

Table 14.2.16: Summary of FEV<sub>1</sub> Changes from Baseline on Day 42 (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 42	T15': 15 Min Post-Dose	Change from Baseline	n	149	151	148	150
			Mean (SD)	7.9 (9.9)	9.0 (9.4)	7.3 (9.2)	6.9 (8.6)
			95% CI [1]	6.3 - 9.5	7.5 - 10.5	5.8 - 8.8	5.5 - 8.3
			Median	7.5	8.0	6.0	5.3
			Min - Max	-24 - 49	-17 - 43	-23 - 37	-13 - 42
Day 42	T30': 30 Min Post-Dose	Change from Baseline	n	152	150	148	152
			Mean (SD)	9.2 (9.9)	10.3 (9.8)	8.8 (9.3)	7.8 (8.5)
			95% CI [1]	7.6 - 10.8	8.7 - 11.9	7.3 - 10.3	6.4 - 9.1
			Median	8.8	9.3	7.5	6.0
			Min - Max	-29 - 49	-14 - 43	-14 - 36	-13 - 42
Day 42	T45': 45 Min Post-Dose	Change from Baseline	n	150	151	148	149
			Mean (SD)	9.7 (10.1)	11.0 (9.8)	9.4 (9.3)	8.8 (8.2)
			95% CI [1]	8.1 - 11.3	9.5 - 12.6	7.9 - 10.9	7.5 - 10.2
			Median	9.5	10.5	7.8	7.0
			Min - Max	-34 - 58	-17 - 48	-18 - 39	-7 - 43
Day 42	T1H: 1 Hour Post-Dose	Change from Baseline	n	153	151	147	151
			Mean (SD)	10.2 (10.1)	11.2 (9.6)	9.8 (9.7)	9.0 (8.7)
			95% CI [1]	8.6 - 11.8	9.7 - 12.8	8.2 - 11.4	7.6 - 10.4
			Median	9.5	10.5	8.5	7.5
			Min - Max	-28 - 50	-12 - 48	-17 - 39	-12 - 43

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 42	T2H: 2 Hours Post-Dose	Change from Baseline	n	153	152	149	152
			Mean (SD)	11.1 (10.7)	12.1 (9.9)	11.1 (9.9)	9.5 (9.6)
			95% CI [1]	9.3 - 12.8	10.5 - 13.7	9.5 - 12.7	8.0 - 11.1
			Median	10.5	11.5	10.5	8.8
			Min - Max	-24 - 55	-16 - 42	-19 - 37	-15 - 46
Day 42	T3H: 3 Hours Post-Dose	Change from Baseline	n	153	152	149	152
			Mean (SD)	10.6 (10.8)	11.7 (11.2)	11.0 (9.9)	8.9 (9.6)
			95% CI [1]	8.9 - 12.3	9.9 - 13.5	9.4 - 12.6	7.3 - 10.4
			Median	9.5	10.5	10.5	8.5
			Min - Max	-31 - 49	-22 - 43	-18 - 43	-18 - 46
Day 42	T4H: 4 Hours Post-Dose	Change from Baseline	n	152	151	148	152
			Mean (SD)	9.5 (10.2)	11.0 (10.7)	9.8 (10.1)	8.1 (9.7)
			95% CI [1]	7.9 - 11.2	9.2 - 12.7	8.2 - 11.5	6.5 - 9.6
			Median	9.0	9.5	8.5	7.5
			Min - Max	-27 - 39	-19 - 43	-15 - 43	-25 - 45
Day 42	T6H: 6 Hours Post-Dose	Change from Baseline	n	153	151	149	152
			Mean (SD)	7.9 (10.4)	8.8 (11.0)	7.9 (10.1)	6.6 (9.4)
			95% CI [1]	6.2 - 9.5	7.0 - 10.6	6.3 - 9.5	5.1 - 8.1
			Median	7.0	7.0	6.5	5.5
			Min - Max	-27 - 52	-24 - 49	-17 - 41	-21 - 39
Day 42	T8H: 8 Hours Post-Dose	Change from Baseline	n	152	152	148	151
			Mean (SD)	6.0 (10.1)	7.3 (10.3)	6.8 (10.6)	4.8 (9.7)
			95% CI [1]	4.4 - 7.7	5.6 - 8.9	5.1 - 8.6	3.3 - 6.4
			Median	5.5	5.0	6.0	4.0
			Min - Max	-24 - 47	-26 - 40	-23 - 45	-24 - 40

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 42	T11H30': 11 Hours and 30 Min Post-Dose	Change from Baseline	n	154	150	147	152
			Mean (SD)	4.2 (9.7)	5.1 (10.1)	3.8 (10.9)	3.1 (8.8)
			95% CI [1]	2.7 - 5.8	3.5 - 6.8	2.1 - 5.6	1.7 - 4.5
			Median	4.0	4.8	3.5	3.0
			Min - Max	-33 - 37	-29 - 42	-26 - 34	-20 - 39
Day 42	T12H: 12 Hours Post-Dose	Change from Baseline	n	154	150	149	152
			Mean (SD)	4.3 (10.1)	4.5 (9.5)	4.5 (10.2)	3.4 (8.7)
			95% CI [1]	2.7 - 5.9	2.9 - 6.0	2.8 - 6.1	2.0 - 4.8
			Median	4.0	3.5	4.0	3.0
			Min - Max	-34 - 40	-23 - 41	-28 - 39	-27 - 37