



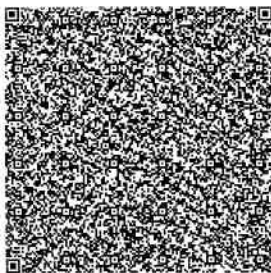
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INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

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Certificate No.	: IN-DL73206550360108P
Certificate Issued Date	: 20-Apr-2017 05:53 PM
Account Reference	: IMPACC (IV)/ dl719703/ DELHI/ DL-DLH
Unique Doc. Reference	: SUBIN-DL71970347025481731176P
Purchased by	: JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Description of Document	: Article 5 General Agreement
Property Description	: Not Applicable
Consideration Price (Rs.)	: 0 (Zero)
First Party	: JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Second Party	: MGMMC AND HOSPITAL AURANGABAD
Stamp Duty Paid By	: JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	: 100 (One Hundred only)



Please write or type below this line.....

DATED 05 MAY 2017

**JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
(AS THE CRO)**

AND

**DR. ASHISH RAMCHANDRARAO DESHMUKH
(AS THE PRINCIPAL INVESTIGATOR)**

AND

**MAHATMA GANDHI MISSION'S MEDICAL COLLEGE AND HOSPITAL
(AS THE SITE/INSTITUTION)**

CLINICAL TRIAL AGREEMENT

STUDY: VBP-245-MCV
Statutory Alert:

Page 1 of 22

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
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This Clinical Trial Agreement (the "Agreement") is dated: **05 May 2017**.

BETWEEN:

1. **JSS Medical Research India Private Limited.**, a company registered under the provisions of Indian Companies Act, 1956, having its office at 12/2, 6th Floor, Tower-B, Vatika Mindscapes, Sector 27-D, Faridabad-121003, Haryana, India acting through Dr. Renu Razdan, Vice President, India being authorized to sign this Agreement on behalf of Sponsor, Veloce BioPharma LLC (hereinafter referred to as "**JSS India**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

And

2. **Dr Ashish Ramchandrarao Deshmukh** , working as Professor & Head at Skin & VD Department, Mahatma Gandhi Mission's Medical College and Hospital having his residence at Aurangabad (hereinafter referred to as the "PI" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

And

3. **Mahatma Gandhi Mission's Medical College and Hospital**, a hospital/health care registered under the provisions of [Indian Companies Act, 1956 OR any other relevant law], having its registered office at N-6, Cidco, Aurangabad-431003. Maharashtra. acting through its Dr Rajendra Bohra being authorized to sign this Agreement (hereinafter referred to as the "Site" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

JSS India, the PI, and the Site shall hereinafter be referred to individually as "*Party*" and collectively as "*Parties*".

Whereas:

- A. JSS India is a CRO and is in the business of providing Clinical Trial Site Management Services, Clinical Trial Monitoring Services and Clinical Data Management Services and certain other services related to any clinical study including site and principal investigator identification, regulatory, pharmacy services, identification and management of other agencies related to a clinical study translation of documents.
- B. The Site is engaged in Health care and the PI is an Employee [employee/consultant] at the Site.
- C. Veloce BioPharma LLC is the Sponsor, desires to conduct a clinical trial in respect of the **Topical Povidone-Iodine (PVP-I, 2% [W/W]) in Pediatric Subjects for the Treatment of Molluscum Contagiosum**, and JSS India, the PI and the Site have represented willingness to participate in the Clinical Trial.
- D. The Parties are now desirous of conducting the Clinical Trial in accordance with the terms and conditions hereof.

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1. Definitions and Interpretations

1.1 In this Agreement:

“Adverse Event” shall mean adverse event(s) as provided in the Protocol or any Clinical Trial Document, which may occur to a Subject due to administration of the Clinical Trial Drug.

“Applicable Laws” shall mean any applicable statute, law ordinance, regulation, rule, guideline, order, by law, administrative interpretation, writ, injunction, directive, judgment, or decree or other instrument which has the force of law in India.

“Budget” shall mean the budget agreed by the Parties in respect of conducting the Clinical Trial as more specifically described in Schedule B.

“Case Report Form” shall mean the case record form for each Subject in the form and manner provided by the Sponsor.

“Clinical Trial” shall mean a clinical trial conducted as per the Protocol.

“Clinical Trial Documents” shall mean and include all documentation received from the Sponsor in respect of a Project, including but not limited to (i) Protocol; (ii) Information Brochure, (iii) Informed Consent Form; (iv) Case Record Form; (v) Questionnaires; (vi) Patient Diaries and (vii) any other document as the Sponsor may, from time to time, provide.

“Disability” shall mean an event where either Party may be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, acts of god, inclement weather or other reason or cause beyond that Party’s reasonable control.

“Dispute Notice” shall mean a written notice issued by an aggrieved Party to the other Party in relation to any controversy, conflict or dispute of any nature arising out of or relating to or in connection with the provisions of this Agreement.

“Drug” or **“Clinical Trial Drug”** shall mean the chemical compound invented by the Sponsor, excluding a placebo, in respect of which the Clinical Trial is being conducted.

