

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 154th meeting held on 30.04.2021 & 01.05.2021 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Name of Firm/ Applicant	Recommendation
New Drug Division			
1.	IND/CT/21/00008 Molnupiravir capsules	M/s Natco Pharma Limited	<p>The firm presented their Phase III Clinical Protocol before the committee.</p> <p>After detailed deliberation, the committee noted that, this drug is not approved anywhere in the world, and innovator study is ongoing.</p> <p>Accordingly, firm should revise phase-III clinical trial protocol with respect to the following:</p> <ol style="list-style-type: none"> 1. The Primary objective, Primary Efficacy End Point should be clearly defined. 2. The study should be conducted in mild and moderate COVID-19 patients with statistically significant sample size. <p>Accordingly, the firm should submit revised protocol for consideration.</p>
2.	ND/MA/21/000044 Molnupiravir 200 mg, 400 mg and 800 mg capsules	M/s Optimus Pharma Pvt Ltd	<p>The firm presented their Phase III Clinical Protocol before the committee.</p> <p>After detailed deliberation, the committee noted that, this drug is not approved anywhere in the world, and innovator study is ongoing.</p> <p>Accordingly, firm should revise phase-III clinical trial protocol with respect to the following:</p> <ol style="list-style-type: none"> 1. The Primary objective, Primary Efficacy End Point should be clearly defined. 2. The study should be conducted in mild and moderate COVID-19 patients with statistically significant sample size. <p>Accordingly, the firm should submit revised protocol for consideration.</p>

3.	ND/MA/21/000039 Molnupiravir capsules	M/s Stride	<p>The firm presented their proposal with Clinical Trial waiver before the committee.</p> <p>After detailed deliberation committee not recommended Emergency Use Approval of the drug due to inadequate clinical data.</p>
4.	ND/MA/21/000049 Molnupiravir capsules	M/s Cipla	<p>The firm presented their Phase III Clinical Protocol before the committee.</p> <p>After detailed deliberation, the committee noted that, this drug in not approved anywhere in the world, and innovator study is ongoing.</p> <p>Accordingly, firm should revise phase-III clinical trial protocol with respect to the following:</p> <ol style="list-style-type: none"> 1. The Primary objective, Primary Efficacy End Point should be clearly defined. 2. The study should be conducted in mild and moderate COVID-19 patients with statistically significant sample size. <p>Accordingly, the firm should submit revised protocol for consideration.</p>
5.	ND/MA/21/000050 Molnupiravir capsules	M/s Hetero	<p>The firm presented their Phase III Clinical Protocol before the committee.</p> <p>After detailed deliberation, the committee noted that, this drug in not approved anywhere in the world, and innovator study is ongoing.</p> <p>Accordingly, firm should revise phase-III clinical trial protocol with respect to the following:</p> <ol style="list-style-type: none"> 1. The Primary objective, Primary Efficacy End Point should be clearly defined. 2. The study should be conducted in mild and moderate COVID-19 patients with statistically significant sample size. <p>Accordingly, the firm should submit revised protocol for consideration.</p>

6.	ND/CT21/BO/2020/23 164 Aviptadil Injection	M/s Zuventus	<p>The firm presented their proposal for Emergency Use approval in parallel to the ongoing Phase III Clinical Trial on 150 patients.</p> <p>After detailed deliberation committee recommended that firm should submit 20 patient's data in each arm, evaluated for atleast 28 days with proper methodology for further consideration.</p>
7.	IND/CT/20/000037 2-Deoxy-D-Glucose oral powder	M/s Dr. Reddy	<p>In light of earlier SEC meeting held on 13.10.2020, the firm presented their Interim Phase III Clinical Trial report and request for Emergency Use Approval.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacture and market of the drug for restricted use under Emergency situation as an adjunct therapy only in moderate to severe Covid-19 patients.</p> <p>The firm should also submit the complete Phase III Clinical Trial report within 06 weeks of the approval alongwith package insert to CDSCO.</p>
8.	12-02/20-DC PNB001	M/s Biosphere Clinical Research Private Limited	<p>The firm presented their proposal for Emergency Use approval based on the Interim Phase II Clinical Trial report.</p> <p>After detailed deliberation committee did not recommend for Emergency Use approval of the drug as clinical data is in adequate.</p> <p>The Firm should submit Phase III Clinical Trial protocol to CDSCO for further consideration by the committee.</p>
Biological Division			
9.	BIO/CT18/FF/2021/25 220 Casirivimab 120 mg/ml and Imdevimab 120mg/ml concentrate for solution for infusion	M/s Roche Products (India)	<p>The firm presented the Phase-II and Phase-III safety and efficacy data of Casirivimab and Imdevimab concentrate for solution for infusion along with their proposal for restricted use in emergency situation for the treatment in COVID-19 patients with combined dose of 2400 mg or with 1200</p>

	(REGN-COV2)		<p>mg.</p> <p>The committee noted that, the combination of the drug with 1200 mg and 2400 mg has similar efficacy and the safety profile is relatively better with 1200 mg. The drug is approved under Emergency use Authorization in US, EU and other countries.</p> <p>After detailed deliberation, the committee recommended for grant of permission for Import of the combination of Casirivimab and Imdevimab for restricted use in emergency situation, at combine dose of 1200 mg, IV or SC route, for the treatment of mild to moderate corona virus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with laboratory confirmed SARS-COV2 infection and who are at high risk of severe COVID-19 and does not require oxygen with waiver of local clinical trial. Further, the committee recommended that, the pack size of the drug to be imported may be 300 or 1332 mg each of Casirivimab and Imdevimab</p>
Subsequent New Drugs Division			
10.	12-01/2020-DC (Pt-NSRT-SND) Eflornithine Granules 2.5 gm to 5.0 gm	M/s Navein Saxena Research & Technology	<p>The firm presented revised protocol of Phase-IIB CT of Eflornithine Granules 2.5 gm to 5.0gm and also requested for Emergency Use Approval.</p> <p>After detailed deliberation committee recommended for approval of the revised protocol subject to condition that additional samples need not to be collected. As regard emergency approval the committee recommended that the firm should submit adequate clinical data for further consideration.</p>

11.	SND/MA/20/000339 Remdesivir Injection 100mg/20 ml (5mg/ml) (Without Cyclodextrin)	M/s Cipla Limited	<p>In light of recommendation of SEC dated 18.01.2021 & 19.01.2021 and issues regarding availability of Remdesivir in pandemic situation in the country, the firm presented their proposal for approval of the Cyclodextrin free Remdesivir injection of already approved strength along with in-vitro data and toxicity data.</p> <p>After detailed deliberation the Committee recommended for grant of permission to manufacture and Market the product. However, the firm should complete the BE study and submit its results for review by the committee.</p>
12.	SND/MA/20/000344 Baricitinib Tablets 1mg, 2mg, and 4mg	M/s Natco Pharma Limited	<p>In light of earlier recommendation of the committee dated 18.01.2021 & 19.01.2021 and present pandemic situation, the firm presented their proposal of Baricitinib Tablets for Emergency use approval along with supportive clinical data including published data.</p> <p>Emergency Use Authorization of Baricitinib tablet for COVID-19 has been granted by USFDA and PMDA Japan.</p> <p>After detailed deliberation the committee recommended for grant of permission to Manufacture and Market the drug for restricted use in emergency situation for the indication “Baricitinib, in combination with Remdesivir, for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).”, subject to condition that the firm should conduct Phase IV CT study and accordingly, the firm should submit Phase IV CT protocol within 15 days of approval.</p>