

File No: BIO/CT/23/000155  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Biological Division)

**From:**

The Drugs Controller General, India  
Directorate General of Health Services,

FDA Bhawan Kotla Road,  
New Delhi-110002

Dated:

**To,**

M/s GSK Pharma India Private Limited,  
01, Battery House Bhulabhai Desai Road  
Mumbai (India) – 400026

**Subject:** Permission for conducting a phase III clinical trial titled "A Phase 3, randomized, placebo-controlled, observer blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3 OA investigational vaccine when administered to older adults  $\geq 60$  years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease vide protocol no.: 221265 protocol amendment 01 Dated 19-Apr-2024.- regarding.

**Reference:** Your Application No. BIO/CT04/FF/2023/41093 dated 21-DEC-2023 on the subject mentioned above.

**Sir,**

Please refer to your application no. BIO/CT04/FF/2023/41093 dated 21-DEC-2023 received by this office on the above subject. In this regard, please find enclosed herewith permission to conduct a Phase III clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

You are required to comply with the requirements of Drugs and Cosmetics Rules, 1945 and communication of Central Licencing Authority.

Please acknowledge receipt of the same.

RAJEEV SINGH  
RAGHUVANSHI

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(Dr.Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)  
Central Licencing Authority

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Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
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**FORM CT-06**

(See rules 22, 25, 26, 29 and 30)

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG**

The Central Licencing Authority hereby grant permission to M/s GSK Pharma India Private Limited, 01, Battery House Bhulabhai Desai Road Mumbai (India) - 400026 Telephone No.: 02229959634 FAX: 0222495949 E-mail: GSK.PHARMAINDIA1@GSK.COM to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: 221265 protocol amendment 01 Dated 19-Apr-2024 to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

**CT No.: CT-08 /2024**

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.
4. It may kindly be noted that merely granting permission to conduct clinical trials with the vaccine does not convey or imply that based on the clinical trial data generated with the vaccine, permission to market this vaccine in the country with automatically be granted to you.

Date:  
Place: New Delhi

**RAJEEV SINGH**  
**RAGHUVANSHI**

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(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)  
Central Licensing Authority

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**Annexure: Details of New Drug or Investigational New Drug:**

<b>Name of the new drug or investigational new drug:</b>	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)		
<b>Therapeutic class:</b>	Vaccine		
<b>Dosage form:</b>	Suspension for injection		
<b>Composition:</b>	<b>Each 0.5 ml vial contains</b>		
	<b>Active ingredient</b>	<b>Quantity in container</b>	<b>Reconstituted with AS01E Adjuvant System</b>
	RSVPreF3*	163 µg	120 µg
	<b>Inactive ingredient</b>		
	Trehalose	20 mg	14.7 mg
	Polysorbate 80	0.25 mg	0.18mg
	KH <sub>2</sub> PO <sub>4</sub>	0.40 mg	0.29 mg
	K <sub>2</sub> HPO <sub>4</sub>	0.36 mg	0.26 mg
	<b>AS0<sub>E</sub> Adjuvant System components</b>		
	QS-21 (a triterpene glycoside purified from the bark of Quillaja saponaria)	25 µg	
	MPL(3-O-desacyl-4'-monophosphoryl lipid A)	25 µg	
	DOPC (dioleoyl phosphatidylcholine)	500 µg	
	Cholesterol	125 µg	
	NaCl	4.4 mg	
	Na <sub>2</sub> HPO <sub>4</sub>	0.15 mg	
	KH <sub>2</sub> PO <sub>4</sub>	0.54 mg	
	Water for injections	0.5 ml qs	
Note: RSVPreF3* 36% overage, 120 µg target dose			
<b>Indication:</b>	For active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 60 years of age and older and adults 50-59 years of age at increased risk of LRTD due to RSV.		

**Details of clinical trial sites-**

<b>S. No.</b>	<b>Name and Address of Clinical Trial Site</b>	<b>Ethics Committee details</b>	<b>Name of Principal Investigator</b>
1	Calcutta School of Tropical Medicine, 108, Chittaranjan Avenue, Kolkata West Bengal –	Clinical Research Ethics Committee, (CREC- STM), Calcutta School Of Tropical Medicine, 108, Chittaranjan Avenue, Kolkata-	Dr Shantanu Munshi

