

Recommendations of the SEC (Oncology & Haematology) made in its 119th meeting held on 24.02.2022 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	4-30/Roche/PAC-R-Atezolizumab/19-BD (Pt-II) Atezolizumab	M/s. Roche Products India Pvt. Ltd.	The firm presented the proposal before the committee. During the presentation, the firm requested to defer the proposal to the next SEC meeting. Accordingly, the proposal was deferred.
2.	4-394/Roche/16-BD (Pt-I) Atezolizumab	M/s. Roche Products (India) Pvt Ltd	<p>In light of the SEC meeting dated 27.01.2022, the firm presented their proposal before the committee.</p> <p>The committee noted that the firm was granted accelerated approval by US FDA subject to the condition that continued approval for the indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. Further, the drug did not meet the primary endpoints in the Phase III confirmatory trial.</p> <p>The committee noted that the initial approval for Atezolizumab was accorded in March 2017 based on the Phase II data generated in USA (accelerated approval). However, the indication has been voluntarily withdrawn in consultation with US FDA as the Phase III study IMPassion 131 did not meet the primary end-point.</p> <p>After detailed deliberation, the committee recommended that the firm should submit safety and efficacy data from Phase III clinical trial in Indian Population for continued marketing of the drug in the Triple negative breast cancer and also recommended that the approval for marketing for the indication in the country for Triple negative breast cancer should be withdrawn till safety and efficacy data are available in Indian population.</p>
3.	4-394/Roche/16-BD (Pt-I) Atezolizumab	M/s. Roche Products (India) Pvt Ltd	<p>In light of the SEC meeting dated 27.01.2022, the firm presented their proposal before the committee.</p> <p>The committee noted that the firm was</p>

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			<p>granted accelerated approval by US FDA subject to the condition that continued approval for the indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. Further, the drug did not meet the primary endpoints in the Phase III confirmatory trial.</p> <p>The committee noted that the initial approval for Atezolizumab was accorded in March 2017 based on the Phase II data generated in USA (accelerated approval). However, the indication has been voluntarily withdrawn in consultation with US FDA as the Phase III study IMvigor211 did not meet the primary end-point.</p> <p>After detailed deliberation, the committee recommended that the firm should submit safety and efficacy data from Phase III clinical trial in Indian Population along with the safety and efficacy results of the Indian sub-set in the global clinical trial carried out in the country for continued marketing of the drug in the Urothelial carcinoma. The committee further recommended that the approval for marketing for the indication in the country for Urothelial carcinoma should be withdrawn till such time safety and efficacy data are available in Indian population.</p>
4.	4-350/BMS/160BD (Part-I) Nivolumab	M/s. Bristol Myers Squibb	<p>The firm presented their proposal for voluntary withdrawal of the drug in hepatocellular carcinoma in USA and also informed that currently a confirmatory Phase III clinical trial related to the use of Nivolumab as monotherapy in the hepatocellular indication is ongoing overseas.</p> <p>The committee noted that the firm was granted accelerated approval by US FDA subject to the condition that continued approval for the indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. Further, the drug did</p>

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			not meet the primary endpoints in the Phase III confirmatory trial. After detailed deliberation, the committee recommended that the firm should submit safety and efficacy data from Phase III confirmatory clinical trial meeting the endpoint of the study for continued marketing of the drug in the indication of hepatocellular carcinoma. The committee further recommended that the approval for marketing for the indication in the country for hepatocellular carcinoma should be withdrawn till safety and efficacy data are available in Indian population.
5.	BIO/CT/19/000059 Trastuzumab	M/s. Cura TeQ Biologics Pvt. Ltd.	The firm presented the proposal for amendment in the already approved clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of approval for the amended protocol CR201-1.8, version 1.0, amendment 01, dated 09.09.2021
GCT Division			
6.	CT/76/21 Savolitinib Plus Durvalumab Versus Sunitinib & Durvalumab	M/s. Labcorp	The firm didn't turn up for presentation.
7.	CT/136/21 Belantamab Mafoclotin	M/s. GSK	In light of earlier SEC recommendations dated 27.01.2022, the firm presented the proposal and during the presentation the firm requested to defer the proposal to the next SEC meeting. Accordingly, it was deferred. The committee also opined that the proposal needs to be deliberated in the presence of Ophthalmologist.
8.	CT/86/20 Durvalumab	M/s. AstraZeneca	The firm presented the proposed protocol amendment to protocol no. D910DC00001, Version 3.0 dated 19-MAY-2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
9.	CT/11/21 Erdafitinib	M/s. Johnson & Johnson	In light of earlier SEC recommendation dated 09.12.2021 & 10.12.202, the firm

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			again presented protocol amendment 4, dated 08 Feb 2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
10.	CT/21/21 OQL011	M/s. CBCC Global Research	The firm presented the Part-I study data of Phase II study protocol no. OQL011B002, Version 5.1 dated 10FEB2021 before the Committee to comply with CT NOC condition. After detailed deliberation, the committee noted that the Part-I study was completed and recommended for allowing initiation of the Part-II of the study in the country.
11.	CT/171/21 Entrectinib	M/s. Roche	The firm presented the proposed Phase III clinical trial protocol no- MO41552, Version 4 dated 28 Sep 2021 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed clinical trial. (Dr. R. T. Chacko did not participate in the deliberation.)