

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

	placebo (N=15)	20 mg (N=22)	40 mg (N=18)	80 mg (N=15)	160 mg (N=13)	total (N=83)
Body Mass Index (kg/m²)^d						
mean (SD)	29	34 (10)	28 (6)	32 (12)	27 (5)	30 (9)
median (min, max)	28 (20, 37)	30 (20, 60)	29 (17, 44)	28 (20, 61)	26 (19, 38)	29 (17, 61)
BMI Categories (kg/ m²; N,%)						
< 30	9 (60)	12 (55)	13 (72)	9 (60)	10 (77)	53 (64)
≥ 30	6 (40)	10 (45)	5 (28)	6 (40)	3 (23)	30 (36)
Smoking status (N,%)						
never	5 (33)	12 (55)	8 (44)	5 (33)	5 (39)	35 (42)
current	7 (47)	7 (32)	4 (22)	4 (27)	6 (26)	28 (34)
ex	3 (20)	3 (14)	6 (33)	6 (40)	2 (15)	20 (24)
Female Reproductive Status (N,%)						
postmenopausal	1 (7)	0	0	0	0	1 (1)
surgically sterile	2 (13)	3 (14)	0	1 (7)	0	6 (7)
female of childbearing potential	4 (27)	7 (32)	4 (22)	2 (13)	4 (31)	21 (25)
n/a (male)	8 (53)	12 (55)	14 (78)	12 (80)	9 (69)	55 (66)

d. BMI is calculated from the weight taken prior to the first dose of study drug and height taken as Screening.