सत्यमेव जयते

Government of India
Central Drugs Standard Control Organisation (Headquarter)
(Directorate General of Health Services)
FDA Bhavan, ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail: dci@nic.in

File No. BIO/CT/25/000019 Dated: 25-07-2025

To,

M/s Intas Pharmaceuticals Ltd.
Corporate House, Near Sola Bridge S.G. Highway,
Thaltej Ahmedabad (India) – 380054

Subject: Application for grant of permission to conduct Phase I/III study titled – "A Prospective, Randomized, Double-Blind, Active-Controlled, Multi-Centre, Two-Arm, Phase-I/III Study to Investigate Safety, Efficacy, Pharmacokinetics and Immunogenicity of Intas Daratumumab (INTP33) Compared of DARZALEX® in Transplant-Ineligible Participants with Newly Diagnosed Multiple Myeloma" vide Protocol No. 0327-24, Version No. 1.0 dated 01-Jan-2025.- regarding

Ref. No.: Your Application No. BIO/CT04/FF/2025/47762 dated 10-02-2025 -reg

Sir,

With reference to your application No BIO/CT04/FF/2025/47762 dated 10-02-2025, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

(I) Firm is required to provide post trial access treatment to trial subjects who will be benefitted from the study drug as per NDCT Rules.

(II) Firm is required to submit samples of batches manufactured for clinical trial to NIB for testing and submit reports to CDSCO.

(III) CSR shall be submitted to this office after completion of trial.

(IV) CT-21 application shall be made by a person who manufactures new drug in the form of active pharmaceutical ingredient or pharmaceutical formulation for sale or distribution.

(V) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licensing Authority under rule 8

(VI) Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

(VII) In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

(VIII) The Central Licensing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;

(IX) Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial.

(X) Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules.

(XI) Status of enrolment of the trial subjects shall be submitted to the Central Licensing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

(XII) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority electronically in the SUGAM portal.

(XIII) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination.

(XIV) Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licensing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI.

(XV) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter.

(XVI) In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter.

(XVII) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial.

(XVIII) The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority.

(XIX) The Central Licensing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial.

(XX) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(XXI) It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.07.25 10:41:22 +05'30'

Yours faithfully,

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

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 Licensing Authority hereby permits M/s Intas Pharmaceuticals Ltd. Corporate House, Near Sola Bridge S.G. Highway, Thaltej Ahmedabad (India)- 380054 to Phase I/III study titled **– "A Prospective, Randomized, Double-Blind, Active-Controlled, Multi-Centre, Two-Arm, Phase-I/III Study to Investigate Safety, Efficacy, Pharmacokinetics and Immunogenicity of Intas Daratumumab (INTP33) Compared of DARZALEX® in Transplant-Ineligible Participants with Newly Diagnosed Multiple Myeloma"** vide Protocol No. 0327-24, Version No. 1.0 dated 01-Jan-2025 in the below mentioned clinical trial sites.

2. Details of 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 trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

Place: New Delhi
Date: 25.07.2025

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.07.25 10:42:13 +05'30'

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

Annexure:

Details of new drug or investigational new drug:

