

## Tata Medical Center

14 Major Arterial Road (EW)  
Newtown, Rajarhat, Kolkata - 700 160  
Tel.: + 91 33 66057000, Email : info@tmckolkata.com  
www.tmckolkata.com



### UNDERTAKING BY THE INVESTIGATOR

#### 1. Full name, address and title of the Principal Investigator

Dr. Jeevan Kumar  
MBBS, MD. DrNB  
Consultant, Clinical Hematology & Cellular Therapies  
Tata Medical Center  
14, MAR (EW), New Town, Rajarhat  
Kolkata-700160, West Bengal, India

#### 2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted:

Tata Medical Center  
14, MAR (EW), New Town, Rajarhat  
Kolkata-700160, West Bengal, India

**Education, training & experience that qualify the Investigator for the trial:** (Attach details including Medical Council registration number, and/or any other statement(s) of qualification(s))

☒ Curriculum Vitae

☒ GCP

☒ MRC

#### 3. Name and address of all clinical laboratory facilities to be used in the study.

##### Central Laboratories:

##### 1) Lab Corp Regional Facilities:

- a) Indianapolis  
8211 SciCor Drive Indianapolis IN 46214-2985
- b) Geneva  
Rue Moïse-Marcinhes 7, 1217 Meyrin/Genève-CH
- c) Singapore  
1 International Business Park The Synergy, #03-14
- d) Shanghai  
Building 9, No.338 Jialilue Road Zhangjiang Hi-Tech Park  
Shanghai 201203
- e) Tokyo  
BML General Laboratory CB Laboratory 1687-1 Matoba, Kawagoe, Saitama  
Japan 350-110

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- 2) **Hematogenix Laboratory Services**  
Attn: Accessioning Department- FISH testing  
8150 W. 185th Street Ste A  
Tinley Park, IL 60487 USA
- 3) **Kingmylab/KingMed**  
Guangzhou international BiotechIsland No. 10Luoxuan 3rd Road Guangdong510005China
- 4) **Greenfield Biorepository :**  
LabCorp Biorepository, 671 South Meridian Rd, Bldg. 210, Greenfield, Indiana, USA 46140
- 5) **Mechelen Biorepository:**  
Labcorp Biorepository, LabcorpBV, Zandvoortstraat 2Mechelen, 2800 Belgium
- 6) **Singapore Biorepository:**  
Labcorp Biorepository  
#04-14B The Synergy  
1 International Business Park, Singapore 609917
- 7) **Johnson & Johnson Sample Storage Center**  
Room 42-1204, 1400 Welsh & McKean Roads  
Spring House, PA 19477. USA
- 8) **ICON Bioanalytical Laboratory**  
EORI# NL007429757Amerikaweg 18, 9407 TK Assen  
THE NETHERLANDS

### Local Laboratories:

#### **A- Local Laboratory:**

Department of laboratory Sciences,  
Tata Medical Center, Phase I, 1<sup>st</sup> Floor  
14, MAR (EW), New Town, Rajarhat  
Kolkata-700160, West Bengal, India  
Ph No. +91-33-6605-7773/7774

#### **B- Radiology Laboratory:**

Department of Radiology,  
Tata Medical Center, Phase 1,  
Grand Floor 14, MAR (EW), New Town, Rajarhat Kolkata-700160, West Bengal, India  
Ph No. +91-33-6605-7850

4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the

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study.

Institutional Review Board  
Tata Medical Center, Phase II, 1<sup>st</sup> Floor  
14, MAR (EW), New Town, Rajarhat  
Kolkata-700160, West Bengal, India  
Ph No. +91-33-6605-8146/7579

### EC Registration No. ECR/269/Inst/WB/2013/RR-24

5. Names of the other members of the research team (Co-or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation(s).

- Dr. Arijit Nag  
MBBS, MD, MRCP, DM  
Consultant
- Dr. Debranjani Chattopadhyay  
MBBS, MD, DM, DrNB  
Consultant
- Dr. Dibakar Podder  
MBBS, MD, DM  
Consultant
- Dr. Shourio Ghosh  
MBBS, MD, DM  
Consultant
- Dr. Saswata Saha  
MBBS, MD, DM  
Consultant

6. Protocol number: 79635322MMY3002

Protocol Title: A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Antibody and Lenalidomide

### 7. Commitments:

- (i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct of the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
- (ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval/favorable

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opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.

- (iii) I agree to personally conduct and/ or supervise the clinical trial at my site.
- (iv) I agree to inform all trial Subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trial Rules, 2019GCP guidelines are met.
- (v) I agree to report to the Sponsors all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory requirements and GCP guidelines.
- (vi) I have read and understood the information in the Investigator's brochure and/ or Prescribing Information of the drug product, including the potential risks and side effects of the drug.
- (vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
- (viii) I agree to maintain adequate and accurate records and to make those records available for audit/ inspection by the Sponsor, Ethics Committee, Central Licensing Authority or their authorized representatives, in accordance with regulatory provisions and the GCP guidelines. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
- (ix) I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
- (x) I agree to inform all serious adverse events to the Central Licensing Authority, Sponsor as well as the Ethics Committee within twenty-four hours of their occurrence. In case, of failure to do so, I shall furnish the reason for the delay to the satisfaction of the Central Licensing Authority along with the report of the serious adverse event.
- (xi) The report of the serious adverse event, after due analysis, shall also be forwarded by me to the Central Licensing Authority, the Chairperson of the Ethics Committee and the Head of the Institution where the trial has been conducted within fourteen days in accordance with the regulatory requirements.
- (xii) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.
- (xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

8. Signature of Investigator with Date and Hospital stamp:

*Jeevan Kumar*  
06/3/2026

Dr. Jeevan Kumar  
Senior Consultant,  
Clinical Haematology and Cellular therapies  
Tata Medical Center  
Kolkata-700160, W.B.