MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (MoU) effective 23rd September 2022 is made by & between;

Rectitude Ethics Committee, the institutional Ethics Committee (IEC) of DNS Hospitals Pvt.Ltd. having its Registered Office at 14 Anoop Nagar, A. B. Road,Near L. I. G. Square, Indore 452008, **India**, established to ensure the rights, safety, well-being of human participants in research conducted [hereinafter referred to as the "**Reviewing Committee**" (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its successors and permitted assigns)

AND

Dr. Amit Katlana, Professor – Department of Surgery, Index Medical College Hospital & Research Centre at **Index City, NH – 59A, Near Khudel, Nemawar Road, Indore, Madhya Pradesh 452016, India** [hereinafter referred to as the "**Investigator**" and Index Medical College Hospital & Research Centre, Indore as "**Institution**" (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its representatives, agents and permitted assigns etc.)

AND

DNS Hospitals Pvt.Ltd., (In association with SRJ Healthcare Pvt. Ltd),

Indore, Madhya Pradesh 452008, India, a Company registered under the provisions of Indian Companies Act, NH/0282/MAR-2020, having its registered office at 14 Anoop Nagar, A. B. Road, Near L. I. G. Square, Indore acting through its Director, Rajesh Jain, being authorized to sign this Agreement (hereinafter referred to as the "Institute" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

(Hereinafter individually "**Party**" or collectively "**Parties**")

WHEREAS the Reviewing Committee is recognized for its expertise and is mandated to review and monitor any and all types of research in which human subjects are involved.

Malwanchal University INDORE

College Address : Index City, Near Khudel, NH-59A, Nemawar Road, Dist., INDORE (M.P.)- 452 016 Ph. 0731-4013600
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E-mail : medical@indexgroup.co.in, deanindex1@gmail.com I website : www.indexgroup.co.in,

WHEREAS THE Investigator shall in association with **Raptim Research Pvt. Ltd.,** (hereinafter called as **"Sponsor")** a Pharmaceutical company involved in research, development, manufacture and sale of pharmaceutical products for use in humans is desirous of conducting the Clinical Trial at Index Medical Hospital & Research Centre; A Multicentric, Open-label, Randomized, Two Period, Two Treatment, Two Sequence, Cross Over, Multiple Dose, Steady state Bioequivalence Study of Pazopanib tablets 200 mg of Eugia Pharma Specialities Limited (Test) with VOTRIENT® (pazopanib) tablets 200 mg of Novartis Pharmaceuticals Corporation, USA (Reference) in adult patients with advanced renal cell carcinoma already receiving Pazopanib HCl tablets in standard therapy, and who are tolerating a stable dosing regimen of 800 mg/day (4 × 200 mg) under fasting conditions.

AND WHEREAS the Investigator approached the Review Committee for review of the Study. In consideration of the mutual promises of the parties herein, and of the mutual covenants and conditions hereinafter set forth, the parties agree as follows:

1. Reviewing Committee shall review the study to be conducted by the investigator and evaluate the performance of the surgeon & his team and shall use its best efforts to deliver the finding and recommendations with a view to ensure the rights, safety, and well-being of human participants in research conducted.

2. The Parties represent and warrant that they each have the authority to enter into this Agreement. The Institution and/or Investigator will ensure the availability of and/or access to any resources necessary to perform the Clinical Trial at the Trial Site, including departments, facilities and Research Staff and support personnel, and the Principal Investigator represents that he/she holds the necessary registration and has the necessary qualifications, expertise and time to perform the Clinical Trial.

3. The Sponsor and the Investigator agree to perform the Clinical Trial in accordance with the terms and conditions of this Agreement and are expected to conduct the study in compliance with applicable local regulations, guidelines and standard operating procedures.

4. The Investigator and study team will report and update the Reviewing Committee about detailed status of study on a bi-monthly basis for the first year from site initiation and quarterly basis from second year till site close out or last patient last follow-up visit, whichever is earlier.

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5. The Investigator and study team will report to the Reviewing Committee by email / letter (in standard detailed format) all Adverse Events, Serious Adverse Events and all deviations related to Protocol, related to applicable guidelines, related to local regulations and any other general, situational and any other deviation irrespective of severity of the effect of the deviation or event promptly. Any delay in the same may result in immediate suspension of conduct of the trial at the Investigator site and result in a for-cause audit and/or inspection.

6. Reviewing Committee will have access to all requested data of study subjects as and when required for review.

7. Reviewing Committee may conduct audit and/or inspection of the study conduct and related data as and when required.

8. Reviewing Committee expects information, notification, pre-initimation & pre-approval (wherever necessary) of any change or update in any of the study Protocol, documents, procedure or any other change in connection or in relation to the study.