<table>
<tr><td>Names of the new drug or investigational new drug:</td><td>Daratumumab Concentrate for Solution for Infusion 100 mg/5 mL Vial and 400 mg/20 mL Vial (r-DNA origin)</td></tr>
<tr><td>Therapeutic class</td><td>Anticancer</td></tr>
<tr><td>Dosage form:</td><td>Concentrate for solution for infusion</td></tr>
<tr><td>Composition:</td><td>Each mL contains: Daratumumab 20 mg.
Each 5 mL vial contains: Daratumumab 100 mg.
Each 20 mL vial contains: Daratumumab 400 mg.
<table>
<tr><th>Name of Ingredients</th><th>Quantity (mg/mL)</th><th>Function</th></tr>
<tr><td>Daratumumab drug substance, In house</td><td>20 mg</td><td>Active ingredient</td></tr>
<tr><td>Glacial acetic acid, Ph.Eur ,IP, USP,EP,JP</td><td>0.18 mg</td><td>To adjust the pH of the formulation buffer</td></tr>
<tr><td>Mannitol USP,EP,BP,JP</td><td>25.50 mg</td><td>Stabilizer and tonicity modifier</td></tr>
<tr><td>Polysorbate-20, Ph.Eur ,IP , In –HouseUSP,EP,BP,JP</td><td>0.40 mg</td><td>Prevent surface adsorption and stabilizer of protein against protein aggregation</td></tr>
<tr><td>Sodium acetate trihydrate In –House, Ph.Eur,USP NF</td><td>2.96 mg</td><td>For maintenance of pH of formulation buffer and formulated bulk</td></tr>
<tr><td>Sodium chloride Ph.Eur,IP, In –House, USP,EP,BP</td><td>3.50 mg</td><td>Stabilizer and tonicity modifier</td></tr>
<tr><td>Water for injection, USP, Ph. Eur., IP</td><td>q.s. to 1mL</td><td>Vehicle</td></tr>
</table></td></tr>
<tr><td>Indications:</td><td>Indicated for the treatment of:
• in combination with lenalidomide and dexamethasone or with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
• in combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.
• in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
• as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.</td></tr>
</table>

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	Jeevan Amrut Hospital, Plot no. 47, Parijat Nagar, Sector N-4 CIDCO, Near Gokul Sweets, Chhatrapati Sambhajinagar (Aurangabad), Maharashtra, India-431001.	Oriion Citicare Hospital Institutional Ethics Committee, ORIION Citicare Superspeciality Hospital, Opp. Kalash Mangal Karyalay, New Osmanpura Kranti Chowk, Aurangabad, Maharashtra - 431005, India. **EC reg No.** ECR/1548/Inst/MH/2021	Dr. Manoj Murlidhar Toshniwal
2	Sparsh Hospital & Critical Care (P) Ltd., A/407, Saheed Nagar, Bhubaneswar, Orissa, India-751007.	Institutional Ethics Committee, Sparsh Hospitals and Critical Care Private Limited, Plot No-A/407, Saheed Nagar, Bhubaneswar, Khordha, Orissa - 751007, India. **EC reg No.** ECR/68/Inst/OR/2013/RR-22	Dr. Ghanashyam Biswas
3	Indrayani Hospital and Cancer Institute, Alandi Chakan Road, Alandi Devachi, Tel. Khed, Pune-412105, Maharashtra, India.	Narsimha Saraswati Medical Foundation, Indrayani Hospital And Cancer Institute, Alandi-Chakan Road, Alandi Devachi, Pune Maharashtra – 412105, India. **EC reg No.** ECR/1121/Inst/MH/2018/RR-21	Dr. Abhijit Baheti
4	Dr. Bafna's Star Superspeciality Clinic and Hospital, Rukmini Nagar, E Ward, Near LIC Ground, Kolhapur-416005, Maharashtra, India.	Zenith Institutional Ethics Committee, Kolhapur Institute Of Orthopaedic And Trauma, 204, Kh, 6/7, Behind Hotel Tourist, New Shahupuri, Near CBS, Karveer Kolhapur, Kolhapur, Maharashtra-416001, India. **EC reg No.** ECR/1976/Inst/MH/2024	Dr. Varun Ashok Bafna

