**Recommendations of the COVID-19 SEC made in its 105th meeting held on 01.09.2020 under accelerated approval process at CDSCO HQ New Delhi:**

| Agenda No | File Name &Drug Name, Strength | Firm Name | Recommendation |
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| New Drug Division | | | |
| 1. | 12-01/20-DC (Pt-284)<br>RP7214(Pre-submission meeting) | M/s Incozen Therapeutics Pvt Ltd | In light of earlier recommendation dated 17.07.2020, firm presented their plan to conduct Phase-I SAD study in healthy volunteers and MAD study in mild/asymptomatic COVID patients.<br>After detailed deliberation, the committee reiterated its earlier recommendation dated 17.07.2020 to follow the standard regulatory pathway and plan to conduct both SAD and MAD study in Healthy Volunteers as the investigational product is NCE not yet tried in Human being and hence there is no point of consideration of accelerated development pathway for the product at this stage. |
| 2. | 12-01/20-DC (Pt-333)<br>Anti-corona virus therapy | M/s. St. John's | The applicant presented their proposal for conduct of clinical trial.<br><br>After detailed deliberation, the committee recommended that the firm should submit the following-<br>1. Clear justification of having two arms viz outpatient and inpatient arms in the same protocol. It appears that there is no justification for having inpatient arm in the study.<br>2. Detailed justification for use of each of the four drugs as proposed in the clinical trial, which are not included in the COVID-19 management protocol.<br>3. Justification for use of colchicines for 28 days proposed in the study in mild cases.<br>4. The inclusion and exclusion criteria should be clearly defined in respect of severity of the disease as per Govt. of India Guidelines.<br>5. Appropriate Primary and co-primary end points should be specified considering the inclusion and exclusion criteria. |

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| 3. | 12-02/20-DC<br><br>PNB 001 Cap | M/s.<br>Biosphere<br>clinical | In-light of recommendation of SEC dated 31.07.2020 the firm presented the proposal before the committee.<br>After detailed deliberation, the committee recommended that the protocol should be revised as under-<br>1. The trial should be a pilot study on 40 moderate COVID patients, 20 in each arm with SOC including corticosteroid in both the arm.<br>2. The primary end point should be clinical improvement based on WHO ordinal scale and mortality up to 28 days.<br>3. The assessment of defervescense should be deleted from the primary end points and assessment of pain in VAS scale should be deleted from secondary end point.<br>Accordingly, the revised clinical trial protocol should be submitted for review by the committee. |
| Biological Division | | | |
| 4. | BIO/MA/20/000073<br>Mycobacterium w (Immunomodulator)<br><br>(Additional Indication) | M/s Cadila Pharmaceuticals Ltd., Ahmadabad | The firm presented report of the drug from exploratory clinical trial for grant of marketing authorization in critically ill COVID-19 patients on expedited review.<br>After detailed deliberation the committee observed that the number of patients in the trial is small and therefore recommended for conducting confirmatory Phase III clinical trial on large number of patients. Accordingly, the firm may submit protocol for consideration of the committee. |
| 5. | BIO/CT/20/000077<br><br>Whole Virion Inactivated Corona Virus Vaccine, [BBV152]<br><br>(Phase I/II clinical trial) | M/s Bharat Biotech International Ltd., Hyderabad | The firm presented proposed amendments to the Phase II part of clinical trial protocol along with interim Phase I safety data and animal challenge study data.<br>Based on animal data the firm requested for protocol amendment to allow 3mcg dose in phase II trial.<br>After detailed deliberation the committee recommended that the firm should submit the following for further consideration:<br>1. The complete animal challenge |

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| | | | study details including the necropsy data.<br>2. The immunogenicity data from Phase I study is yet to be evaluated & not presented. Hence the strategy to be adopted in case the immunogenicity data from 6 mcg cohort is found to be significantly different from the 3 mcg cohort is not clarified in protocol and presentation. |