A First in Human Clinical Study on the Safety and Tolerability of Two Escalating Single Doses of CHF5633 (Synthetic Surfactant) in Preterm Neonates with Respiratory Distress Syndrome (24-MONTH CLINICAL ASSESSMENT)

ADDENDUM TO CLINICAL STUDY REPORT

No: CCD-1011–CSR–0098

(24-MONTH CLINICAL ASSESSMENT)

Table 7.2.: Health Status Questionnaire – Section A: Development Assessment-Bayley Scale (Children Examined at 24 Months CA or Whose Parents Were Interviewed)

	100 mg/kg CHF5633 N=17	200 mg/kg CHF5633 N=18	Total N=35
Cognitive Status was Evaluated Using			
Bayley II	5 (29.4)	1 (5.6)	6 (17.1)
Bayley III	10 (58.8)	8 (44.4)	18 (51.4)
Missing	2 (11.8)	9 (50.0)	11 (31.4)
BSID II MDI Score			
n	5	1	6
Mean (SD)	101.8 (14.60)	124.0 (NE)	105.5 (15.90)
95% CI	83.7, 119.9	NE, NE	88.8, 122.2
Median	103.0	124.0	104.5
Min, Max	82, 122	124, 124	82, 124
BSID III Composite Score			
n	10	8	18
Mean (SD)	89.5 (9.6)	102.5 (11.3)	95.3 (12.1)
95% CI	82.7, 96.3	93.0, 112.0	89.3, 101.3
Median	87.5	102.5	97.5
Min, Max	70, 100	85, 120	70, 120
Number and % of children below normal range	1 (5.9)	0	1 (2.9)

Abbreviations: Max = maximum; Min = minimum; NE = not estimable; SD = standard deviation.

Note: Below normal range is defined as BSID-II MDI score < 70, or BSID-III composite score < 85.