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
5	KIMS Kingsway Hospitals, 44, Parwana Bhawan, Kingsway, Nagpur-440001, Maharashtra, India.	KIMS KINGSWAY HOSPITALS ETHICS COMMITTEE, KIMS KINGSWAY HOSPITALS, 44, Parwana Bhawan, Kingsway, Nagpur, Maharashtra- 440001, India. **EC reg No.** ECR/1269/Inst/MH/2025	Dr. Riya Ballikar
6	All India Institute of Medical Sciences, OPD Building, Department of Medical Oncology & Haematology, Ground Floor, G-Block, Sijua, Patrapada, Bhubaneswar, Orissa, India-751019.	INSTITUTIONAL ETHICS COMMITTEE, AIIMS, Bhubaneswar, All India Institute of Medical Sciences, BBSR, AIIMS Bhubaneswar, Sijua P/O Patrapada, Bhubaneswar, Khordha, Orissa - 751019, India. **EC reg No.** ECR/534/Inst/OD/2014/RR-20	Dr. Sourav Kumar Mishra
7	Government Royapettah Hospital, No. 01, West Cott Road, Royapettah, Chennai, Tamil Nadu-600014.	IEC, GKMC GOVT KILPAUK MEDICAL COLLEGE AND HOSPITAL, THE DEAN GKMC CHENNAI, Tamil Nadu-600010, India. **EC reg No.** ECR/1385/Inst/TN/2020	Dr. M. Pandidurai
8	HCG Hospitals, 1, Maharashtra Society, Near Mithakhali Six Roads, Elishbridge, Ahmedabad-380006, Gujarat, India.	HCG MULTI SPECIALTY ETHICS COMMITTEE, HCG Hospitals, MITHAKALI, ELLISBRIDGE Ahmedabad, Gujarat-380006, India. **EC reg No.** ECR/92/Inst/GJ/2013/RR-24	Dr. Ankit Dhirajlal Raiyani

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
9	Nil Ratan Sircar Medical College and Hospital, 138, A.J.C Bose Road, Kolkata 700014, West Bengal, India.	Ethics Committee, N.R.S. Medical College, NRS Medical College And Hospital, NRS Medical College, 138, A.J.C Bose Road, Kolkata, West Bengal-700014, India. **EC reg No.** ECR/609/Inst/WB/2014/RR-20	Dr. Tuphan Kanti Dolai
10	CRI, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Rama Nagar, Jolly Grant, Dehradun, Uttarakhand, India-248016.	Ethics Committee, Swami Rama Himalayan University, Swami Ram Nagar, P. O. Jolly Grant, Dehradun, Uttarakhand-248016, India. **EC reg No.** ECR/1741/Inst/UK/2022	Dr. Avriti Baveja
11	Sahyadri Super Speciality Hospital, Survey No. 185A, Shastri Nagar, Near MSEB Office Yerwada, Nagar Road, Pune-411006, Maharashtra, India.	SAHYADRI HOSPITALS PRIVATE LIMITED ETHICS COMMITTEE, SAHYADRI HOSPITALS PRIVATE LIMITED, SURVEY NO 89 AND 90, PLOT NO 54, LOKMANYA COLONY, KOTHRUD, Pune, Maharashtra-411038, India. **EC reg No.** ECR/493/Inst/MH/2013/RR-24	Dr. Apte Shashikant Janardan
12	KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India.	Institutional Ethics Committee, KLE University KLE Dr.PK Hospital and MRC, Nehru Nagar, Belagavi (Belgaum) Karnataka-590010, India. **EC reg No.** ECR/211/Inst/KA/2013/RR-24	Dr. Rohan Bhise

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
13	Oncowin Cancer Centre, 7th Floor, HR Elanza, Vikas Gruh Road, Nr. Mahalaxmi Five Roads, Paldi, Ahmedabad-380007, Gujarat, India.	Sangini Hospital Ethics Committee, Sangini Hospital, Santorini Square, B/H Abhishree Complex, Opp. Star Bazar, Nr Jodhpur Cross Roads, Satellite, Ahmedabad, Gujarat-380015, India. **EC reg No.** ECR/147/Inst/GJ/2013/RR-24	Dr. Kothari Rushabh Kiran
14	HCG Cancer Centre, Plot no. 10, Survey no. 13 P, APIIC Health City, Chinagadili, Arilova, VisakhaPatnam-530040, Andhra Pradesh, India.	Institutional Ethics Committee HCG Cancer Centre, HCG Cancer Centre, Plot No 10, APIIC Health City, Arilova, Chinnagadili, Mudasarlova Road, Visakhapatnam, Andhra Pradesh-530040, India. **EC reg No.** ECR/864/Inst/AP/2016/RR-20	Dr. Ramesh Uppada
15	HCG Manavata Cancer Centre, Manavata Health Campus, Behind Shivang Auto, Mumbai Naka, Nashik-422002, Maharashtra, India.	Manavata Clinical Research Institute Ethics Committee, HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka, Nashik, Maharashtra-422002, India. **EC reg No.** ECR/500/Inst/MH/2013/RR-20	Dr. Raj Nagarkar

