

FORM CT-04

(See rule 21)

APPLICATION FOR GRANT OF PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

I/We, Ms. Sneha Vajresh Thakur of M/s Johnson & Johnson Pvt. Ltd., HIGI House, L.B.S. Marg, Mulund Mulund West (India) - 400080 Telephone No.: 0124-4647000 FAX: 0124-4647000 E-Mail : RA-JNJIN-REGJJMI@ITS.JNJ.COM hereby apply for grant of permission to conduct clinical trial on new drug or investigational new drug.

The details of the application are as under:

1. Name of Applicant: Ms. Sneha Vajresh Thakur
2. Nature and constitution of applicant: Private Limited
3. (i) Sponsor Address : M/s Johnson and Johnson Private Limited ,
LBS Marg Mulund West , Maharashtra (India) - 400080
Telephone No.: 912225644441 FAX: 912225643410

(ii) Clinical trials site address : M/s Johnson and Johnson Private Limited ,
LBS Marg Mulund West , Maharashtra (India) - 400080
Telephone No.: 912225644441 FAX: 912225643410

(iii) Name and Address of person responsible for payment of compensation, if any : Medical Director,
Arena Space, Off JVLR, Behind Majas Depot, Jogeshwari E,
Mumbai, Maharashtra (India) - 400080
Telephone No.: 2266646464 Email: RA-corporatesecretar@its.jnj.com

(iv) Address for correspondence : M/s Johnson and Johnson Private Limited,
Higi House, L.B.S. Marg, Mulund (W), Mumbai, Maharashtra (India) - 400080
Telephone No.: 912225936700 FAX: 912225936700

4.Details of new drugs or investigational new drugs and clinical investigation site [As per Annexure].

Names of the new drug or investigational new drug:	Therapeutic class:	Dosage form:	Composition:	Indications:

Amivantamab and Lazertinib	Anticancer	Solution for infusion, Tablets	Amivantamab =350.0000 milligram (mg) In House Specification Active L-Histidine =2.3000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive L-Histidine Hydrochloride Monohydrate =8.6000 milligram (mg) J.P.,Ph.Eur Inactive Sucrose =595.0000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive Polysorbate 80 =4.2000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive L-Methionine =7.0000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive EDTA Disodium Salt Dihydrate =0.1400 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive Water for Injection =0.1000 ml U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive	Amivantamab in combination with Lazertinib is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations
Amivantamab and Lazertinib	Anticancer	Solution for infusion, Tablets	Amivantamab =350.0000 milligram (mg) In House Specification Active L-Histidine =2.3000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive L-Histidine Hydrochloride Monohydrate =8.6000 milligram (mg) J.P.,Ph.Eur Inactive Sucrose =595.0000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive Polysorbate 80 =4.2000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive L-Methionine =7.0000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive EDTA Disodium Salt Dihydrate =0.1400 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive Water for Injection =0.1000 ml U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive	Amivantamab in combination with carboplatin and pemetrexed for the treatment of patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with osimertinib

Amivantamab and Lazertinib	Anticancer	Solution for infusion, Tablets	Amivantamab =350.0000 milligram (mg) In House Specification Active L-Histidine =2.3000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive L-Histidine Hydrochloride Monohydrate =8.6000 milligram (mg) J.P.,Ph.Eur Inactive Sucrose =595.0000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive Polysorbate 80 =4.2000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive L-Methionine =7.0000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive EDTA Disodium Salt Dihydrate =0.1400 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive Water for Injection =0.1000 ml U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive	Lazertinib in combination with Amivantamab is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations
Amivantamab and Lazertinib	Anticancer	Solution for infusion, Tablets	Lazertinib Mesylate Monohydrate =96.4800 milligram (mg) In House Specification Active Hydrophobic Colloidal Silica =1.9000 milligram (mg) U.S.P.,Other than the above mentioned types,Ph.Eur Inactive Microcrystalline Cellulose =218.3200 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive Mannitol =50.0000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive Croscarmellose Sodium =9.5000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive Magnesium Stearate =3.8000 milligram (mg) U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive Opadry QX 321A220024 Yellow =11.4000 milligram (mg) In House Specification Inactive Purified Water =0.0000 ml U.S.P.,J.P.,Other than the above mentioned types,Ph.Eur Inactive	Amivantamab in combination with Lazertinib is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations

Amivantamab and Lazertinib	Anticancer	Solution for infusion, Tablets	Lazertinib Mesylate Monohydrate =96.4800 milligram (mg) In House Specification Active Hydrophobic Colloidal Silica =1.9000 milligram (mg) U.S.P., Other than the above mentioned types, Ph.Eur Inactive Microcrystalline Cellulose =218.3200 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Mannitol =50.0000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Croscarmellose Sodium =9.5000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Magnesium Stearate =3.8000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Opadry QX 321A220024 Yellow =11.4000 milligram (mg) In House Specification Inactive Purified Water =0.0000 ml U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive	Amivantamab in combination with carboplatin and pemetrexed for the treatment of patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with osimertinib
Amivantamab and Lazertinib	Anticancer	Solution for infusion, Tablets	Lazertinib Mesylate Monohydrate =96.4800 milligram (mg) In House Specification Active Hydrophobic Colloidal Silica =1.9000 milligram (mg) U.S.P., Other than the above mentioned types, Ph.Eur Inactive Microcrystalline Cellulose =218.3200 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Mannitol =50.0000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Croscarmellose Sodium =9.5000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Magnesium Stearate =3.8000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Opadry QX 321A220024 Yellow =11.4000 milligram (mg) In House Specification Inactive Purified Water =0.0000 ml U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive	Lazertinib in combination with Amivantamab is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations

Amivantamab and Lazertinib	Anticancer	Solution for infusion, Tablets	Lazertinib Mesylate Monohydrate =289.4400 milligram (mg) In House Specification Active Hydrophobic Colloidal Silica =5.7000 milligram (mg) U.S.P., Other than the above mentioned types, Ph.Eur Inactive Microcrystalline Cellulose =654.9600 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Mannitol =150.0000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Croscarmellose Sodium =28.5000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Magnesium Stearate =11.4000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Opadry QX 321A200022 Reddish Purple =34.2000 milligram (mg) In House Specification Inactive Purified Water =0.0000 ml U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive	Amivantamab in combination with Lazertinib is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations
Amivantamab and Lazertinib	Anticancer	Solution for infusion, Tablets	Lazertinib Mesylate Monohydrate =289.4400 milligram (mg) In House Specification Active Hydrophobic Colloidal Silica =5.7000 milligram (mg) U.S.P., Other than the above mentioned types, Ph.Eur Inactive Microcrystalline Cellulose =654.9600 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Mannitol =150.0000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Croscarmellose Sodium =28.5000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Magnesium Stearate =11.4000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Opadry QX 321A200022 Reddish Purple =34.2000 milligram (mg) In House Specification Inactive Purified Water =0.0000 ml U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive	Amivantamab in combination with carboplatin and pemetrexed for the treatment of patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with osimertinib

Amivantamab and Lazertinib	Anticancer	Solution for infusion, Tablets	Lazertinib Mesylate Monohydrate =289.4400 milligram (mg) In House Specification Active Hydrophobic Colloidal Silica =5.7000 milligram (mg) U.S.P., Other than the above mentioned types, Ph.Eur Inactive Microcrystalline Cellulose =654.9600 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Mannitol =150.0000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Croscarmellose Sodium =28.5000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Magnesium Stearate =11.4000 milligram (mg) U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive Opadry QX 321A200022 Reddish Purple =34.2000 milligram (mg) In House Specification Inactive Purified Water =0.0000 ml U.S.P., J.P., Other than the above mentioned types, Ph.Eur Inactive	Lazertinib in combination with Amivantamab is indicated for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations
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Names and address of clinical trial site:	Ethics committee details:	Name of investigator:	Clinical
Tata Medical Center,, 14, MAR, E-W, New Town, Rajarhat Kolkata, West Bengal - 700160	INSTITUTIONAL REVIEW BOARD	Dr Prashant Pandey	Department of Laboratory sciences Tata Medical Center, 14-Mar (EW), New Town, Rajarhat Kolkata West Bengal - 700160
HCG Manavata Cancer Centre,, Manavata Health Campus, Mumbai Naka, Nashik Maharashtra - 422002	ManavataClinicalResearchInstitute Ethics Committee	Dr Raj Nagarkar	HCG Manavata Cancer Centre (Department of Pathology), HCG Manavata Cancer Centre, Manavata Health Campus, Mumbai Naka, Nashik-422002 Maharashtra, India Nashik Nashik Maharashtra - 422002
Basavatarakam Indo-American Cancer Hospital and Research Institute,, Road No 10, Banjara Hills, Telangana Telangana -500034	INSTITUTIONAL ETHICS COMMITTEE	Dr MVT Krishna Mohan	Dept of Laboratory Medicine Basavatarakam Indo American Cancer Hospital and Research Institute, Road No 10, Banjara hills, Hyderabad Hyderabad Telangana - 500034

5. Phase of the Clinical Trial **Phase 4**

6. Clinical trial protocol number with date: **Protocol No.: 61186372NSC4018 Version No. 1 Protocol Date 10-DEC-2025**

7. Fee paid on **16-DEC-2025** Rs **200000.00** receipt/challan/transaction id **1612250011963**.

8. I have enclosed the documents as specified in the Second Schedule of the New Drugs and Clinical Trials Rules, 2019.

9. I hereby state and undertake that:

(i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.

Date: 24-Dec-25

Place: Mumbai

Signature

**Sneha
Thakur**

Digitally signed by Sneha Thakur
DN: c=US, st=New Jersey, o=Johnson & Johnson,
2.5.4.97=NTRUS+NJ-5106301000,
email=spatil44@its.jnj.com, sn=Thakur,
givenName=Sneha, cn=Sneha Thakur
Reason: I have reviewed this document.
Date: 2025.12.24 22:47:23 +05'30'
Adobe Acrobat version: 2024.002.20759

(Name and Designation) : Sneha Thakur

Senior Manager - Regulatory Affairs