“Drugs Act” shall mean the Drugs and Cosmetics Act, 1945 and rules made there under or any other enactment that may be in force in India.

“Effective Date” shall mean the date on which this Agreement shall come into effect.

“Ethics Committee” or **“Institutional Ethics Committee”** shall mean the ethics committee formed by the Site and the independent ethics committees formed in accordance with the Applicable Laws to review and approve all types of research proposals involving human participants on the Site with a view to safeguard the dignity, rights, safety and well being of all such actual and potential research participants.

“Feasibility Study” shall mean a feasibility study conducted by JSS India to assess the feasibility of conducting clinical study(ies) in respect of a Project prior to commencement of a Project.

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“Fee” shall mean the fees and expenses, expenses and pass-through costs incurred in performing the Services payable by the Sponsor, or if so authorized by JSS India in respect of each Project and/or Clinical Trial as provided in Schedule B, herein.

“ICH GCP Guidelines” shall mean the International Conference on Harmonization-Good Clinical Practice issued by Helsinki Declaration in June, 1964 with applicable updates and amendments thereof.

“ICH” shall mean International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

“Indian GCP” shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research. **“Information Brochure”** shall mean the information brochure of the Sponsor.

“Informed Consent Form” or **“ICF”** shall mean a written consent form provided by the Sponsor which is duly approved by the appropriate authorities and the Ethics Committee in respect of a Clinical Trial, which is required to be signed and acknowledged by the Subject .

“Investigational Products” shall mean the chemical compound invented by the Sponsor, including a placebo, in respect of which the Clinical Trial is conducted or any medical device, etc. developed by the Sponsor.

“Invoice” shall mean an invoice issued in respect of the services performed by the PI and/or the Site, in accordance with this Agreement.

“Subject” shall mean the patient upon whom the Clinical Trial is being conducted by the PI and/or the Site.

“Payment Milestone” shall mean payment milestones for payment of the Fees as more specifically described in Schedule B.

“Protocol” shall mean Protocol No. VBP-245-MCV as provided by the Sponsor.

“Price” shall mean the approved payment rates detailed in the budget proposal attached hereto as Schedule ‘C’ and in accordance with the milestones mentioned therein (the “Price and Payment Schedule”). The Price shall be the total consideration and includes the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the Clinical Trial.

“Screen Failure” shall mean the screen failure as defined in the Protocol.

“Serious Adverse Event” or an **“SAE”** includes all adverse experience(s) which are defined as serious in accordance with the Protocol, ICH guidelines and/or any other Applicable Laws.

“Services” shall mean the services detailed in Schedule ‘A’.

“Site Indemnitee” shall mean the Site and its employees and its associated staff.

“Sponsor Property” shall mean all data and information generated or derived by JSS India arising out of any Services performed by JSS India.

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“Standard Operating Procedures” or “SOP” shall mean the written code specifying the standard operating procedures in respect of the Clinical Trial of the relevant Party.

1.2 In this Agreement:

- 1.2.1 words denoting the plural number include the singular and vice versa;
- 1.2.2 references to Recitals, Clauses and Schedules are references to recitals, clauses and schedules to or of this Agreement;
- 1.2.3 references to this Agreement include the Recitals and the Schedules;
- 1.2.4 the headings and contents page(s) are for the purpose of reference only, have no legal or other significance, and shall be ignored in the interpretation of this Agreement;
- 1.2.5 references to any document (including, without limitation, to all or any of the Relevant Documents) are, unless the context otherwise requires, references to that document as amended, supplemented, novated or replaced from time to time;
- 1.2.6 references to statutes or provisions of statutes are references to those statutes, or those provisions, as from time to time amended, replaced or re-enacted; and
- 1.2.7 references to any Party include its successors, transferees and permitted assignees.

2. **Scope of the Agreement**

The PI agrees to perform the Clinical Trial for and on behalf of the JSS India/Veloce BioPharma in accordance with the Protocol and/or any other document specifically provided in this respect by JSS India.

3. **Term**

- 3.1 This Agreement shall commence on the Effective Date and shall continue till the Clinical Trial is completed as per the Protocol or till the date it is terminated earlier in accordance with this Agreement (the “Term”).

4. **Clinical Trial**

- 4.1 Clinical Trial Initiation: JSS India shall provide the PI all Clinical Trial Documents. The PI and/or the Site shall obtain the approval of the Ethics Committee in respect of the Clinical Trial. If the PI and/or the Site are unable to obtain the approval of the Ethics Committee within such duration, the Parties shall agree upon an alternative duration within which the PI and/or the Site shall obtain such approval. It is expressly agreed that the JSS India may terminate this Agreement if such approval is not obtained by the PI and/or the Site within the time period prescribed hereunder.
- 4.2 Duration: The estimated duration for a Clinical Trial is defined in the Protocol including follow-ups. The Site and the PI acknowledge that a Clinical Trial may be discontinued at any time, upon written instructions from JSS India.

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- 4.3 Completion of Subject related procedures: A Clinical Trial shall be considered to be completed when criteria for completion as specified in the Protocol are met.

