



ગુજરાત ગુજરાત GUJARAT તા. ૧૫/૦૯/૨૦૧૮ શ. ૨૦૧૮  
નામ ૨૩ માટે ૭  
સરનામું  
લા.નં.એસ.બી.૧૬૪/૧૬૫/૮૮/૧૯૬૮  
નિખીલ જીતેન્દ્રકુમાર શાહ  
મિરઝાપુર કોર્ટના સર્કલ અમદાવાદ  
લેનારની સહી X

Cadila Pharmaceuticals Limited 84099  
"Cadila Corporate Campus"  
Sarkhej-Dholka Road, Bhat,  
Ahmedabad-382210.

Clinical Trial Investigator's Agreement  
dated \_\_\_\_\_

blw  
Cadila Pharmaceuticals Limited

AND  
Dr Sheermila Patel  
AND

Mrs. Suresh Patel  
AND

Ms. Mehul Shah.

APPENDIX -A

FINANCIAL AGREEMENT

Sponsor Study No. : CRSC16004

Protocol Title : A Phase III, multicentre, randomized, observer blind, parallel group, three arms, controlled clinical trial to evaluate the efficacy and safety of topically applied Calcipotriol/AKVANO 50 µg/g cutaneous solution against Calcipotriol Ointment 50 micrograms/g, Sandoz and placebo in patients with mild to moderate plaque psoriasis.

Sponsor : Cadila Pharmaceuticals Ltd.

Cadila CRO on behalf of Sponsor offers to pay Dr. Sharmila Patil, (Principal Investigator), Dr. DY Patil medical College and Hospital, Sector 5, Nerul, Navi Mumbai – 400706, India (Institution) as follows for the study under taken. Cadila CRO will make a maximum payment of Rs. 30,000 per completed patient to Dr. Sharmila Patil on behalf of the Cadila Pharmaceutical. This per patient grant will take care of all the on-site expenses (administrative and clinical) and all the on-site Admissions and Investigations that are required by the Protocol as per the schedule mentioned therein.

Cadila CRO will make payment on monthly basis upon receiving bills or receipt for all the study procedures including payment to patient for their transportation.

Cadila CRO is expecting Dr. Sharmila Patil to finish the enrollment of 30 to 35 subjects out of 10 to 15 subjects of Fitzpatrick type I, II and III only, before \_\_\_\_\_. The enrollment is competitive had patient load will be redistributed to site where the recruitment is faster to achieve the largest sample size quickly.

In case the patient is not able to complete the study, the per patient grant will be paid to the PI depending upon the following parameters:

**Milestones:**

1. Fixed Cost as PI fees: Cadila Pharmaceuticals Limited, India will pay maximum up to Rs. 20,000/- per patient upon achieving the below milestones.

Milestone	Payment
Screening - Visit 1	4000
Visit 2	4000
Visit 3	4000
Visit 4	4000
Visit 5	4000

2. Rs. 10,000 will be paid to Observer physician as per the below milestones.

Milestone	Payment
Screening - Visit 1	Nil
Visit 2	3000
Visit 3	2000
Visit 4	2000
Visit 5	3000

**Terms of Payment:**

**STUDY TITLE:** A Phase III, multicentre, randomized, observer blind, parallel group, three arms, controlled clinical trial to evaluate the efficacy and safety of topically applied Calcipotriol/AKVANO 50 µg/g cutaneous solution against Calcipotriol Ointment 50 micrograms/g, Sandoz and placebo in patients with mild to moderate plaque psoriasis.

1. Fixed Cost as PI fees: Cadila Pharmaceuticals Limited, India will pay maximum up to Rs. 20000/- per completed Patient as per above table.
2. Maximum up to Rs. 10,000 will be paid to Observer physician as per above table.
3. Patient compensation will be provided Rs. 500/- per visit per study completed patient.
4. Study coordinator fees will be paid Rs. 12,000/- per month from SIV (Site initiation visit) to SCV (Site closeout visit). In case of no recruitment at the site, CRC fees will be given only for 3 months after SIV. In any case, CRC fees will not be paid for more than 9 months unless there is a written CRC term extension confirmed by Cadila management.
5. Administrative cost (for stationary, courier, telephone, fax, internet) will be paid Rs. 10,000/- for entire study.
6. Study medications will be provided by sponsor. (As mentioned in protocol)
7. TDS will be deducted as per government policy.
8. As per new regulations, applicable GST will be paid over and above of total budget.
9. Screen failure charges will be paid Rs. 500/- with laboratory charges on actual basis not exceeding as per below table of laboratory charges, per screen failed patient up to a maximum of one subject.

10. Laboratory charges will be paid as per actual upon submission of original bills not exceeding as per the below milestones.

11. Laboratory charges will be paid as per actual upon submission of original bills not exceeding as per the below milestones.

Milestone	Payment
Screening - Visit 1	4000
Visit 3	2100
Visit 4	2100
Visit 5	2500

12. Reimbursement of related Adverse Events/SAE medication management cost on actual as per DCGI Guidelines. In most situations where AE/SAE is prima facie unrelated, medical management cost will not be paid unless meeting all criteria of detailed DCGI guidelines.

13. Rs. 30,000/- will be given for archiving the documents for 15 years

14. A minimum of 20 subject recruitment is mandatory prior to release of payment from Cadila. However payments directly linked with subject compensation for participating in study will be reimbursed upon request. Payments other than PI charges has to be released once in two month as per expenses occurred.

**Investigator has to complete below information:**

A. Payment Cheque required in favour of/payable to:

**"PARSHWA LIFE SCIENCES"**

Account No.: 33070645453

Bank Name: **CENTRAL BANK OF INDIA**

IFSC Code **CBIN0283253**

B. Address where payment Cheque would be sent:

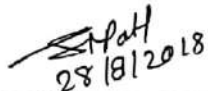


**Mr. MEHUL SHAH**  
Parshwa Life Sciences  
B-001, Jay Poonam Nagar,  
Mira –Bhayander Road, Mira –Road (East)-401107,  
Mira-Road (East) Thane-Maharashtra-India.

C. PAN Number or TAN Number, if applicable: APAPS7000M

Service Tax No.:

GST No.: 27APAPS7000M1ZR

By signing this FINANCIAL AGREEMENT, Cadila CRO, Ahmedabad and the Principal Investigator agree to adhere to the terms and conditions mentioned in the CLINICAL TRIAL INVESTIGATOR's AGREEMENT.

For: <b>CADILA PHARMACEUTICALS LTD.</b>	For: <b>PRINCIPAL INVESTIGATOR</b>  28/8/2018
Name: Dr. Manjul Joshipura Designation: Sr. Vice -President Place: Ahmedabad Date:	Name: <b>Dr. Sharmila Patil</b> Designation: Place: Navi Mumbai Date:
Name: Amitabha Banerjee Designation: Consultant - Finance	For Institute name  28/8/2018 <b>Dr. DY Patil medical College and Hospital</b> Place: Navi Mumbai Date:
Name : Designation : Finance Controller	 Name : <b>Mr. MEHUL SHAH</b> Designation: SMO Place: Navi Mumbai Date: 26/08/2018
Name : Vinod Jain Designation :	
Name: Hetal Hindocha Designation: DGM - Legal	