

Table 14.2.16: Summary of FEV₁ Changes from Baseline on Day 1 (ITT Population)

Day	Time Point			Foster 400/24 µg + CHF5259 100 µg (N=157)	Foster 400/24 µg + CHF5259 50 µg (N=156)	Foster 400/24 µg + CHF5259 25 µg (N=152)	Foster 400/24 µg (N=153)
Day 1	T15': 15 Min Post-Dose	Change from Baseline	n	155	152	148	153
			Mean (SD)	6.2 (6.5)	7.2 (6.6)	6.5 (6.9)	5.7 (5.3)
			95% CI [1]	5.2 - 7.3	6.2 - 8.3	5.4 - 7.7	4.8 - 6.5
			Median	5.5	6.5	5.5	5.0
			Min - Max	-10 - 36	-5 - 42	-8 - 27	-16 - 28
Day 1	T30': 30 Min Post-Dose	Change from Baseline	n	157	154	148	151
			Mean (SD)	7.9 (6.9)	9.3 (7.0)	8.3 (6.5)	7.4 (6.2)
			95% CI [1]	6.8 - 8.9	8.2 - 10.4	7.3 - 9.4	6.4 - 8.4
			Median	7.0	8.0	7.5	6.5
			Min - Max	-13 - 32	-7 - 36	-9 - 31	-5 - 51
Day 1	T45': 45 Min Post-Dose	Change from Baseline	n	153	153	147	151
			Mean (SD)	8.9 (7.0)	10.1 (7.6)	9.0 (6.5)	8.2 (6.5)
			95% CI [1]	7.7 - 10.0	8.9 - 11.4	7.9 - 10.0	7.2 - 9.3
			Median	8.5	9.5	8.0	7.5
			Min - Max	-16 - 32	-16 - 43	-8 - 32	-6 - 42
Day 1	T1H: 1 Hour Post-Dose	Change from Baseline	n	154	153	150	152
			Mean (SD)	9.6 (6.6)	10.2 (7.1)	10.3 (6.6)	8.8 (6.3)
			95% CI [1]	8.5 - 10.6	9.1 - 11.4	9.2 - 11.3	7.8 - 9.8
			Median	9.0	9.5	8.8	8.0
			Min - Max	-16 - 33	-5 - 35	-5 - 36	-5 - 38

Day	Time Point			Foster 400/24 µg + CHF5259 100 µg (N=157)	Foster 400/24 µg + CHF5259 50 µg (N=156)	Foster 400/24 µg + CHF5259 25 µg (N=152)	Foster 400/24 µg (N=153)
Day 1	T2H: 2 Hours Post-Dose	Change from Baseline	n	156	153	150	153
			Mean (SD)	10.9 (8.0)	11.2 (8.4)	11.4 (8.6)	9.8 (7.3)
			95% CI [1]	9.7 - 12.2	9.9 - 12.6	10.0 - 12.8	8.7 - 11.0
			Median	10.5	10.5	10.0	9.0
			Min - Max	-15 - 36	-20 - 39	-8 - 53	-18 - 40
Day 1	T3H: 3 Hours Post-Dose	Change from Baseline	n	156	153	150	152
			Mean (SD)	10.9 (8.7)	11.0 (8.7)	11.6 (9.0)	9.3 (7.3)
			95% CI [1]	9.5 - 12.2	9.6 - 12.4	10.1 - 13.0	8.1 - 10.4
			Median	10.5	10.5	10.5	9.3
			Min - Max	-19 - 39	-19 - 42	-10 - 50	-19 - 37
Day 1	T4H: 4 Hours Post-Dose	Change from Baseline	n	155	153	149	152
			Mean (SD)	10.1 (8.4)	10.3 (8.3)	10.7 (9.5)	8.7 (7.7)
			95% CI [1]	8.8 - 11.5	9.0 - 11.6	9.2 - 12.3	7.5 - 9.9
			Median	9.5	9.5	9.0	7.5
			Min - Max	-17 - 50	-18 - 40	-7 - 57	-14 - 42
Day 1	T6H: 6 Hours Post-Dose	Change from Baseline	n	155	152	150	151
			Mean (SD)	8.9 (8.5)	8.8 (9.0)	8.8 (8.8)	7.0 (8.1)
			95% CI [1]	7.6 - 10.3	7.4 - 10.3	7.4 - 10.2	5.7 - 8.3
			Median	8.0	7.8	8.0	5.5
			Min - Max	-15 - 40	-17 - 41	-11 - 43	-18 - 37
Day 1	T8H: 8 Hours Post-Dose	Change from Baseline	n	156	152	150	151
			Mean (SD)	7.1 (7.8)	7.1 (8.9)	7.6 (9.3)	5.4 (8.0)
			95% CI [1]	5.9 - 8.3	5.7 - 8.6	6.1 - 9.1	4.1 - 6.6
			Median	5.5	6.5	5.5	5.0
			Min - Max	-12 - 47	-21 - 36	-13 - 52	-17 - 37

Day	Time Point			Foster 400/24 µg + CHF5259 100 µg (N=157)	Foster 400/24 µg + CHF5259 50 µg (N=156)	Foster 400/24 µg + CHF5259 25 µg (N=152)	Foster 400/24 µg (N=153)
Day 1	T11H30': 11 Hours and 30 Min Post-Dose	Change from Baseline	n	155	153	150	149
			Mean (SD)	4.4 (8.8)	4.7 (8.5)	4.4 (9.5)	3.9 (8.1)
			95% CI [1]	3.0 - 5.8	3.3 - 6.0	2.9 - 5.9	2.6 - 5.2
			Median	3.5	4.0	2.5	3.0
			Min - Max	-19 - 46	-28 - 33	-15 - 57	-21 - 38
Day 1	T12H: 12 Hours Post-Dose	Change from Baseline	n	156	153	150	149
			Mean (SD)	4.4 (8.6)	4.3 (8.7)	4.6 (8.5)	3.6 (8.3)
			95% CI [1]	3.1 - 5.8	2.9 - 5.6	3.2 - 6.0	2.3 - 5.0
			Median	3.5	3.5	3.3	3.0
			Min - Max	-19 - 33	-22 - 46	-15 - 42	-21 - 43