5. Responsibilities and Obligations of the Parties

5.1 JSS India shall be responsible for the following:

- i. Clinical Trial Documents, Investigational Products: Providing all the Clinical Trial Documents and the Investigational Products in advance or on time to the PI and/or the Site on behalf of veloce BioPharma.
- ii. Other Duties: Site Monitoring, Medical Monitoring, Clinical Data Management, including electronic data capture Statistical Programming, Clinical Study Report preparation & IMP logistic management

5.2 The PI and/or the Site shall be responsible for the following:

- a. The PI shall be responsible that the Trial should be conducted as per the Protocol, GCP Guidelines and Investigator's undertaking. For the tasks performed, Standard Operating procedures are to be documented.
- b. PI shall be responsible for the identification and documentation of any and all Adverse Events and/ or Serious Adverse Events.
- c. Upon request by JSS India, the PI will provide JSS India all information needed by JSS India and/or Veloce BioPharma in the clinical sections of regulatory submissions to any regulatory agency including but not limited to, the "Investigational New Drug", annual report and the NDA ("**New Drug Application**") safety update, as well as regulatory submissions to other such agencies, in accordance with the Applicable Laws.
- d. The PI agrees that as soon as minimum essential information about an SAE becomes available to PI, it will immediately report such information to JSS India and/or the Sponsor, as directed in the Protocol. The PI will act reasonably to provide to the JSS India with at least the minimum essential information about an SAE, as identified in the Clinical Trial Documents at the earliest. The PI will not postpone or cause delay in reporting any such information to JSS India and/or the Sponsor irrespective of whether more detailed information may become available at a later time, or because the available information is not yet confirmed.
- e. The PI is responsible for making available any and all other safety information, as directed by JSS India and/or the Sponsor, in accordance with regulatory standards and the Clinical Trial Documents.

- 5.3 Regulatory Agency Audit: The PI and the Site will inform JSS India within twenty-four (24) hours of being notified of a regulatory agency audit (if advance notice is given by any applicable regulatory agency) or within twenty-four (24) hours of the beginning of any applicable regulatory agency audit (if no advance notice is given by the applicable regulatory agency). The PI and the Site shall provide JSS India with a copy of all Clinical Trial specific observations made during a regulatory audit at the PI and/or the Site's facilities, immediately upon receipt of such information. The PI shall cooperate fully with JSS India in any such investigation, and in the implementation of appropriate action plans for such observations.

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6 Representations, Warranties and Covenants.

6.1 JSS India represents, warrants and covenants to the Sponsor as follows:

- (a) Formation/Power and Authority: JSS India is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.
- (b) Compliance with Applicable Law: JSS India represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.
- (c) Permits: JSS India will or it shall cause the Sponsor to identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of a Project.
- (d) Freedom to Use: JSS India hereby represents and warrants that the Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that JSS India conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.
- (e) Debar: JSS India certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

JSS India agrees that it will promptly notify the other Parties in the event of any such debarment, conviction, threat or indictment occurring during the Term.

6.2 The Site represents, warrants and covenants to JSS India and the Sponsor as follows:

- (a) Formation/Power and Authority: The Site is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.
- (b) Compliance with Applicable Law: The Site represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.
- (c) Ethics Committee: The Site represents that it is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.
- (d) Freedom to Use: The Site hereby represents and warrants that the JSS India/Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that the Site conveys or provides hereunder without restriction and without infringing or

misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

- (e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.
- i. The Site agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or the three (3) year period following the termination or expiration of this Agreement.
 - ii. The Site agrees not to employ or otherwise engage during the Term any individual who will be rendering services to the PI and/or the Site in respect of the Clinical Trial who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.
 - iii. Upon JSS India request from time to time, the Site will certify in writing, the Site's compliance with the foregoing provisions of this paragraph.

6.3 The PI represents, warrants and covenants to JSS India as follows:

- (a) Power and Authority: The PI hereby represents that it is duly registered in accordance with the Applicable Laws, and it has all power and authority (legal, corporate or other) to execute and deliver this Agreement and to perform its obligations hereunder.
- (b) Ethics Committee: The PI representing that he is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers till the study recruitment target is achieved as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.
- (c) Debar: The PI represents that it has never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.
 - i. The PI agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or three (3) year period following the termination or expiration of this Agreement.
 - ii. Upon JSS India request from time to time, PI will certify in writing, the PI compliance with the foregoing provisions of this paragraph.

7 Use of Name

No Party shall use the name of another Party either expressly or by implication in any news or publicity release, policy recommendation or commercial fashion without the express written approval of that Party. Nothing herein shall be construed as prohibiting by JSS India and/or the Sponsor from reporting on this study to a governmental agency and to other investigators studying the Drug, or of exercising its publication rights in accordance with Clause 10.

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8 Ownership of Property and Data

Veloce BioPharma LLC shall have sole ownership and rights to any inventions or discoveries relating to the Drug, whether patentable or not, made in the performance of this Agreement.

