ⁶Patient Safety and Pharmacovigilance Department, Nippon Boehringer Ingelheim Co., Ltd., Tokyo, Japan; ⁷PMS Center, EPS Corporation, Tokyo, Japan; ⁸Division of Pulmonary Medicine, Department of Medicine, Nerima Hikarigaoka Hospital, Tokyo, Japan; ⁹Department of Respiratory Medicine, Tohoku University, Miyagi, Japan

Corresponding author: Takashi Ogura

Email: takaoguogu@gmail.com

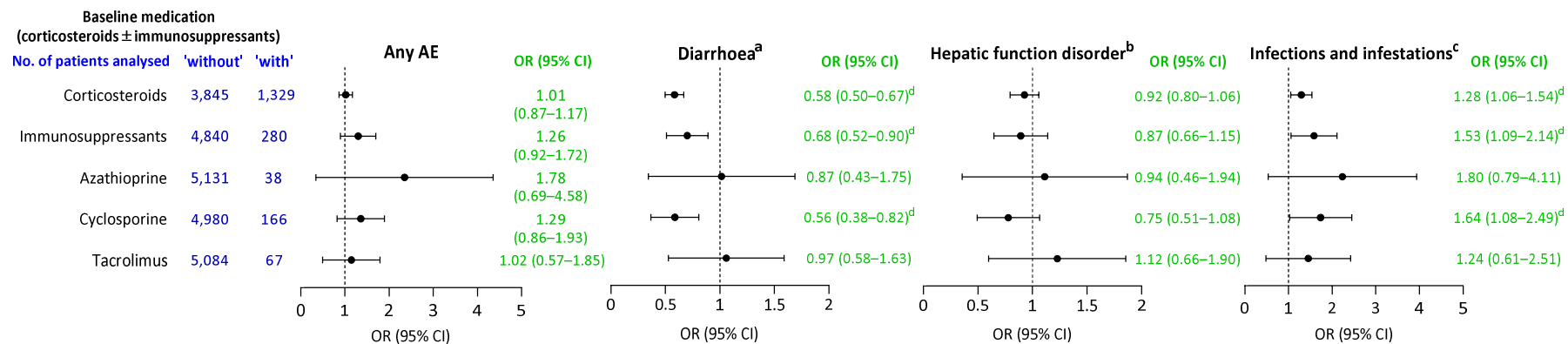
Supplementary Table S1. Frequency of acute exacerbation of interstitial pulmonary fibrosis during 12 months of nintedanib treatment

AE or ADR	Corticosteroid treatment at baseline	Total, N	Patients with acute exacerbation, n (%)	Patients without acute exacerbation, n (%)	OR (95% CI)
AE	Yes	1,329	196 (14.7)	1,133 (85.3)	3.42 (2.77–4.23) ^a
	No	3,845	185 (4.8)	3,660 (95.2)	
ADR	Yes	1,329	23 (1.7)	1,306 (98.3)	2.80 (1.58–4.98) ^a
	No	3,845	24 (0.6)	3,821 (99.4)	

ADR adverse drug reaction, AE adverse event, CI confidence interval, OR odds ratio (Wald method)

^aUpper 95% CI is <1 or lower 95% CI is >1

Supplementary Figure S1. Odds ratio (95% confidence interval) of any adverse event, diarrhoea, hepatic function disorder or infections and infestations according to baseline medication for idiopathic pulmonary fibrosis



AE adverse event, CI confidence interval, OR odds ratio (Wald method)

^aDiarrhoea: diarrhoea (preferred term)

^bHepatic function disorder: liver-related investigations, signs and symptoms (SMQ: 20000008), cholestasis and jaundice of hepatic origin (sub-SMQ: 20000009), hepatitis, non-infectious (sub-SMQ: 20000010) and hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (sub-SMQ: 20000013)

^cInfections and infestations: infections and infestations (system organ class)

^dUpper 95% CI is <1 or lower 95% CI is >1