CLINICAL TRIAL AGREEMENT

Date: 21.04.2017

An agreement made in Mumbai between Macleod's Pharmaceuticals Ltd, (also called the sponsor) G-2, Mahakali Caves Road, Shanti Nagar, Andheri (East) Mumbai – 400093, India

AND

I Dr Deepak Sadashiv Bhosle [MBBS,M.D(Grad. Diploma in Diabetes) Mahatma Gandhi Missions medical college & Hospital, N6 Cidco, Aurangabad, 4310003 (MH), INDIA.

AND

Grapecity Research Solutions LLP, a legal entity, having its registered office at Block no. 2, Prakash Housing society, Thergaon, Pune-411033. Maharashtra, India. duly represented by Dr Sushil R Chaudhary hereinafter referred to as "_ Grapecity Research Solutions LLP ."

AND

Mahatma Gandhi Missions Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India.

Whereas Macleod's Pharmaceuticals Ltd wishes to conduct the following Study with Dr Deepak Sadashiv Bhosle as the Principal Investigator:

1. Title: An open label, Two arm, Comparative, Randomized Phase IV Clinical Study evaluating efficacy and safety of Alrista Forte (Epalrestat 150 Mg + Methylcobalmin 1500 Mcg + Pregabalin 150 Mg) Tablet versus Pregabalin 150 Mg Capsule in patients with Diabetic Neuropathy.
   Protocol No.: CT-213-EMP(F)-2016

2. The objective of the trial is to compare the safety and efficacy of Alrista Forte (Epalrestat 150 Mg + Methylcobalmin 1500 Mcg + Pregabalin 150 Mg) Tablet versus Pregabalin 150 Mg Capsule in patients with Diabetic Neuropathy.

Corporate Office :
304-Atlanta Arcade, Marol-Church Road,
Andheri (East), Mumbai 400059, INDIA
Phone : +91 22 66762800
Fax : +91 22 29256599/29256229
Website: www.macleodspharma.com
CIN : U24239MH1989PLC052049

Research Centre :
G-2, Mahakali Caves Road, Shanti Nagar,
Andheri (East), Mumbai 400 093,
INDIA
Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

It is hereby agreed by and between Macleod's Pharmaceuticals Ltd., the Principal Investigator, Mahatma Gandhi Missions Medical College and Hospital And Grapecity Research Solutions LLP here to as follows

1. The site of the trial would be MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India
2. The trial will be conducted as per the provision of 'Declaration of Helsinki'.
3. The Principal investigator will be paid a sum of INR 12000 including overhead and Laboratory Investigation Charges as per actual bill for patient enrolled and as per the visits completed in the study.

No. of Visits	Payment (Rs.)
Visit 1	2000/-
Visit 2	2000/-
Visit 3	2500/-
Visit 4	2500/-
Visit 5	3000/-

Role and responsibilities of Dr Deepak Sadashiv Bhosle (Principal Investigator)

1) To conduct the above referenced Study as the Principal Investigator.
2) The Principal investigator has to complete 20 patients. The number of patients can be increased by Macleod's Pharmaceuticals Ltd.
3) The recruitment period for the study is one months. The sponsor expects a total of 20 patients from the site during the recruitment period. Any changes in achieving the target enrolment would have to be discussed among all the 4 signatories and decisions to be made accordingly.
4) The Principal investigator should be aware of, and should comply with, GCP and the applicable Ethics committee requirements.
5) The investigator/Co - investigator should be available and permit monitoring and auditing by the sponsor, and inspection by the appropriate authority
6) The investigator along with Co - investigator should ensure that all persons assisting with the study are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.
7) The investigator should conduct the trial in compliance with the protocol agreed to by the sponsor and, which was given approval/favorable opinion by the IEC.
8) The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects,

Corporate Office :
304-Atlanta Arcade, Marol-Church Road,
Andheri (East), Mumbai 400059, INDIA
Phone : +91 22 66762800
Fax : +91 22 29256599/29256229
Website: www.macleodspharma.com
CIN : U24239MH1989PLC052049