9 Record Retention and Site Audits

- a. The Site shall retain all records and documents pertaining to a Clinical Trial for a period of at least fifteen (15) years, following the latest of the following dates: **(a)** the date on which a marketing application for the particular Clinical Trial Drug is approved by the appropriate government body and/or other applicable regulatory authorities and until there are no pending or contemplated marketing applications in an ICH region (*any other applicable regulation*) **(b)** the date of completion of the Clinical Trial, or **(c)** if the Clinical Trial is discontinued before completion, the date on which the any applicable regulatory authorities are so notified.
- b. JSS India / Veloce may monitor and audit the Site and the PI's performance of the Clinical Trial. Such audits may, as JSS India/Veloce so elect, comprise: **(a)** inspection of the PI's and/or the Site's facilities and records relating to the rendering of services to or for a Clinical Trial; **(b)** review of the PI and/or the Site's compliance with licensures and certifications as per the Applicable Laws; and **(c)** the PI's adherence to Applicable Laws, including in particular, but without limitation, Indian GCP and ICH GCP Guidelines.

10 Publications

JSS India and the Sponsor shall retain ownership of all original Case Report Forms, data, analyses and reports that result from the Clinical Trial. Notwithstanding the foregoing, the PI and the Site understand and agree that participation in the Clinical Trial may involve a commitment to publish the data from the Clinical Trial in a cooperative publication with other investigators prior to publication or presentation of individual investigator results. The PI and the Site may only publish the results of the Clinical Trial in accordance with Applicable Laws and with prior written information to the Sponsor and JSS India. The PI and the Site agrees to delete any information that may be confidential or proprietary.

11 Fees

- 11.1 Budget: The CRO, PI and/or the Site shall provide an estimate of the budget to the other Parties on or before site selection. The Parties shall negotiate and agree on the Budget. The Budget shall include Fees, the costs for conducting the Clinical Trial and any other incidental and/or overhead charges.
 - 11.1.1 The Budget may only be modified in exigent circumstances, and only with the prior written consent of JSS India. It is expressly agreed that tests or services not required by the Protocol or performed in excess of Protocol requirements shall not be compensated by the JSS India unless the PI and/or the Site have taken the written consent of JSS India before administration of such tests or services.
- 11.2 Payment of Fees and Expenses to the PI and/or the Site: The CRO- JSS India shall provide the PI and/or the Site the Fees in accordance with Schedule B.

The PI and/or the Site shall be paid for all patients, including any Screen Failure patients. In case the PI and/or the Site recruits more or less than the number of Subjects provided in the Protocol, the consideration for their services will be prorated according to the actual number

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of Subjects enrolled and the agreed per Subject consideration. The PI and/or the Site will also be paid for Screen Failure patients. This consideration will be paid in addition to patients actually randomized, in accordance with Schedule C.

11.2.1 Unless otherwise agreed by the Parties, the following shall apply:

- (a) the PI and/or the Site will issue its invoice for the Fees to the JSS India, on reaching the Payment Milestone (as defined in Schedule B)] on a monthly basis; and
- (b) the JSS India, if so authorized, shall pay the invoiced amount within forty five (45) business days of the date of the original invoice received at JSS. The payment shall be made through crossed cheque/DD, as applicable:

PAYEE INFORMATION:

The Total study budget will be paid to below payee details (after TDS deduction)

Payee details:

PAYEE NAME	MGM MEDICAL COLLEGE
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	AAATM4256E
ACCOUNT NUMBER AND BANK DETAILS	0376104000000107 IDBI Bank, Aurangabad IFSC Cod:- IBKL0000376 MICR CODE:- 431259008 Bank AD Code:- 6910452-6240008 Swift Code:- IBKLINBBABD

11.2.2 Taxes: Any service tax, duty, value added tax, or other government instituted tax or levy that may become payable in respect of the services offered in this Agreement shall be to the PI's and/or the Sponsor's account. The payment shall be made after deducting all applicable deductions as per Applicable Law, including tax deducted at source.

11.2.3 Final Payment: Upon completion or termination of the study, the PI and/or the Site shall provide a written notice to JSS that all work requested under this Agreement has been completed and all monies due have been received. Acceptance of the payments as "final" constitutes such acknowledgement.

12 Insurance

- a. JSS India shall maintain all adequate insurance coverage, including a (i) professional liability insurance, (ii) indemnity insurance covering JSS India, the PI and the Site, (iii) human clinical trial insurance covering JSS India, the PI and the Site during the Term.
- b. The JSS shall deliver copies of the certificate evidencing the insurance coverage in accordance with Clause 13.4.1 to the Site and the PI.

13 Indemnification

13.1 Indemnity: JSS India on behalf of the Veloce BioPharma LLC. shall indemnify, defend and hold harmless the Site, the PI, the Site Indemnitees, the Clinical Trial, and JSS India and any of the associated staff against any liability, loss, damage or expense (including reasonable attorneys'

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fees and expenses of litigation) (“**Loss**”) incurred by or imposed on the Site Indemnitees or the Site, the PI, the Clinical Trial or JSS India or any of the associated staff in connection with any claims, suits, actions, demands or judgments made or instituted against Site, the Clinical Trial and/or JSS India to the extent (i) they are the direct result of the administration of the Study Drug to a Study Subject furnished by or on behalf of Sponsor or by a properly-performed Study procedure, and (ii) such activities were conducted in compliance with the Agreement, the Protocol and Investigator’s Brochure.

