

**Recommendations of the SEC (Pulmonary) made in its 70<sup>th</sup> meeting held on 10.05.2023 at CDSCO (HQ), New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	BIO/CT04/FF/2023/36081  Omalizumab 75mg and 150mg solution for injection in PFS	M/s. Curateq Biologics Private Limited	The firm presented the protocol for conduct of Phase I/III clinical trial titled “A prospective, randomized, double blind, multicentric, parallel group phase-III clinical study to evaluate the efficacy, safety, immunogenicity, pharmacokinetics and pharmacodynamics of BP11 (Omalizumab) and EU approved Xolair <sup>®</sup> in patients with moderate to severe persistent asthma” as per protocol No. ICS/CUR/2023-001; V2.0 Date: 01-Apr-2023.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I/III clinical trial as per presented protocol subject to the condition that firm should submit PK/PD data as and when generated as a part of Phase I study to CDSCO for further review.
<b>FDC Division</b>			
2.	04-01/2022-DC (Misc. 47)  Chlorpheniramine Maleate IP 2mg + Phenylephrine HCl IP 5mg drop/ml	Nil	The proposal was deferred for next meeting.
3.	FDC/MA/22/000239  Glycopyrronium Bromide + Fluticasone Furoate + Vilanterol Trifenatate (50mcg/50mcg+100mcg/200mcg+25mcg/25mcg) Dry Powder for inhalation	M/s. Glenmark Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
4.	FDC/MA/22/000091  Bilastine + Dextromethorphan	M/s. Glenmark Pharmaceuticals	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Hydrobromide + Phenylephrine Hydrochloride (3.3mg+10mg+5mg) Syrup		
5.	FDC/MA/23/000035  Dextromethorphan Hydrobromide 10mg I.P. Phenylephrine Hydrochloride 5.0000mg I.P. Chlorpheniramine Maleate 2 mg I.P. tablets	M/s. Stedmen Pharmaceuticals Pvt. Ltd.	The proposal was deferred for next meeting.
6.	FDC/MA/23/000114  Glycopyrrolate IP Eq. to Glycopyrronium 12.5mcg/25mcg+Formoterol Fumarate Dihydrate IP Eq. to Formoterol Fumarate 6mcg/12mcg+Budesonide IP 200mcg/400mcg Inhalation Powder	M/s. Malik Life Sciences Pvt. Ltd.	The proposal was deferred for next meeting.
7.	FDC/MA/23/000125  Ambroxol HCl 20mg+Dextromethorphan HBr 10mg+Chlorpheniramine Maleate 2mg Syrup	M/s. Zuventus Healthcare Ltd.	The proposal was deferred for next meeting.
8.	FDC/MA/23/000069  Indacaterol maleate eq. to Indacaterol 75mcg/150mcg + Budesonide IP 200mcg/400mcg Dry Powder for inhalation (capsules)	M/s. Zydus	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
9.	FDC/MA/23/000068  Indacaterol Maleate eq. to Indacaterol 75mcg + Budesonide IP 200mcg Inhaler (metered dose inhaler)	M/s. Zydus	The proposal was deferred for next meeting.
10.	FDC/MA/18/000028  Budesonide IP 400mcg + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12mcg inhalation preparation	M/s. Lupin Ltd.	The proposal was deferred for next meeting.
11.	FDC/CT/20/000001  Formoterol Fumarate 12mcg + Budesonide 400mcg inhaler	M/s. Lupin Ltd.	The proposal was deferred for next meeting.
<b>GCT Division</b>			
12.	CT/168/22 Online Submission (35220)  BI 1015550	M/s.IQVIA RDS	In light of earlier SEC recommendation dated 05.04.2023, the firm presented their response for long term toxicology data, pharmacological data before the committee for Phase III clinical trial protocol number :1305-0014 (FIBRONEERTM-IPF) version 2.0 dated 26-July-2022.  After detailed deliberation, the committee recommended for grant of permission for conduct of Phase III clinical trial subject to the condition that the firm should include at least equal number of government sites as that of private sites across the country.
13.	CT/171/22 Online Submission (35282)  BI 1015550	M/s. IQVIA RDS	In light of earlier SEC recommendation dated 05.04.2023, the firm presented their response for long term toxicology data, pharmacological data before the committee for Phase III clinical trial protocol number :1305-0023 (FIBRONEERTM-ILD) version 2.0 dated 26-July-2022.

**SEC (Pulmonary) meeting dated 10.05.2023**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase III clinical trial subject to the condition that the firm should include at least equal number of government sites as that of private sites across the country.
14.	CT/55/20 Online Submission (24183)  C21	M/s. QED Clinical Services	The firm presented the protocol amendment version V8.0 25-Jan-2023 before the committee.  After detailed deliberation, the committee recommended for grant of approval of the proposed protocol amendment.
15.	CT/21/23 Online Submission (36554)  PC945	M/s. PSI CRO	The firm did not turn up for presentation.
16.	CT/16/23 Online Submission (36258)  BLU-5937	M/s. IQVIA	The firm presented the proposal for Phase III clinical trial protocol number BUS-P3-01, (Original protocol, 04-August-2022) before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial with following conditions:  1. As per the protocol, the test for latent TB has to be done in India, as India is endemic country for TB. 2. The firm should include more Government sites in the study.
17.	CT/127/22 Online Submission (34427)  Tozorakimab (MEDI3506)	M/s. AstraZeneca	In light of earlier SEC recommendation dated 08.02.2023, the firm presented study for acute viral infection respiratory failure (ARDS) except for COVID-19 and recommended to conduct Phase II study vide protocol no: D9185C00001 version 1.0, 15-sep-2022 and local CSP Addendum IND-1: version 1.0, dated 14-Oct-2022 before the committee.  After detailed deliberation, the committee recommended for grant of permission for conduct of Phase II clinical trial as presented by the firm.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
18.	CT/93/22 Online Submission (24857)  LYT-100	M/s. Novotech	The firm presented the protocol amendment version V:5.0 26-Feb-2023 before the committee.  After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.