

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

Parameter (unit)	Day	Time Point		CHF 5259 pMDI (N=97)	Placebo pMDI (N=98)
FVC (L)	Day 42	T-45': 45 min pre-dose	n	97	97
			Mean (SD)	0.103 (0.333)	0.036 (0.329)
			95% CI [1]	0.036 - 0.170	-0.031 - 0.102
			Median	0.085	0.000
			Min - Max	-0.94 - 1.30	-0.66 - 1.44
	Day 42	T-15': 15 min pre-dose	n	97	96
			Mean (SD)	0.113 (0.352)	0.024 (0.343)
			95% CI [1]	0.042 - 0.184	-0.046 - 0.093
			Median	0.090	-0.025
			Min - Max	-0.90 - 1.57	-1.05 - 1.40
		T15': 15 min post-dose	n	96	96
			Mean (SD)	0.146 (0.317)	0.046 (0.350)
			95% CI [1]	0.081 - 0.210	-0.025 - 0.117
			Median	0.140	-0.015
			Min - Max	-0.73 - 1.35	-0.65 - 1.36
		T30': 30 min post-dose	n	94	94
			Mean (SD)	0.165 (0.342)	0.044 (0.353)
			95% CI [1]	0.095 - 0.235	-0.028 - 0.116
			Median	0.153	-0.015
			Min - Max	-0.81 - 1.14	-0.66 - 1.36

FVC (L)	Day 42	T45': 45 min post-dose	n	93	96
			Mean (SD)	0.159 (0.340)	0.067 (0.347)
			95% CI [1]	0.089 - 0.229	-0.004 - 0.137
			Median	0.150	0.060
			Min - Max	-1.17 - 1.14	-0.76 - 1.21
		T1H: 1 hour post-dose	n	96	95
			Mean (SD)	0.146 (0.350)	0.093 (0.381)
			95% CI [1]	0.075 - 0.217	0.015 - 0.170
			Median	0.127	0.070
			Min - Max	-1.21 - 1.21	-0.77 - 1.30
		T2H: 2 hours post-dose	n	97	97
			Mean (SD)	0.149 (0.344)	0.101 (0.357)
			95% CI [1]	0.080 - 0.219	0.030 - 0.173
			Median	0.115	0.045
			Min - Max	-1.14 - 1.01	-0.76 - 1.23
FVC (L)	Day 42	T3H: 3 hours post-dose	n	97	97
			Mean (SD)	0.189 (0.339)	0.117 (0.377)
			95% CI [1]	0.120 - 0.257	0.041 - 0.193
			Median	0.135	0.075
			Min - Max	-0.59 - 1.21	-0.69 - 1.20
		T4H: 4 hours post-dose	n	96	97
			Mean (SD)	0.169 (0.343)	0.139 (0.378)
			95% CI [1]	0.100 - 0.238	0.063 - 0.215
			Median	0.138	0.120
			Min - Max	-0.74 - 1.41	-0.61 - 1.43

FVC (L)	Day 42	T6H: 6 hours post-dose	n	96	96
			Mean (SD)	0.148 (0.326)	0.124 (0.365)
			95% CI [1]	0.082 - 0.214	0.050 - 0.198
			Median	0.073	0.095
			Min - Max	-0.71 - 1.12	-0.74 - 1.39
		T8H: 8 hours post-dose	n	96	97
			Mean (SD)	0.176 (0.365)	0.108 (0.362)
			95% CI [1]	0.102 - 0.250	0.035 - 0.181
			Median	0.120	0.080
			Min - Max	-0.76 - 1.68	-1.08 - 1.39
		T11H30': 11 hours and 30 min post-dose	n	96	96
			Mean (SD)	0.137 (0.358)	0.057 (0.348)
			95% CI [1]	0.064 - 0.209	-0.014 - 0.127
			Median	0.130	0.020
			Min - Max	-1.02 - 1.54	-1.00 - 0.82
		T12H: 12 hours post-dose	n	95	96
			Mean (SD)	0.096 (0.340)	0.068 (0.346)
			95% CI [1]	0.027 - 0.165	-0.002 - 0.139
			Median	0.065	0.090
			Min - Max	-0.76 - 1.43	-0.95 - 0.97