13.2 Exclusions from Indemnification: The JSS India obligation to indemnify in accordance with Clause 13.1, expressly excludes any indemnity obligations to indemnify, defend and hold harmless any Study Subject liability, damage, loss or expense incurred by or imposed on the Site Indemnitees or any one of them in connection with any claim, suit, action, demand or judgment arising:

- (i) from malpractice, negligence, recklessness, intentional or willful misconduct or omission of, or the breach of the Agreement and/or the Protocol on the part of any Site Indemnitee;
- (ii) from any activities contrary to or outside the scope of the Protocol or to other information provided to any Site Indemnitee in connection with the Study or the Study Drug, including, but not limited to information provided in the Investigator’s Brochure;
- (iii) from any unauthorized representations and/or warranties made by any Site Indemnitee concerning the Study Drug;
- (iv) in any case in which a Study Subject did not sign and agree to an Informed Consent Form;
- (v) due to any failure on the part of a Site Indemnitee to comply with any Applicable Laws, regulations or governmental requirements for which the Site shall indemnify, defend and hold harmless Sponsor and its employees, officers, directors, contractors, successors, assign, representatives or agents;
- (vi) due to an omission by any Site Indemnitee to inform Study Subjects, to
 - a. inform PI and/or Site of any new diseases or medical conditions that have arisen during the Study;
 - b. immediately notify Investigator, PI and/or Site of a personal injury or other damage that may be the consequence of the Study;
 - c. agree in writing to all reasonable measures (which may include a post-mortem examination) the objective of which is to investigate the cause and the extent of the damage suffered or to mitigate such damage.

13.3 The Site, the PI, the Site Indemnitees, the Clinical Trial and JSS India or the associated staff (each Party referred to as “**Indemnified Party**”) seeking indemnification under Clause 3 above, directly or due to a third party claim shall give written notice to the JSS India, against whom such indemnification rights are claimed. Pursuant to Clause 3 after receiving written notice of any such claim or legal proceeding against it or discovering the liability, obligation, or facts giving rise to such claim for indemnification, describing the claim, the amount thereof (if known and quantifiable), and the basis thereof in reasonable detail; provided, however, that the failure to so notify the JSS India/Sponsor shall not relieve the JSS India/Sponsor of its obligations hereunder except to the extent such failure shall have materially prejudiced the JSS India/Sponsor or its defences. With respect to any claim by a third party with respect to which indemnification is being sought by the Indemnified Party under Clause 3 above, the Indemnified Party shall have the right, at its election and at the sole cost and expense of the Sponsor, to proceed with the defense (including settlement or compromise) of such claim or legal proceeding on its own if the Sponsor fails to initiate the same within fifteen (15)

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business days of receipt of the notice in writing of such legal claim or proceeding from the Sponsor; provided, however, that: (i) the Indemnified Party shall obtain the prior written consent of the JSS India/Sponsor (which shall not be unreasonably withheld or delayed) before entering into any settlement of a claim if (A) pursuant to or as a result of such settlement, injunctive or other equitable relief will be imposed against the Sponsor, (B) such settlement does not expressly unconditionally release the JSS India/Sponsor from all liabilities and obligations with respect to such claim or legal proceeding and all other claims arising out of the same or similar facts and circumstances, with prejudice; or (C) involves criminal or quasi-criminal allegations against the JSS India/Sponsor; provided, however, such consent shall not be required if such settlement provides solely for the payment of monetary damages and an unconditional release of liability of the Indemnified Party with respect to such claim; (ii) no such settlement or compromise shall be conclusive evidence of the amount of Loss incurred by the Indemnified Party or payable by the Sponsor in connection with such claim or legal proceeding; (iii) the JSS India/Sponsor shall be entitled to participate in the defence of such action, lawsuit, proceeding, investigation or other claim giving rise to the Indemnified Party's claim for indemnification, at its own expense; and (iv) if the Indemnified Party abandons or fails to reasonably assume the defence of any such claim or legal proceeding, JSS India/Sponsor may assume control of the defence of such claim or legal proceeding at its own expense; provided, however, that if the JSS India/Sponsor shall control the defence of any such claim or legal proceeding it shall select legal counsel reasonably acceptable to the Indemnified Party, the JSS India/Sponsor shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of a claim or ceasing to defend such claim, if (A) pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against the Indemnified Party, (B) such settlement does not expressly unconditionally release the Indemnified Party from all liabilities and obligations with respect to such claim and all other claims arising out of the same or similar facts and circumstances, with prejudice, or (C) involves criminal or quasi-criminal allegations.

- 13.4.3 Site and Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Site, the Clinical Trial and JSS India as contained in the Clinical Trial Agreement.

13.5 Entire Obligation

The foregoing terms constitute the entire indemnification obligation of JSS India/Sponsor in relation to the Study.