सत्यमेव जयते

Government of India
Central Drugs Standard Control Organisation (Headquarter)
(Directorate General of Health Services)
FDA Bhavan, ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail: dci@nic.in

File No. BIO/CT/25/000019 Dated: 25-07-2025

To,

M/s Intas Pharmaceuticals Ltd.
Corporate House, Near Sola Bridge S.G. Highway,
Thaltej Ahmedabad (India) – 380054

Subject: Application for grant of permission to conduct Phase I/III study titled – "A Prospective, Randomized, Double-Blind, Active-Controlled, Multi-Centre, Two-Arm, Phase-I/III Study to Investigate Safety, Efficacy, Pharmacokinetics and Immunogenicity of Intas Daratumumab (INTP33) Compared of DARZALEX® in Transplant-Ineligible Participants with Newly Diagnosed Multiple Myeloma" vide Protocol No. 0327-24, Version No. 1.0 dated 01-Jan-2025.- regarding

Ref. No.: Your Application No. BIO/CT04/FF/2025/47762 dated 10-02-2025 -reg

Sir,

With reference to your application No BIO/CT04/FF/2025/47762 dated 10-02-2025, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

(I) Firm is required to provide post trial access treatment to trial subjects who will be benefitted from the study drug as per NDCT Rules.

(II) Firm is required to submit samples of batches manufactured for clinical trial to NIB for testing and submit reports to CDSCO.

(III) CSR shall be submitted to this office after completion of trial.

(IV) CT-21 application shall be made by a person who manufactures new drug in the form of active pharmaceutical ingredient or pharmaceutical formulation for sale or distribution.

(V) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licensing Authority under rule 8

(VI) Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

(VII) In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

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(XV) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter.

(XVI) In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter.

(XVII) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial.

(XVIII) The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority.

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(XX) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(XXI) It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.07.25 10:41:22 +05'30'

Yours faithfully,

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

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 Licensing Authority hereby permits M/s Intas Pharmaceuticals Ltd. Corporate House, Near Sola Bridge S.G. Highway, Thaltej Ahmedabad (India)- 380054 to Phase I/III study titled **– "A Prospective, Randomized, Double-Blind, Active-Controlled, Multi-Centre, Two-Arm, Phase-I/III Study to Investigate Safety, Efficacy, Pharmacokinetics and Immunogenicity of Intas Daratumumab (INTP33) Compared of DARZALEX® in Transplant-Ineligible Participants with Newly Diagnosed Multiple Myeloma"** vide Protocol No. 0327-24, Version No. 1.0 dated 01-Jan-2025 in the below mentioned clinical trial sites.

2. Details of 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 trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

Place: New Delhi
Date: 25.07.2025

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.07.25 10:42:13 +05'30'

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

Annexure:

Details of new drug or investigational new drug:

<table>
<tr><td>Names of the new drug or investigational new drug:</td><td>Daratumumab Concentrate for Solution for Infusion 100 mg/5 mL Vial and 400 mg/20 mL Vial (r-DNA origin)</td></tr>
<tr><td>Therapeutic class</td><td>Anticancer</td></tr>
<tr><td>Dosage form:</td><td>Concentrate for solution for infusion</td></tr>
<tr><td>Composition:</td><td>Each mL contains: Daratumumab 20 mg.
Each 5 mL vial contains: Daratumumab 100 mg.
Each 20 mL vial contains: Daratumumab 400 mg.
<table>
<tr><th>Name of Ingredients</th><th>Quantity (mg/mL)</th><th>Function</th></tr>
<tr><td>Daratumumab drug substance, In house</td><td>20 mg</td><td>Active ingredient</td></tr>
<tr><td>Glacial acetic acid, Ph.Eur ,IP, USP,EP,JP</td><td>0.18 mg</td><td>To adjust the pH of the formulation buffer</td></tr>
<tr><td>Mannitol USP,EP,BP,JP</td><td>25.50 mg</td><td>Stabilizer and tonicity modifier</td></tr>
<tr><td>Polysorbate-20, Ph.Eur ,IP , In –HouseUSP,EP,BP,JP</td><td>0.40 mg</td><td>Prevent surface adsorption and stabilizer of protein against protein aggregation</td></tr>
<tr><td>Sodium acetate trihydrate In –House, Ph.Eur,USP NF</td><td>2.96 mg</td><td>For maintenance of pH of formulation buffer and formulated bulk</td></tr>
<tr><td>Sodium chloride Ph.Eur,IP, In –House, USP,EP,BP</td><td>3.50 mg</td><td>Stabilizer and tonicity modifier</td></tr>
<tr><td>Water for injection, USP, Ph. Eur., IP</td><td>q.s. to 1mL</td><td>Vehicle</td></tr>
</table></td></tr>
<tr><td>Indications:</td><td>Indicated for the treatment of:
• in combination with lenalidomide and dexamethasone or with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
• in combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.
• in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
• as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.</td></tr>
</table>

