

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 188th meeting held on 11.10.2021 at CDSCO, HQ New Delhi:

| Agenda No | File Name & Drug Name, Strength | Firm Name | Recommendation |
|----------------------------|---|---|---|
| Biological Division | | | |
| 1. | BIO/MA/21/000124 Whole Virion, Inactivated Corona Virus Vaccine (BBV152) | M/s Bharat Biotech International Limited, Hyderabad | <p>The firm presented its proposal for grant of market authorization of Whole Virion, Inactivated Corona Virus Vaccine (BBV152) in the age group of >2 to <18 years for restricted use in emergency situation along with the interim safety and immunogenicity data of Phase II/III clinical trial conducted in the age group of >2 to <18 years.</p> <p>The committee noted that the interim safety data of the Phase II/III clinical trial was reviewed by the committee in its meeting dated 26.08.2021. The overall GMT for the paediatric population is comparable with GMT of the adult population in Phase-III efficacy study.</p> <p>After detailed deliberation, the committee recommended for grant of market authorization of the vaccine for the age group of >2 to <18 years for restricted use in emergency situation subject to the following conditions:</p> <ol style="list-style-type: none"> 1. The firm should continue the study as per the approved clinical trial protocol. 2. The firm should provide updated prescribing information/package Insert (PI), Summary of Product Characteristics (SmPC) and Factsheet. 3. The firm should submit safety data including the data on AEFI and AESI, with due analysis, every 15 days for the first two months and monthly thereafter and also as per requirement of New Drugs & Clinical Trials Rules, 2019. 4. The firm should submit Risk management plan. <p>Further all other conditions of the earlier approval in the age group of \geq 18 years shall remain same.</p> |
| 2. | BIO/CT/20/000182 mRNA Vaccine for | M/s Gennova Biopharmaceuticals Limited | <p>The firm presented its proposal for relieving the placebo group participants in its Phase I part of the Phase I/II trial of HGCO19 mRNA Vaccine for Injection (COVID-19).</p> |

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| | Injection (COVID-19) | | After detailed deliberation, the committee recommended for relieving the placebo group participants in its Phase I part of the Phase I/II trial of HGCO19 mRNA Vaccine for Injection (COVID-19). |
| SND Division | | | |
| 3. | SND/CT/21/000044 Remdesivir Powder for Inhalation | M/s Lupin | In light of recommendations of the earlier committee meeting held on 29.07.2021 the firm presented the revised Phase II CT study protocol before the committee. After detailed deliberation the committee recommended for grant of permission for conduct of the Phase II CT study subject to following conditions: <ol style="list-style-type: none"> 1. Hospitalization criteria should be included as secondary efficacy parameter. 2. Antivirals & corticosteroids should not be given as SOC. 3. Concomitant medication should be as per the Government treatment guidelines. |
| 4. | SND/MA/21/000203 Remdesivir Oral solution 100mg/5mL | M/s Lupin | In light of the recommendations of the earlier committee meeting held on 04.08.2021, the firm presented the multiple dose PK study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed multiple dose PK study as per the protocol presented. |
| 5. | SND/CT/21/00036 Ursodiol Injection 625mg/25 mL (25 mg/mL) | M/s Shilpa | In light of the recommendations of the earlier meeting held on 09.09.2021, the firm presented the revised Phase II CT study protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the proposed Phase II CT study as per the protocol presented. |