9. In the event of any substantial amendments being made to the Protocol, the amendments shall be signed by the Investigator and shall be implemented by the Research Staff as required by the Sponsor or CRO after approval of the amendments by the Competent Authority and a favourable opinion of the Reviewing Ethics Committee.

10. Reviewing Committee needs to be informed of any protocol waiver granted to any subject; in case of any emergency/life threatening circumstances.

11. The Parties shall conduct the Clinical Trial in accordance with:
    a. the Agreement;
    b. the Protocol;
    c. the terms and conditions of the Clinical Trial Authorization granted by the Competent Authority and the opinion of the Reviewing Ethics Committee; and
    d. the applicable Laws.

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5/11/22

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INDEMNIFICATION

Subject to the limitations set out hereinafter, Investigator shall indemnify, defend and hold harmless the Reviewing Committee, its representatives, members, agents & the assigners (the "Indemnitees") against all claims, demands, actions or proceedings (to include any settlements or ex-gratia payments made with the consent of the Parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise):

(i) by or on behalf of any Clinical Trial Subject in connection with personal injury or death arising out of the administration or use of the Investigational Product during or as a result of the Clinical Trial, or of any clinical intervention or procedure provided for or required by the Protocol, to which the Clinical Trial Subject would not have been exposed but for its participation in the Clinical Trial;

(ii) by Institution, the Principal Investigator or by or on behalf of a Clinical Trial Subject for compensation of reasonable and necessary medical costs and expenses incurred by the Clinical Trial Subject who has suffered personal injury as described in above.

INSURANCE

The Investigator and Institution will take out or maintain an insurance cover in respect of the potential liability of Investigator & Institution, the Research Staff, the Principal Investigator and any other employees and Agents involved with the conduct of the Clinical Trial pursuant to this Agreement. Institution shall produce on request the copies of Clinical Trial Agreement with the sponsor and insurance certificates, together with evidence that the policies to which they refer remain in full force and effect during the term of this Agreement and any period thereafter as may be required by mandatory law.

Further, the terms of any insurance or the amount of cover shall not relieve Institution or the Principal Investigator of any liabilities under this Agreement.

The Ethics Committee expressly disclaims any liability in connection with the content of the Protocol and the Investigational Product, including any liability for any product claim arising out of a condition caused by or allegedly caused by the administration of such product and willful and intentional misconduct of the study team.

The Principal Investigator shall make sure that the Clinical Trial Subjects (and/or their legal representatives) will, in accordance with applicable Law, be duly informed and that each give his/her audio-visual informed consent prior to participation in the Clinical Trial. Institution will provide Ethics Committee an opportunity to review the content of any Clinical Trial recruitment materials directed to potential Clinical Trial Subjects before such materials are used, regardless of medium.

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In the event that the Ethics Committee reasonably believes there has been any research misconduct in relation to the Clinical Trial, Site Parties shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Ethics Committee, the results of which the Party on whose behalf the investigation was undertaken shall, subject to any obligations of confidentiality, communicate to the Principal Investigator & Institution.

The investigator &/or Institution shall take appropriate measures and cause the Research Staff to take appropriate measures and corrective actions without delay as the Ethics Committee may reasonably require in order to solve all problems found and reported by the Trial Monitors and any of the aforesaid Auditors, by or on behalf the representatives of the Ethics Committee.

The Investigator and Study Team shall ensure that all procedures defined in the Protocol are complied with, so that all data generated at the Trial Site are reliable and have been processed correctly and will ensure that the content of the CRFs (Case Report Forms) will accurately reflect source documents.

CONFIDENTIALITY

The Parties agree that each will comply with their respective obligations as required under applicable privacy and data protection laws. The Institute and the Investigator will obtain the consent of each Research Subject for the use, processing, holding and transfer of their data to other countries that may not have same level of data protection as in India. It is the responsibility of Investigator and Institution to effect and maintain all registrations for the processing of Clinical Data as required by the applicable law and legislation. Each Party shall be responsible for its own processing of personal data in accordance with all law and regulations and with the informed consents obtained from Clinical Trial Subjects.

The Parties agree to adhere to the principles of medical confidentiality in relation to Clinical Trial Subjects.

The Receiving Party shall ensure that only those of its officers and employees (and those of its Affiliates and members of the Research Staff) and Agents directly concerned with the carrying out of this Agreement have access to the Confidential Information of the Disclosing Party. The Receiving Party shall take all practicable steps to ensure that such persons abide by the same obligations of confidentiality as apply to the Receiving Party under this Agreement. The Receiving Party undertakes to treat as strictly confidential and

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not to disclose to any third party any Confidential Information of the Disclosing Party, except where disclosure is required by a regulatory authority or by law, in which case the

Receiving Party shall inform the Disclosing Party of such requirement and the information to be disclosed and Disclosing Party take reasonable steps to limit the scope of such disclosure. Notification will be within a reasonable time prior to being required to make the disclosure or if such time is not available, immediately upon becoming known of the requirement to disclose Confidential Information. The Receiving Party undertakes not to make use of any Confidential Information of the Disclosing Party, other than in accordance with this Agreement, without the prior written consent of the Disclosing Party.

