

Table 14.2.4.11.2: Summary of Change from Baseline in FVC at Each Time Point on Days 1 (ITT Population)

Day	Time Point			CHF 5259 pMDI (N=97)	Placebo pMDI (N=98)
FVC (L)	Day 1	T15': 15 min post-dose	n	94	97
			Mean (SD)	0.085 (0.175)	0.085 (0.242)
			95% CI [1]	0.049 - 0.121	0.037 - 0.134
			Median	0.073	0.035
			Min - Max	-0.33 - 0.72	-0.30 - 1.30
		T30': 30 min post-dose	n	95	95
			Mean (SD)	0.135 (0.220)	0.046 (0.234)
			95% CI [1]	0.091 - 0.180	-0.001 - 0.094
			Median	0.115	0.060
			Min - Max	-0.65 - 0.80	-0.59 - 0.84
		T45': 45 min post-dose	n	95	96
			Mean (SD)	0.137 (0.236)	0.077 (0.242)
			95% CI [1]	0.089 - 0.185	0.028 - 0.126
			Median	0.130	0.075
			Min - Max	-0.52 - 0.92	-0.55 - 0.98
FVC (L)	Day 1	T1H: 1 hour post-dose	n	96	97
			Mean (SD)	0.158 (0.243)	0.072 (0.245)
			95% CI [1]	0.109 - 0.207	0.023 - 0.121
			Median	0.117	0.070
			Min - Max	-0.55 - 0.86	-0.73 - 0.84

FVC (L)	Day 1	T2H: 2 hours post-dose	n	97	98
			Mean (SD)	0.180 (0.268)	0.086 (0.269)
			95% CI [1]	0.126 - 0.234	0.032 - 0.140
			Median	0.135	0.087
			Min - Max	-0.38 - 1.49	-0.80 - 1.00
		T3H: 3 hours post-dose	n	97	98
			Mean (SD)	0.188 (0.277)	0.121 (0.267)
			95% CI [1]	0.132 - 0.244	0.068 - 0.175
			Median	0.150	0.103
			Min - Max	-0.43 - 1.46	-0.39 - 0.92
		T4H: 4 hours post-dose	n	96	97
			Mean (SD)	0.173 (0.416)	0.160 (0.296)
			95% CI [1]	0.089 - 0.258	0.100 - 0.220
			Median	0.132	0.125
			Min - Max	-1.21 - 2.65	-0.41 - 1.28
		T6H: 6 hours post-dose	n	97	97
			Mean (SD)	0.206 (0.397)	0.173 (0.312)
			95% CI [1]	0.126 - 0.287	0.110 - 0.236
			Median	0.145	0.135
			Min - Max	-0.48 - 2.77	-0.47 - 1.24
		T8H: 8 hours post-dose	n	97	98
			Mean (SD)	0.140 (0.306)	0.129 (0.273)
			95% CI [1]	0.078 - 0.202	0.074 - 0.184
			Median	0.090	0.093
			Min - Max	-0.37 - 1.72	-0.61 - 0.99

FVC (L)	Day 1	T11H30': 11 hours and 30 min post-dose	n	97	96
			Mean (SD)	0.093 (0.277)	0.076 (0.293)
			95% CI [1]	0.037 - 0.149	0.016 - 0.135
			Median	0.070	0.060
			Min - Max	-0.51 - 1.00	-0.56 - 1.09
		T12H: 12 hours post-dose	n	97	97
			Mean (SD)	0.105 (0.348)	0.114 (0.319)
			95% CI [1]	0.035 - 0.175	0.050 - 0.178
			Median	0.085	0.080
			Min - Max	-0.98 - 1.59	-0.57 - 1.05