- 13.6 The CRO shall pay the cost of all reasonable and necessary medical diagnoses and treatment of any injury or illness sustained by a Subject arising out of or reasonably attributable to the Clinical Trial Drug, but only to the extent that said Subject's insurance or other third-party insurance is insufficient to cover said costs or as per the regulatory requirement. The CRO shall not be liable for payments for a Subjects' lost wages.

14 Confidentiality

- a. All of the information disclosed by JSS India or developed hereunder by the PI, the Site or associated staff shall be subject to the following provisions: (a) neither the PI, the Site, nor associated staff or any other person engaged in the Clinical Trial shall disclose the information to any third party (other than JSS India or its representatives) without the prior written permission of by JSS India and (b) neither the PI, the Site nor

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associated staff or any other person engaged in the Clinical Trial shall use the information for any purpose other than the conduct of the Clinical Trial. However, nothing herein shall be construed as preventing the PI or the Site from publishing the data generated from the study, as provided in Clause 7 above.

- b. In handling a Subject's medical records, the PI, the Site and associated staff shall hold in strict confidence the identity of the Subject, and shall comply fully with any and all Applicable Laws regarding the confidentiality of such records.

15 Termination

- 15.1 JSS India may terminate the Clinical Trial by written notice of at least one (1) month in advance.
- 15.2 The CRO may terminate for any of following reasons:
 - a. Notification to any of the Parties from the local regulatory authorities to terminate Clinical Trial.
 - b. Determination by JSS India that the PI and/or the Site is not performing the Clinical Trial as required in the Protocol or is not meeting any agreed requirements.
 - c. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial to provide access by JSS India and/or its representatives to any and all original medical records necessary to verify entries on the Case Report Forms.
 - d. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial (excluding Subjects) to be available, upon reasonable notice by JSS India, to meet with JSS India or its representatives during the course of the Study as necessary to discuss information relevant to the Study.
 - e. Failure of the PI and/or the Site to comply with any regulatory requirements, under the Applicable Laws of India.
 - f. Unauthorized replacement of PI
 - g. Determination by JSS India in writing that business or scientific considerations require termination.
 - h. Case Report Forms provided to the PI and/or the Site or its associated staff by JSS India or its representatives for use in the Study, are not completed and forwarded to JSS India or its designated representative, within the timelines prescribed by JSS India.
- 15.2 In case PI is unable to continue as PI, he will propose the name of another investigator in writing to JSS India. However, JSS India shall have the sole right to determine the acceptability of a new PI.
- 15.3 In the event that JSS India exercise its right to terminate the Study based on any of the enumerated grounds above, written notice of its decision to exercise such right shall be given by registered mail delivered fifteen (15) business days before said termination.

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- 15.4 Immediately upon receipt of any notice of termination, the PI and/or the Site shall stop recruiting patients into the Clinical Trial and shall cease treatment with the Drug, to the extent medically permissible, on the Subjects. In the event of termination, the payments under this Agreement shall be prorated based on actual work performed in accordance with the Protocol. The PI and/or the Site shall cause to return to the JSS India (i) all documentation in respect of the Clinical Trial; and (ii) any funds not due under this calculation but already paid to the PI and/or the Site.

16 Miscellaneous

- 16.1 Notices and Deliveries: Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be deemed given on the date received if delivered by hand or by a reputable overnight delivery service, or three (3) business days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to JSS India:

JSS Medical Research India Private Limited
Vatika Mindscapes (Tower B), 6th Floor,
Plot 12/2, Sector 27D, Faridabad-121003,
Haryana, India

Attention: Dr. Renu Razdan
Designation: Vice President, India Operations
Telephone: +91 129 6613 500

E-mail: renu.razdan@jssresearch.com

If to the PI:

Dr Ashish Deshmukh
Skin & VD Department, Mahatma Gandhi
Mission's Medical College & Hospital,
N-6 CIDCO, Aurangabad – 431003.
Maharashtra.

If to the Site:

Clinical Research Department, Opposite
Blood Bank,
Mahatma Gandhi Mission's Medical
College & Hospital, N-6 CIDCO,
Aurangabad – 431003. Maharashtra.

- 16.2 Amendment: No Party may amend any of the terms of this Agreement except by a written amendment/agreement signed by the Parties. In addition, any amendment to the Protocol must be approved in writing by the Sponsor, DCGI and Institutional Ethic Committee.