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	Jeevan Amrut Hospital, Plot no. 47, Parijat Nagar, Sector N-4 CIDCO, Near Gokul Sweets, Chhatrapati Sambhajinagar (Aurangabad), Maharashtra, India-431001.	Oriion Citicare Hospital Institutional Ethics Committee, ORIION Citicare Superspeciality Hospital, Opp. Kalash Mangal Karyalay, New Osmanpura Kranti Chowk, Aurangabad, Maharashtra - 431005, India. **EC reg No.** ECR/1548/Inst/MH/2021	Dr. Manoj Murlidhar Toshniwal
2	Sparsh Hospital & Critical Care (P) Ltd., A/407, Saheed Nagar, Bhubaneswar, Orissa, India-751007.	Institutional Ethics Committee, Sparsh Hospitals and Critical Care Private Limited, Plot No-A/407, Saheed Nagar, Bhubaneswar, Khordha, Orissa - 751007, India. **EC reg No.** ECR/68/Inst/OR/2013/RR-22	Dr. Ghanashyam Biswas
3	Indrayani Hospital and Cancer Institute, Alandi Chakan Road, Alandi Devachi, Tel. Khed, Pune-412105, Maharashtra, India.	Narsimha Saraswati Medical Foundation, Indrayani Hospital And Cancer Institute, Alandi-Chakan Road, Alandi Devachi, Pune Maharashtra – 412105, India. **EC reg No.** ECR/1121/Inst/MH/2018/RR-21	Dr. Abhijit Baheti
4	Dr. Bafna's Star Superspeciality Clinic and Hospital, Rukmini Nagar, E Ward, Near LIC Ground, Kolhapur-416005, Maharashtra, India.	Zenith Institutional Ethics Committee, Kolhapur Institute Of Orthopaedic And Trauma, 204, Kh, 6/7, Behind Hotel Tourist, New Shahupuri, Near CBS, Karveer Kolhapur, Kolhapur, Maharashtra-416001, India. **EC reg No.** ECR/1976/Inst/MH/2024	Dr. Varun Ashok Bafna

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
5	KIMS Kingsway Hospitals, 44, Parwana Bhawan, Kingsway, Nagpur-440001, Maharashtra, India.	KIMS KINGSWAY HOSPITALS ETHICS COMMITTEE, KIMS KINGSWAY HOSPITALS, 44, Parwana Bhawan, Kingsway, Nagpur, Maharashtra- 440001, India. **EC reg No.** ECR/1269/Inst/MH/2025	Dr. Riya Ballikar
6	All India Institute of Medical Sciences, OPD Building, Department of Medical Oncology & Haematology, Ground Floor, G-Block, Sijua, Patrapada, Bhubaneswar, Orissa, India-751019.	INSTITUTIONAL ETHICS COMMITTEE, AIIMS, Bhubaneswar, All India Institute of Medical Sciences, BBSR, AIIMS Bhubaneswar, Sijua P/O Patrapada, Bhubaneswar, Khordha, Orissa - 751019, India. **EC reg No.** ECR/534/Inst/OD/2014/RR-20	Dr. Sourav Kumar Mishra
7	Government Royapettah Hospital, No. 01, West Cott Road, Royapettah, Chennai, Tamil Nadu-600014.	IEC, GKMC GOVT KILPAUK MEDICAL COLLEGE AND HOSPITAL, THE DEAN GKMC CHENNAI, Tamil Nadu-600010, India. **EC reg No.** ECR/1385/Inst/TN/2020	Dr. M. Pandidurai
8	HCG Hospitals, 1, Maharashtra Society, Near Mithakhali Six Roads, Elishbridge, Ahmedabad-380006, Gujarat, India.	HCG MULTI SPECIALTY ETHICS COMMITTEE, HCG Hospitals, MITHAKALI, ELLISBRIDGE Ahmedabad, Gujarat-380006, India. **EC reg No.** ECR/92/Inst/GJ/2013/RR-24	Dr. Ankit Dhirajlal Raiyani

