

Daiichi Sankyo, Inc.
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Erratum to the Sponsor Briefing Document
Pexidartinib NDA 211810

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Table 6.3 (Page 52) has a numerical correction to the table. The median for Pexidartinib (N=61) under the Characteristic RECIST v1.1 SLD (mm) was previously listed as 8.1 but is corrected as 86.1.

Table 6.3: Demographic and Disease Characteristics in Part 1 (Randomized) of ENLIVEN (ITT Analysis Set)

Characteristic	Placebo (N=59)	Pexidartinib (N=61)	Total (N=120)
Age (years)			
Mean (standard deviation)	44.3 (13.6)	44.6 (13.2)	44.5 (13.4)
Median	45.0	44.0	44.5
Sex, n (%)			
Male	23 (39.0)	26 (42.6)	49 (40.8)
Female	36 (61.0)	35 (57.4)	71 (59.2)
Race, n (%)			
White	54 (91.5)	52 (85.2)	106 (88.3)
Black or African American	1 (1.7)	3 (4.9)	4 (3.3)
Asian	2 (3.4)	1 (1.6)	3 (2.5)
American Indian or Alaskan Native	0	2 (3.3)	2 (1.7)
Native Hawaiian or Other Pacific Islander	2 (3.4)	2 (3.3)	4 (3.3)
Other (multiracial)	0	1 (1.6)	1 (0.8)
Ethnicity, n (%)			
Hispanic/Latino	8 (13.8)	9 (15.5)	17 (14.7)
Time from diagnosis to randomization (days)			
Mean (standard deviation)	1428 (1495)	2449 (3099)	1947 (2489)
Median	926.0	1456.0	1272.0
Extremity involvement, n (%)			
Upper	5 (8.5)	5 (8.2)	10 (8.3)
Lower	54 (91.5)	56 (91.8)	110 (91.7)
Hip	7 (11.9)	6 (9.8)	13 (10.8)
Knee	39 (66.1)	34 (55.7)	73 (60.8)
Ankle	7 (11.9)	14 (23.0)	21 (17.5)
RECIST v1.1 SLD (mm)			
Mean (standard deviation)	105.5 (73.5)	101.3 (63.1)	103.4 (68.2)
Median	82.7	86.1	84.4

Characteristic	Placebo (N=59)	Pexidartinib (N=61)	Total (N=120)
ROM in affected joint (% of reference standard)			
Mean (standard deviation)	62.9 (21.8)	62.5 (24.8)	62.7 (23.3)
Median	64.3	63.3	63.3
BPI Worst Pain Numeric Rating Scale (0 [no pain] to 10 [pain as bad as can be imagined])			
Mean (standard deviation)	5.7 (2.2)	5.6 (1.6)	5.7 (1.9)
Median	6.1	5.7	5.8
Worst Stiffness Numeric Rating scale (0 [no stiffness] to 10 [stiffness as bad as can be imagined])			
Mean (standard deviation)	5.9 (1.9)	5.6 (1.7)	5.8 (1.8)
Median	6.0	6.0	6.0
Baseline surgical assessment			
Probability of complete resection, n (%)			
None	37 (66.1)	37 (63.8)	74 (64.9)
Low	13 (23.2)	18 (31.0)	31 (27.2)
Medium	3 (5.4)	2 (3.4)	5 (4.4)
High	3 (5.4)	1 (1.7)	4 (3.5)
Missing	3	3	6
Postoperative morbidity, n (%)			
None	0	0	0
Mild	1 (1.8)	2 (3.4)	3 (2.6)
Moderate	25 (44.6)	24 (41.4)	49 (43.0)
Severe	30 (53.6)	32 (55.2)	62 (54.4)
Missing	3	3	6
Operative risk due to other medical conditions, n (%)			
Low	35 (64.8)	35 (62.5)	70 (63.6)
Medium	15 (27.8)	14 (25.0)	29 (26.4)
High	4 (7.4)	7 (12.5)	11 (10.0)
Missing	5	5	10

Note: All standard deviation values are rounded to one decimal place.

Abbreviations: BPI = Brief Pain Inventory; ITT = intent-to-treat; RECIST = Response Evaluation Criteria in Solid Tumors; ROM = range of motion; SLD = sum of longest diameter.

Source: 2.5 Clinical Overview, Table 4.1, plx108-10-study-rpt-body.pdf, Table 7-3.