

Table 2: Demographic Characteristics – ITT

			Active Mode 1	Active Mode 2	Control	Total	p-value (Active Mode 1 vs Control)
Age (years)	N		163	37	149	349	
	Mean (SD)		47.1 (13.33)	45.0 (12.25)	45.9 (13.47)	46.4 (13.26)	0.4391(*)
	Median [Range]	% (n/N)	47.4 [20.6;77.8]	44.0 [22.2;76.0]	44.8 [22.1;78.1]	45.0 [20.6;78.1]	
Gender	Male	% (n/N)	12.3% (20/163)	24.3% (9/37)	15.4% (23/149)	14.9% (52/349)	0.4177(#)
	Female	% (n/N)	87.7% (143/163)	75.7% (28/37)	84.6% (126/149)	85.1% (297/349)	
Race / Ethnicity	Caucasian	% (n/N)	47.2% (77/163)	59.5% (22/37)	40.3% (60/149)	45.6% (159/349)	
	Hispanic or Latino	% (n/N)	19.0% (31/163)	8.1% (3/37)	22.8% (34/149)	19.5% (68/349)	
	Black or African American	% (n/N)	25.2% (41/163)	29.7% (11/37)	26.2% (39/149)	26.1% (91/349)	0.7624(#)
	Asian / Pacific Islander	% (n/N)	6.1% (10/163)	2.7% (1/37)	8.1% (12/149)	6.6% (23/349)	
	Other	% (n/N)	2.5% (4/163)	-	2.7% (4/149)	2.3% (8/349)	

(*) t-test

(#) X² test

Effectiveness Results

The pre-specified interim analysis was conducted on the results available from 116 subjects. At the interim analysis timepoint, the Active Mode 2 arm was dropped, and the study continued with only 2 arms: the most promising effectiveness treatment arm (Active Mode 1) and the placebo arm.

Table 3 presents the CSBM1 and CSBM2 success rates by study arm and analysis set. In the IT set, the CSBM1 success rate was higher in the treatment arm than in the control arm by 17.6 percentage points (chi-square p-value = 0.0011); and the CSBM2 success rate was higher in the active arm than in the placebo arm by 10.0 percentage points (chi-square p-value = 0.0085). The primary effectiveness results met the study success criteria with both the CSBM1 and the CSBM2 success rates statistically significantly higher in the active arm compared to the control. These results were also found in the PP and ITT analysis sets.

Table 3: CSBM1 and CSBM2 Success Rates in mITT, ITT, and PP Analysis Sets

		Treatment		Placebo		p-value (chi-square)
		% (n/N)	97.5% CI (Wilson Score)	% (n/N)	97.5% CI (Wilson Score)	
mITT	Imp. by ≥ 1 CSBM - 6 out of 8 weeks	40.51% (64/158)	[32.18%;49.42%]	22.92% (33/144)	[16.06%;31.60%]	0.0011
	Imp. by ≥ 2 CSBM - 6 out of 8 weeks	23.42% (37/158)	[16.76%;31.72%]	11.81% (17/144)	[7.03%;19.16%]	0.0085
PP	Imp. by ≥ 1 CSBM - 6 out of 8 weeks	40.65% (63/155)	[32.23%;49.65%]	22.92% (33/144)	[16.06%;31.60%]	0.0010
	Imp. by ≥ 2 CSBM - 6 out of 8 weeks	23.23% (36/155)	[16.54%;31.60%]	11.81% (17/144)	[7.03%;19.16%]	0.0098
ITT	Imp. by ≥ 1 CSBM - 6 out of 8 weeks	39.26% (64/163)	[31.13%;48.04%]	22.15% (33/149)	[15.50%;30.61%]	0.0011
	Imp. by ≥ 2 CSBM - 6 out of 8 weeks	22.70% (37/163)	[16.23%;30.80%]	11.41% (17/149)	[6.79%;18.55%]	0.0085