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- 16.3 Independent Contractor Relationship: The Parties are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint ventures. The Parties agree that all employees/ consultants of the PI and/or the Site shall remain employees/ consultants of the Site and performance of services under this Agreement shall not be construed as transfer of their employment to JSS India.
- 16.4 Assignment: This Agreement may be assigned by JSS India to any of its affiliates or to any third party without prior written confirmation of other parties. The PI and the Site shall not assign this Agreement without the prior written consent of JSS India.
- 16.5 Force Majeure: In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of a Disability, then performance of such act (except for the payment of money owed) shall be excused for the period of such Disability. The Party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability. In case a Disability continues for more than three (3) months, the Party(ies) unaffected by the Disability may terminate this Agreement upon prior written notice to the affected Party. Should the Disability affect the performance of both parties, then such termination shall only be by mutual written agreement.
- 16.6 Survival: Sections 8, 9, 13, 14, 15, 16.2, 16.3 and 16.11 of the agreement shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date.
- 16.7 Severability: If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with Applicable Laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.
- 16.8 Counterparts: This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page of this Agreement by facsimile transmission shall be as effective as delivery of an original executed counterpart of this Agreement.
- 16.9 Governing Law. This Agreement shall be governed by the laws of India, and the courts of Delhi alone shall have exclusive jurisdiction in respect thereof.
- 16.10 Dispute Resolution: The Parties shall endeavor to resolve all disputes amicably by meetings caused between designated officials of each Party, within fifteen (15) days of receipt of a Dispute Notice. If the Parties are unable to resolve any dispute within the above referred fifteen (15) days, then the dispute shall be resolved by arbitration through a sole arbitrator jointly appointed by all Parties as per the provisions of the (Indian) Arbitration and Conciliation Act, 1996, as amended from time to time. If the Parties are not able to agree on a sole arbitrator, within fifteen (15) days of referral of a dispute to arbitration, the dispute shall be resolved by a panel of three (3) arbitrators. The Site and the PI shall appoint one (1) arbitrator, and JSS India and the Sponsor shall appoint one arbitrator. The two (2) arbitrators so appointed shall jointly appoint the third arbitrator which shall be the presiding arbitrator. The venue of arbitration will be New Delhi, India. Cost of arbitration including but not limited to fees of arbitrator(s) shall be shared equally by all Parties or as per the award of the arbitrator(s).
- 16.11 Interim Relief: Nothing shall preclude either Party from seeking an interim, from a court having jurisdiction to grant such relief. The pursuit of interim relief shall not be a waiver of


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the duty of any of the Parties to pursue any remedy (including for monetary damages) through the arbitration as more specifically described in Clause 16.10 above.

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

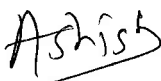
JSS India

By: 
Print Name: Dr. Renu Razdan

Title: Vice President, India- Operations
JSS Medical Research India
Private Limited

Date: May 8, 2017

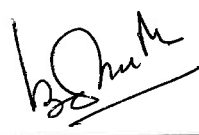
The Principal Investigator

By: 
Print Name: Dr Ashish Ramchandrarao Deshmukh

Title: Professor & Head, Skin & VD Department
Mahatma Gandhi Mission's Medical College & Hospital,
N-6 CIDCO, Aurangabad – 431003. Maharashtra.

Date: 30 May 2017

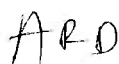
The Site

By: 
Print Name: Dr Rajendra Bohra

Title: Dean
Mahatma Gandhi Mission's Medical College & Hospital, N-6 CIDCO, Aurangabad – 431003. Maharashtra.

Date: 02 June 2017

Dr. A. R. Deshmukh
F.D.D.N.B.
Professor
Dept. of
MGM Medical College, Aurangabad.
Reg.



Schedule A

[List of services to be provided by the PI and/or the Site]

Protocol Title: A Multicenter, Randomized, Double-Blind, Vehicle-Controlled Phase II Study to Evaluate the Efficacy, Tolerability, and Safety of Topical Povidone-Iodine (PVP-I, 2% [W/W]) in Pediatric Subjects for the Treatment of Molluscum Contagiosum
Protocol ID: VBP-245-MCV

List of services to be provided by the PI and/or the Site, but not limited to:

1. Identification of protocol eligible patients for the study
2. Administration of informed consent process and AV recording
3. Recruiting patients as per protocol inclusion & exclusion criteria
4. Treat study participants as per randomization & adequate follow-up
5. Taking complete medical history of the patients
6. Responsibility for adverse events reporting
7. Writing the patient study summary-completion of source documentation
8. Compliance to study subject visits as per Protocol
9. Transcription of data in to electronic case report form & resolution of data queries
10. Allow oversee of the study by CRO or their designee through regular monitoring visits
11. Site readiness for regulatory inspection & external/internal audits
12. IP management as per protocol and Archival of study documents & material
13. Regulatory document submission & management
14. Maintain Study site files

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Schedule B
Budget and Payment Schedules

Payment shall be made against invoices sent every month according to table mentioned below.

The Parties understand and agree that the currency of the Agreement is and shall remain India Rupee (INR) and shall not be modified notwithstanding any exchange fluctuations that may occur.

