Appendix A6.1.5.2 Safety Population

The two following tables present an overview of the safety population from the 8 completed clinical studies.

List of Tables

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Table 1 Subjects Characteristics of Study Safety Population (Single-Use Studies)

Study	ZRHR-PK-01-EU	ZRHR-PK-02-JP	ZRHM-PK-05-JP	ZRHM-PK-06-US
Number of subjects (N)	62	65	73	64
Race/Ethnicity (%)				
• White	100%	-		42.2%
• Black / African American	-	-		54.7%
• Japanese	-	100%	100%	-
• Asian		-	-	1.6%
• Other		-	-	1.6%
Age median (range)	29.0 (21-61)	32.0 (23-55)	30.0 (23-61)	34.0 (22-60)
Gender: male (%)	56.5%	52.3%	50.7%	54.7%
BMI mg/kg^{-1} median-(range)	24.75 (19.4-31.5)	22.30 (18.6-30.3)	22.21 (18.7-30.4)	26.68 (19.1-34.5)
Daily CC use (%)				
• 10 to 19 CPD	67.7%	53.8%	60.3%	
• >19 CPD	32.3%	46.2%	39.7%	
ISO nicotine yields (%)				
• ≤ 0.6 mg	41.9%	49.2%	60.3%	-
• > 0.6 to ≤ 1 mg	58.1%	50.8%	39.7%	-
• ≤ 1 mg	-	-	-	54.7%
• > 1 mg	-	-	-	45.3%

[Source: Clinical Study Reports ZRHR-PK-01-EU, Table 12 and Table 13; ZRHR-PK-02-JP, Table 12 and Table 13; ZRHM-PK-05-JP, Table 12 and Table 13; ZRHM-PK-06-US, Table 13 and Table 14]

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Table 2 Subjects Characteristics of Study Safety Population (5-day and 3-month Studies)

Study	ZRHR-REXC-03-EU	ZRHR-REXC-04-JP	ZRHM-REXA-07-JP	ZRHM-REXA-08_US
Number of subjects (N)	169	166	175	165
Race/Ethnicity (%)				
• White	100%	-	-	63.0%
• Black / African American	-	-	-	30.9%
• Japanese	-	100%	100%	-
• Asian	-	-	-	-
• Other	-	-	-	5.5%
• Missing	-	-	-	0.6%
Age median (range)	32.0 (21-60)	36.0 (23-65)	38.0 (23-65)	35.0 (22-66)
Gender: male (%)	50.3%	50.6%	58.3%	59.4%
BMI mg/kg^{-1} median-(range)	24.70 (18.8-31.8)	22.25 (18.6-30.8)	21.90 (18.5-32.7)	26.60 (18.6-34.9)
Daily CC use (%)				
• 10 to 19 CPD	49.7%	53.0%	53.1%	51.5%
• >19 CPD	50.3%	47.0%	46.9%	47.3%
• Missing	-	-	-	1.2%

[Source: Clinical Study Reports ZRHR-REXC-03-EU, Table 19 and Table 20; ZRHR-REXC-04-JP, Table 19 and Table 20; ZRHM-REXA-07-JP; Table 22 and Table 23. ZRHM-REXA-08-US, Table 26 and Table 27]

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