Research Centre :
G-2, Mahakali Caves Road, Shanti Nagar,
Andheri (East), Mumbai 400 093,
INDIA
Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

9) The Investigator/Co- Investigator is responsible for obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki.
10) All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports.
11) Macleods Pharmaceuticals Ltd. would like to have intermittent report every as required during the course of the study.
12) Macleods Pharmaceuticals Ltd. would like to have all the documents of investigations such as completed case record forms, completed informed consent, investigation reports (i.e. source documents)-if any, trial report - with signature and stamp of the investigator
13) Contents of the report during the clinical trial should not be revealed to any other company in India or outside India without written permission from Macleods Pharmaceuticals Ltd.
14) The data obtained during the trial could not be published by the principal investigator wherein Macleods Pharmaceuticals Ltd. should be acknowledged. Macleods Pharmaceuticals Ltd. will have the right to use this research paper.
15) In case the Principal Investigator fails to recruit the agreed number of patients within the discussed and agreed timelines then the Principal Investigator/Site will only be eligible for the payment for the number of patients who are enrolled in the study.
16) Data obtained from the trial should not be used for any other further comparison studies.
17) Undertaking will be taken from each member of investigating team (other than employees of Macleod's Pharmaceuticals LTD.) expressing total secrecy during & after research vis-à-vis the products mentioned above.

Role and responsibilities of Macleod's Pharmaceuticals Ltd

1) The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs and training to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).
2) The sponsor is responsible for securing agreement from all involved parties including Co-investigator, Hospital etc.
3) The sponsor is responsible to provide appropriately qualified individuals to carry out the overall conduct of the study, to handle the data, to verify the data, to conduct the statistical analyses, and to prepare the trial reports.
4) The sponsor will be responsible for providing insurance to the study subjects and Indemnification to the entire site and any other services provider who will be part of the study.

Corporate Office :
304-Atlanta Arcade, Marol-Church Road,
Andheri (East), Mumbai 400059, INDIA
Phone : +91 22 66762800
Fax : +91 22 29256599/29256229
Website: www.macleodspharma.com
CIN : U24239MH1989PLC052049

Research Centre :
G-2, Mahakali Caves Road, Shanti Nagar,
Andheri (East), Mumbai 400 093,
INDIA
Phone: +91 22 28306435/28314611
Fax : +91 22 28304641

5) The sponsor will be responsible for supplying the investigator(s)/institution(s) with the investigational product(s).
6) The sponsor will be responsible for monitoring and auditing of the study.

It is hereby agreed by and between Macleod's Pharmaceuticals Ltd, Grapecity Research Solutions LLP, MGM Medical College and hospital and Dr Deepak Sadashiv Bhosle (Principal Investigator) to all the terms and conditions as mentioned in this agreement

Signature

Name: Dr. Ashish Mungantiwar
Designation: President -Medical Services
Address: Macleods Pharmaceuticals Ltd.
G-2, Mahakali Caves Road,
Shanti Nagar, Andheri (East),
Mumbai - 400 093.

Signature

Name : Dr Deepak Sadashiv Bhosle
Principal Investigator
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

Signature

Dr Sushil Chaudhary
Designation-Director- Grapecity Research Solutions LLP.
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad - 431003, Maharashtra, India

MGM's Medical College Aurangabad

Signature

Name : Dr. Rajendra Bohra
Designation - Dean
Address: MGM Medical College and Hospital, N-6, Cidco, Aurangabad 431003, Maharashtra, India

Corporate Office :
304-Atlanta Arcade, Marol-Church Road,
Andheri (East), Mumbai 400059, INDIA
Phone : +91 22 66762800
Fax : +91 22 29256599/29256229
Website: www.macleodspharma.com
CIN : U24239MH1989PLC052049

Research Centre :
G-2, Mahakali Caves Road, Shanti Nagar,
Andheri (East), Mumbai 400 093,
INDIA
Phone: +91 22 28306435/28314611
Fax : +91 22 28304641