All invoices shall be sent to the following address:

JSS Medical Research India Private Limited.
Plot No. 12/2, 6th Floor, Vatika Mindscapes Tower-B,
Near Sarai Khwaja Metro Station,
Sector-27D, Faridabad – 121003 (INDIA)

Each invoice must be an original copy (PDF or fax copies are not acceptable) and contain, as a minimum, the following information:

- a) The Research Institution's Name and Address as it is written at the front of this Agreement
- b) A description of the deliverable (e.g. final written report) associated with the invoice
- c) The total invoice amount in the currency specified in this Agreement, Payee Name, PAN
- d) Signed & date by authorized signatory

Payment Schedule/Milestones per patient:

Visit Type	Amount INR	Approx. Percentage
Visit 1 (Screening/Baseline/Randomization)	5200	25%
Visit 2 (Day 14)	5200	25%
Visit 3 (Day 35)	5200	25%
Visit 4 (Day 60/ Study completion)	5200	25%
Total for per protocol completed patient	20,800	100%
		--
Institutional Overhead; 30% of the budget	6240	--
Miscellaneous (Stationaries etc.)	1000	--
Total budget per Patient	28040	--

The cost for the trial will be as mentioned below:

- a) The cost per protocol-correct and completed subject will be INR 28,040 . (including Institutional overhead)

Note: Completed patient means once the subject has completed the final follow up and complete data entered and verified in the eCRF by the monitor.

This will include the following fees, as applicable, but not limiting to:

- The PI fees, study team fees, costs for unscheduled visits, site infrastructure maintenance for this study, stationary, courier and other study-related bills.

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b) If required/requested by site, A refundable advance amount of INR 20,000 would be issued to the site upon receipt of completely executed agreement and unconditional EC approval. This amount will be adjusted from the cost of the 1st subject randomized & completed per protocol.

c) The following costs incurred by site, where applicable, would be reimbursed to site upon receipt by CRO of original receipts/ bills:

- i. Fees related to local Ethics Committee reviews
- ii. SAE management costs: The SAE management costs are applicable to all SAEs only related to the Clinical Trial/ protocol/ Investigational Product. The costs would be reimbursed to the site once the original bills/receipts are made available to CRO i.e. bills pertaining to hospitalization, investigations & procedures, medications for the SAE.
- iii. This Clinical Trial will not involve any monetary expenses. Subjects will be reimbursed for all their expenses in connection with this Clinical Trial on actual basis (e.g. travel costs) by CRO. Subject travel re-imbursement will be paid on actual up to Rs. 500 per visit upon producing the vouchers/ bills for the same to CRO.

d) The fees for a screen failure patient will be INR 2500 /-. This screen failure payment includes all charges.

e) For the Unscheduled visit, travel reimbursement will be paid on actual upto INR 500 per visit upon receipt of bill (upto 2 unscheduled visits during the study period).

e) Institutional overhead 30 % of the total budget.

f) Archival fee as applicable at the study close out INR 75000/- (5000 / Year).

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SCHEDULE C

JSS India on behalf of Veloce will make the payments as follows:

(i) Payments will be made once the CRFs for the patient visits have been verified by the CRO/ designee & query has been resolved. Invoices will be raised on monthly basis and sent to CRO for payment. Invoices will be raised on the basis work completed during previous month. In the event that a subject withdraws or is withdrawn from the Trial for reasons beyond the Investigator's control (but after commencing the dosing regimen in accordance with the Protocol), payment shall be made pro rata (based on the number of visits completed) in respect of that subject provided all data in respect of that subject up to the time of that subject's withdrawal from the Trial have been completed and sent to and accepted by CRO.

(ii) Invoices will be paid within 45 business days of receipts to the payee. Service tax as applicable will be levied on each invoices according to the guidelines of service tax rules of India.

(iii) From each invoice CRO will keep last one completed subjects payment as retention money and the same will be paid once all queries are resolved and Clinical trial/Site is closed out in all respects.

(iv) There is no other amount payable to Institute/Investigator for the Clinical Trial (except) mentioned in this agreement.

(v) The above given budget* is for 1 subject. If number of subjects is randomised more or less, actual invoices will vary in proportion to the work done i.e. visits completed. The agreement will be applicable again subject to recruitment of the Patients.

(vi) Above budget* does not include any Related Adverse Event or Serious Adverse Event expenses. Any related Adverse Event or Serious Adverse Event expenses will be reimbursed on actual. Reimbursement of Adverse Event or Serious Adverse Event management will include but not limited to Investigations, Hospitalisation, Treatment costs. Site agrees to take approval for any special investigations in case of Adverse Events. Site agrees to give timely update on the plan of management in terms of cost, on the cost incurred in management of the above events.

vii) In case of early termination of Clinical Trial, final payment calculation will be based on actual work completed. In case extra payment has been made, payee will refund the extra money. In case there is any amount payable to payee the same will be paid by CRO.

viii) All payments are subject to TDS (other taxes as applicable) except Travel reimbursements of patients and all payments will be made once payment is received by CRO from Sponsor.

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Summary of the items included in payment & items not to be reimbursed:

Items included in payment:

Items included in Professional fees of per patient cost:
• PI fees
• Clinical Trial team fees
• Administrative cost
• Payments for unscheduled visits
• Site infrastructure (including Telephone/ fax/ internet), IMP storage.
• Stationary and Couriers
Pass through costs to be paid on Actuals:
• Ethics Committee fees
• SAE management costs, if any
• Subject Compensation if any
• Travel reimbursements of patients
• Archival Fees

Items not to be reimbursed, but not limited to:

Buying new equipment
Maintenance of equipment
Salary for study staff

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