

#### 14.4.4 Frequency table of patients with conditions worsened into state necessitating a ventilator

There was no patient whose condition worsened into state necessitating a ventilator.

#### 14.4.5 Summary statistics and changes from baseline of O<sub>2</sub> saturation [%]

| Visit                | n | ----- Result ----- |         |         |        |      |     |     | Baseline |         |         |        | --- Change from baseline --- |         |         |        |      |     |     |
|----------------------|---|--------------------|---------|---------|--------|------|-----|-----|----------|---------|---------|--------|------------------------------|---------|---------|--------|------|-----|-----|
|                      |   | Mean               | 95% ICI | 95% uCI | Median | SD   | Min | Max | Mean     | 95% ICI | 95% uCI | Median | Mean                         | 95% ICI | 95% uCI | Median | SD   | Min | Max |
| Screening (-5 to D1) | 3 | 94.3               | 90.5    | 98.1    | 94.0   | 1.53 | 93  | 96  |          |         |         |        |                              |         |         |        |      |     |     |
| Baseline (D1)        | 3 | 94.0               | 91.5    | 96.5    | 94.0   | 1.00 | 93  | 95  |          |         |         |        |                              |         |         |        |      |     |     |
| Day 2                | 3 | 95.3               | 90.2    | 100.5   | 96.0   | 2.08 | 93  | 97  | 94.0     | 91.5    | 96.5    | 94.0   | 1.3                          | -6.3    | 8.9     | 2.0    | 3.06 | -2  | 4   |
| Day 3                | 3 | 96.7               | 92.9    | 100.5   | 97.0   | 1.53 | 95  | 98  | 94.0     | 91.5    | 96.5    | 94.0   | 2.7                          | -2.5    | 7.8     | 2.0    | 2.08 | 1   | 5   |
| Day 4                | 3 | 95.3               | 90.2    | 100.5   | 96.0   | 2.08 | 93  | 97  | 94.0     | 91.5    | 96.5    | 94.0   | 1.3                          | -1.5    | 4.2     | 2.0    | 1.15 | 0   | 2   |
| Day 5                | 2 | 93.5               | 87.1    | 99.9    | 93.5   | 0.71 | 93  | 94  | 94.0     | 81.3    | 106.7   | 94.0   | -0.5                         | -19.6   | 18.6    | -0.5   | 2.12 | -2  | 1   |
| Day 6                | 2 | 96.0               |         |         | 96.0   | 0.00 | 96  | 96  | 94.0     | 81.3    | 106.7   | 94.0   | 2.0                          | -10.7   | 14.7    | 2.0    | 1.41 | 1   | 3   |
| Day 7                | 2 | 96.5               | 90.1    | 102.9   | 96.5   | 0.71 | 96  | 97  | 94.0     | 81.3    | 106.7   | 94.0   | 2.5                          | -16.6   | 21.6    | 2.5    | 2.12 | 1   | 4   |
| Day 8                | 1 | 97.0               |         |         | 97.0   |      | 97  | 97  | 93.0     |         |         | 93.0   | 4.0                          |         |         | 4.0    |      | 4   | 4   |
| Day 9                | 1 | 98.0               |         |         | 98.0   |      | 98  | 98  | 93.0     |         |         | 93.0   | 5.0                          |         |         | 5.0    |      | 5   | 5   |
| Day 14               | 1 | 96.0               |         |         | 96.0   |      | 96  | 96  | 93.0     |         |         | 93.0   | 3.0                          |         |         | 3.0    |      | 3   | 3   |
| EoT                  | 1 | 96.0               |         |         | 96.0   |      | 96  | 96  | 95.0     |         |         | 95.0   | 1.0                          |         |         | 1.0    |      | 1   | 1   |
| EoS (Day 21-28)      | 3 | 96.3               | 92.5    | 100.1   | 96.0   | 1.53 | 95  | 98  | 94.0     | 91.5    | 96.5    | 94.0   | 2.3                          | -3.4    | 8.1     | 1.0    | 2.31 | 1   | 5   |

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.  
Baseline is defined as the last value measured prior to the study treatment start.

