**Supplementary Table 1: Sample size calculation for the primary outcomes at the final analysis, the interim analysis, and the pre-planned meta-analysis of the two stages of the severe COVID-19 outcome**

|                              | Estimation of occurrence | Risk ratio | Alpha (2-sided p-value) | Power | Total number of participants required | % loss to follow up | Total number of participants required (adjusted by drop out) |
|------------------------------|--------------------------|------------|-------------------------|-------|---------------------------------------|--------------------|-----------------------------------------------------------|
|                              | Control group            | BCG group  |                         |       |                                       |                    |                                                           |
| 1st co-primary outcome:      |                          |            |                         |       |                                       |                    |                                                           |
| symptomatic COVID-19         | 55%                      | 45%        | 0.82                    | 0.005 | 10%                                   | 95%                | 2016                                                      | -                | -                                                         |
| 2nd co-primary outcome:      |                          |            |                         |       |                                       |                    |                                                           |
| severe COVID-19              | 4%                       | 2.7%       | 0.67                    | 0.04  | 80%                                   | 80%                | 6076                                                      | 16%              | 7244                                                     |
| Interim analysis             |                          |            |                         |       |                                       |                    |                                                           |
| incidence of severe COVID-19 | 66 cases of severe       | 33 cases   | 0.5                     | 0.005 | 10%                                   | 72%                | 100 cases of severe COVID-19                              | -                | -                                                         |
|                              | COVID-19                  | COVID-19   |                         |       |                                       |                    |                                                           |
| Meta-analysis                |                          |            |                         |       |                                       |                    |                                                           |
| incidence of severe COVID-19 | 4%                       | 2.7%       | 0.67                    | 0.04  | 80%                                   | 80%                | 6076                                                      | 16%              | 7244                                                     |

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