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	700073.	700073. [ECR/194 /Inst/WB/2013/ RR-20]	
2	Sanjivani Super Speciality Hospital Pvt Ltd , 1, Uday Park Society, Near Sunrise Park, Vastrapur Ahmedabad Gujarat - 380015	Sanjivani Hospital Ethics Committee, 1, New Uday Park Society, Near Sunrise park, Vastrapur, Ahmedabad - 380015, Gujarat, India. [ECR/183/Inst/Ahm/2013 /RR-22]	Dr Vinay Bhomia
3	GMERS Medical College, Sola, S.G. Highway, Near New Gujarat High Court, Ahmedabad Gujarat-380061	Institutional Ethics Committee ,GMERS Medical College, and Civil Hospital Sola, Ahmedabad Gujarat - 380061 [ECR/404 /Inst/GJ /2013/RR-20]	Dr Kiran Rami
4	Dept of Medicine, G.S.V.M Medical College, Swaroop Nagar, Kanpur Uttar Pradesh - 208002	Ethics Committee GSVM Medical College , Room No. 125, First Floor, GSVM Medical College, Swaroop Nagar, Kanpur -208002 [ECR/680/Inst/UP/2014/ RR-20]	Dr Saurabh Agarwal
5	Suyash Institute of Medical Sciences, Gudhiyari Road Kota Raipur Chhattisgarh - 492001	Institutional Ethics Committee, Suyash Hospital, Kota Gudhiyari Road, Raipur, Kota, Raipur, Chattishgarh – 492001. [ECR/1546/Inst/CG/2021]	Dr Manoj Lahoti
6	KEM Hospital Research Centre, Vadu Rural Health Program At Post Vadu (Budruk), Taluka Shirur, District Pune 472216.Maharashtra India.	Ethics Committee KEM Hospital Research Centre, TDH building Sardar Moodliar Road Rasta Peth, Pune 411011, India. [ECR/272/Inst/MH/2013/RR-22]	Dr Anand Kawade
7	North Bengal Medical College and Hospital, Sushruta Nagar Siliguri West Bengal - 734012	Institutional Ethics Committee, North Bengal Medical College and Hospital, Sushruta Nagar Siliguri West Bengal – 734012. [ECR/1701/Inst/ WB/2022]	Dr Dipanjan Bandopadhyay
8	Department of Tuberculosis and Chest Disease, Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Civil Line Koil Aligarh Uttar Pradesh - 202002	Institutional Ethics Committee, Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Civil Line Koil Aligarh Uttar Pradesh – 202002 [ECR/1418/Inst/ UP/2020]	Dr Mohammad Shameem
9	Chettinad Hospital and Research Institute, Rajiv Gandhi Salai, Kelambakkam 603103 Tamil Nadu	CARE - Institute Human Ethics Committee for Faculty Research and Education, Rajiv Gandhi Salai (OMR) Kelambakkam- 603103 Tamil Nadu [ECR/1589/Inst/TN/2021]	Dr. Durga Krishnan

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10	Dept of Medicine, Government Medical College & Government General Hospital, Srikakulam-532001 Andhra Pradesh.	Institutional Ethics Committee, GMC & Government General Hospital, Srikakulam- 532001 Andhra Pradesh [ECR/492 /Inst/AP/2013/RR-20]	Dr. K Sunil Naik
11	Amrita Institute of Medical Sciences and Research Centre, AIMS Ponekkara P.O, Kochi - 682041, Kerala.	Institutional Ethics Committee, Amrita Institute of Medical Sciences and Research Centre, AIMS Ponekkara P.O, Kochi - 682041, Kerala. [ECR/129 /Inst/KL/2013/RR-19]	Dr. Dipu T S
12	1 <sup>st</sup> Floor Beside Dialysis Ward, Belagavi Institute of Medical Sciences, Dr. B. R. Ambedkar Road, Belagavi-590001, Karnataka	Institutional Ethics Committee. BIMS, Belagavi institute of Medical Sciences, Dr. B. R. Ambedkar Road, Belagavi-590001, Karnataka [ECR/801/Inst/KA/2016/RR-20]	Dr. R.G. Viveki
13	Dept of General Medicine, Victoria Hospital BMCRI, K R Road Fort, Bangalore -560002, Karnataka.	Ethics Committee of BMCRI Bangalore Medical College and Research Institute, K R Road Fortz, Bangalore 560002, Karnataka [ECR/302/Inst/KA/2013/RR-20]	Dr. Aravind G. N.

In addition to point 4, the permission is subject to following condition(s):

- I. The Phase III clinical trial should be conducted as per title "A Phase 3, randomized, placebo-controlled, observer blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3 OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease vide protocol No.: 221265 protocol amendment 01 Dated 19-Apr-2024.
- II. DSMB is required to be constituted to review the safety data of phase III clinical trial.
- III. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
- IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)  
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Date:  
Place: New Delhi