#### 14.4.6 Summary statistics and changes from baseline of Oxygen flow [L/min]

| Visit                | n | ----- Result ----- |         |         |        |      |     |     | Baseline |         |         |        | ---- Change from baseline ---- |         |         |        |      |     |     |  |
|----------------------|---|--------------------|---------|---------|--------|------|-----|-----|----------|---------|---------|--------|--------------------------------|---------|---------|--------|------|-----|-----|--|
|                      |   | Mean               | 95% ICI | 95% uCI | Median | SD   | Min | Max | Mean     | 95% ICI | 95% uCI | Median | Mean                           | 95% ICI | 95% uCI | Median | SD   | Min | Max |  |
| Screening (-5 to D1) | 3 | 4.0                | -0.3    | 8.3     | 3.0    | 1.73 | 3   | 6   |          |         |         |        |                                |         |         |        |      |     |     |  |
| Baseline (D1)        | 3 | 4.0                | -0.3    | 8.3     | 3.0    | 1.73 | 3   | 6   |          |         |         |        |                                |         |         |        |      |     |     |  |
| Day 2                | 3 | 4.7                | -4.7    | 14.1    | 3.0    | 3.79 | 2   | 9   | 4.0      | -0.3    | 8.3     | 3.0    | 0.7                            | -4.5    | 5.8     | 0.0    | 2.08 | -1  | 3   |  |
| Day 3                | 3 | 3.0                | -3.6    | 9.6     | 4.0    | 2.65 | 0   | 5   | 4.0      | -0.3    | 8.3     | 3.0    | -1.0                           | -6.0    | 4.0     | -1.0   | 2.00 | -3  | 1   |  |
| Day 4                | 3 | 3.3                | -5.4    | 12.1    | 3.0    | 3.51 | 0   | 7   | 4.0      | -0.3    | 8.3     | 3.0    | -0.7                           | -5.8    | 4.5     | 0.0    | 2.08 | -3  | 1   |  |
| Day 5                | 2 | 4.5                | -27.3   | 36.3    | 4.5    | 3.54 | 2   | 7   | 4.5      | -14.6   | 23.6    | 4.5    | 0.0                            | -12.7   | 12.7    | 0.0    | 1.41 | -1  | 1   |  |
| Day 6                | 2 | 3.5                | -28.3   | 35.3    | 3.5    | 3.54 | 1   | 6   | 4.5      | -14.6   | 23.6    | 4.5    | -1.0                           | -13.7   | 11.7    | -1.0   | 1.41 | -2  | 0   |  |
| Day 7                | 2 | 2.0                | -23.4   | 27.4    | 2.0    | 2.83 | 0   | 4   | 4.5      | -14.6   | 23.6    | 4.5    | -2.5                           | -8.9    | 3.9     | -2.5   | 0.71 | -3  | -2  |  |
| Day 8                | 1 | 3.0                |         |         | 3.0    |      | 3   | 3   | 6.0      |         |         | 6.0    | -3.0                           |         |         | -3.0   |      | -3  | -3  |  |
| Day 9                | 1 | 0.0                |         |         | 0.0    |      | 0   | 0   | 6.0      |         |         | 6.0    | -6.0                           |         |         | -6.0   |      | -6  | -6  |  |
| Day 14               | 1 | 0.0                |         |         | 0.0    |      | 0   | 0   | 6.0      |         |         | 6.0    | -6.0                           |         |         | -6.0   |      | -6  | -6  |  |
| EoT                  | 1 | 0.0                |         |         | 0.0    |      | 0   | 0   | 3.0      |         |         | 3.0    | -3.0                           |         |         | -3.0   |      | -3  | -3  |  |
| EoS (Day 21-28)      | 3 | 0.0                |         |         | 0.0    | 0.00 | 0   | 0   | 4.0      | -0.3    | 8.3     | 3.0    | -4.0                           | -8.3    | 0.3     | -3.0   | 1.73 | -6  | -3  |  |

n = Number of subjects, CI = Confidence interval, ICI = Lower limit of CI, uCI = Upper limit of CI, SD = Standard deviation.  
Baseline is defined as the last value measured prior to the study treatment start.