The obligations of confidentiality and non-use set out in above clause hall not apply to information which:

a. is or becomes part of the public domain by any other means than a wrongful act or breach of this Agreement by the Receiving Party;

b. was or becomes in the Receiving Parties' lawful possession prior to the disclosure without restriction on disclosure as evidenced by written records;

c. has been independently developed by the Receiving Party without the use of Confidential Information of the Disclosing Party as evidenced by written records;

d. has been obtained by the Receiving Party from a third party who is not subject to a duty of confidentiality.

TERM AND TERMINATION

This Agreement shall come into effect upon the Effective Date and shall remain in force till the Study is completed and the Parties have discharged their obligations pursuant to this Agreement, unless and until terminated by any party.

Each Party may terminate this Agreement upon one month written notice to the other Parties with immediate effect in the following events:

a. if the approval by the Ethics Committee in charge of the Clinical Trial is not granted or irrevocably revoked;

b. if it can be reasonably concluded that the Clinical Trial must be terminated in the interests of the health of the Clinical Trial Subjects;

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c. If it becomes apparent, following confirmation of the Ethics Committee, that continuation of the Clinical Trial cannot serve a scientific purpose, and this is notified to the Ethics Committee;

d. if the Sponsor and/or the Institution and/or the Investigator become or are declared insolvent or a petition in bankruptcy has been filed against it or if one of them is dissolved;

e. if circumstances beyond a Party's control occur that render continuation of the Clinical Trial unreasonable.

f. if one of the parties fails to comply with the obligations arising from the Agreement and, if capable of remedy, is not remedied within 15 days after receipt of notice from the other Party specifying the non-compliance and requiring its remedy, unless failure to comply is not in reasonable proportion to the premature termination of the Clinical Trial.

In all circumstances causing the early termination of this Agreement pursuant to clauses above, the Sponsor shall confer with the Principal Investigator and Institution shall use their best endeavors to minimize any inconvenience or harm to Clinical Trial Subjects caused by the premature termination of the Clinical Trial. Parties agree that in case of early termination of this Agreement, they will in good faith try to make arrangements concerning the continuation of the treatment of the enrolled patients if such is in their medical best interest.

GOVERNING LAW AND DISPUTE RESOLUTION

This Agreement shall be governed by, and construed in all respects in accordance with the applicable laws without regard to its conflicts of laws rules. Any claims, controversies or disputes arising out of or in connection with this Agreement which cannot be settled amicably between the Parties, shall be subject to the exclusive jurisdiction of the competent court in Indore.

IN WITNESS WHEREOF, The Parties have duly executed this Agreement as of the date first written above.

Reviewing Committee: **Rectitude Ethics Committee** (the institutional Ethics Committee), **DNS Hospitals**

Signature:

Date: 23/09/2022

Name: DR. M.S. GUJRAL

Chairman
Rectitude Ethics Committee
INDORE

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Title: Chairperson/Member Secretary, Rectitude Ethics Committee

Address for Notices: **Rectitude Ethics Committee, DNS Hospitals Ltd., 14 Anoop Nagar, A.B. Road, Near L.I.G. Square, Indore 452008, India**

Institute Signatory Authority: **Dr. Rajesh Jain**

Signature:

Date: 23/9/2022

Name: DR RAJESH JAIN

Title: **Director, DNS Hospitals Pvt.Ltd.,**

Address for Notices: **DNS Hospitals Pvt.Ltd., 14 Anoop Nagar,A.B. Road, Near L.I.G. Square, Indore 452008, India**

Investigator: **Dr. Amit Katlana**

Signature:

Date: 23/09/2022

Name: **Dr. Amit Katlana**

Dr. Amit Katlana
Surgery
Professor
Reg. No.- MP-4771

Title: **Principal Investigator**

Address for Notices: **Index Medical College Hospital & Research Centre at Index City, NH – 59A, Near Khudel, Nemawar Road, Indore, Madhya Pradesh 452016**

Institute Signatory Authority: **Dr. G. S. Patel**

Signature:

Date: 23/9/22

Dean
Index Medical College,
Hospital & R.C.,INDORE

Name: Dr G.S. Patel

Title: **Dean, Index Medical College Hospital & Research Centre**

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