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
9	Nil Ratan Sircar Medical College and Hospital, 138, A.J.C Bose Road, Kolkata 700014, West Bengal, India.	Ethics Committee, N.R.S. Medical College, NRS Medical College And Hospital, NRS Medical College, 138, A.J.C Bose Road, Kolkata, West Bengal-700014, India. **EC reg No.** ECR/609/Inst/WB/2014/RR-20	Dr. Tuphan Kanti Dolai
10	CRI, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Rama Nagar, Jolly Grant, Dehradun, Uttarakhand, India-248016.	Ethics Committee, Swami Rama Himalayan University, Swami Ram Nagar, P. O. Jolly Grant, Dehradun, Uttarakhand-248016, India. **EC reg No.** ECR/1741/Inst/UK/2022	Dr. Avriti Baveja
11	Sahyadri Super Speciality Hospital, Survey No. 185A, Shastri Nagar, Near MSEB Office Yerwada, Nagar Road, Pune-411006, Maharashtra, India.	SAHYADRI HOSPITALS PRIVATE LIMITED ETHICS COMMITTEE, SAHYADRI HOSPITALS PRIVATE LIMITED, SURVEY NO 89 AND 90, PLOT NO 54, LOKMANYA COLONY, KOTHRUD, Pune, Maharashtra-411038, India. **EC reg No.** ECR/493/Inst/MH/2013/RR-24	Dr. Apte Shashikant Janardan
12	KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi-590010, Karnataka, India.	Institutional Ethics Committee, KLE University KLE Dr.PK Hospital and MRC, Nehru Nagar, Belagavi (Belgaum) Karnataka-590010, India. **EC reg No.** ECR/211/Inst/KA/2013/RR-24	Dr. Rohan Bhise

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
13	Oncowin Cancer Centre, 7th Floor, HR Elanza, Vikas Gruh Road, Nr. Mahalaxmi Five Roads, Paldi, Ahmedabad-380007, Gujarat, India.	Sangini Hospital Ethics Committee, Sangini Hospital, Santorini Square, B/H Abhishree Complex, Opp. Star Bazar, Nr Jodhpur Cross Roads, Satellite, Ahmedabad, Gujarat-380015, India. **EC reg No.** ECR/147/Inst/GJ/2013/RR-24	Dr. Kothari Rushabh Kiran
14	HCG Cancer Centre, Plot no. 10, Survey no. 13 P, APIIC Health City, Chinagadili, Arilova, VisakhaPatnam-530040, Andhra Pradesh, India.	Institutional Ethics Committee HCG Cancer Centre, HCG Cancer Centre, Plot No 10, APIIC Health City, Arilova, Chinnagadili, Mudasarlova Road, Visakhapatnam, Andhra Pradesh-530040, India. **EC reg No.** ECR/864/Inst/AP/2016/RR-20	Dr. Ramesh Uppada
15	HCG Manavata Cancer Centre, Manavata Health Campus, Behind Shivang Auto, Mumbai Naka, Nashik-422002, Maharashtra, India.	Manavata Clinical Research Institute Ethics Committee, HCG Manavata Cancer Centre, Behind Shivang Auto, Mumbai Naka, Nashik, Maharashtra-422002, India. **EC reg No.** ECR/500/Inst/MH/2013/RR-20	Dr. Raj Nagarkar