

Online appendix Figure 1.

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 PROTOCOL: #####

Blinded DSMB (Data Cut: 02Jan2017) 01JAN2017 11:00
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Table 10.1.3.1
 Demographic and Baseline Characteristics (Double-Blind Period)
 All Patients Randomized Set

	Number of Subjects (%)		
	Placebo (N=15)	20 mg (N=22)	40 mg (N=18)
Body Mass Index (kg/m ²) (d)			
N	15	22	18
Mean (SD)	28.79(5.358)	33.57(10.209)	27.91(5.947)
Median	28.00	29.70	28.50
Minimum, Maximum	20.0,37.3	20.0,60.1	17.1,43.5
BMI Categories (N[%])			
< 30 kg/m ²	9 (60.0)	12 (54.5)	13 (72.2)
>= 30 kg/m ²	6 (40.0)	10 (45.5)	5 (27.8)
Smoking Classification (N[%])			
Subject has never smoked	5 (33.3)	12 (54.5)	8 (44.4)
Subject is a current smoker	7 (46.7)	7 (31.8)	4 (22.2)
Subject is an ex-smoker	3 (20.0)	3 (13.6)	6 (33.3)
Female Reproductive Status (N[%])			
Postmenopausal	1 (6.7)	0	0
Surgically Sterile	2 (13.3)	3 (13.6)	0
Female of Childbearing Potential	4 (26.7)	7 (31.8)	4 (22.2)
N/A (Subject is Male)	8 (53.3)	12 (54.5)	14 (77.8)

- (a) Age at the date of Informed consent.
- (b) Subject checked more than one race option on case report form.
- (c) Weight measured prior to the first dose of double-blind study drug.
- (d) BMI is calculated from the weight taken prior to the first dose of study drug and height taken as Screening.

Table 10.1.3.1
 Demographic and Baseline Characteristics (Double-Blind Period)
 All Patients Randomized Set

	Number of Subjects (%)		
	80 mg (N=15)	160 mg (N=13)	Total (N=83)
Body Mass Index (kg/m ²) (d)			
N	15	13	83
Mean (SD)	31.90 (11.613)	26.82 (5.086)	30.12 (8.523)
Median	28.40	25.80	28.50
Minimum, Maximum	19.6, 61.0	19.0, 37.6	17.1, 61.0
BMI Categories (N[%])			
< 30 kg/m ²	9 (60.0)	10 (76.9)	53 (63.9)
>= 30 kg/m ²	6 (40.0)	3 (23.1)	30 (36.1)
Smoking Classification (N[%])			
Subject has never smoked	5 (33.3)	5 (38.5)	35 (42.2)
Subject is a current smoker	4 (26.7)	6 (46.2)	28 (33.7)
Subject is an ex-smoker	6 (40.0)	2 (15.4)	20 (24.1)
Female Reproductive Status (N[%])			
Postmenopausal	0	0	1 (1.2)
Surgically Sterile	1 (6.7)	0	6 (7.2)
Female of Childbearing Potential	2 (13.3)	4 (30.8)	21 (25.3)
N/A (Subject is Male)	12 (80.0)	9 (69.2)	55 (66.3)

- (a) Age at the date of Informed consent.
- (b) Subject checked more than one race option on case report form.
- (c) Weight measured prior to the first dose of double-blind study drug.
- (d) BMI is calculated from the weight taken prior to the first dose of study drug and height taken as Screening.