MINUTES OF THE 33rd MEETING OF THE APEX COMMITTEE HELD ON 21.02.2017 UNDER THE CHAIRMANSHIP OF SECRETARY, (H&FW) FOR SUPERVISING CLINICAL TRIALS ON NEW CHEMICAL ENTITIES

Present:

1. **SHRI C.K. MISHRA**
   Secretary
   Department of Health and Family Welfare
   Ministry of Health and Family Welfare &
   Chairman, Apex Committee
2. **Dr. SOUMYA SWAMINATHAN**
   Secretary, DHR & DG ICMR
3. **Dr. JAGDISH PRASAD**
   DGHS
4. **SHRI K. L. SHARMA**
   Joint Secretary
   Department of Health and Family Welfare

Special Invitees:

1. **SHRI R.K.VATS**
   Addl. Secretary and Director General (CGHS)
   Ministry of Health and Family Welfare
2. **Dr. G. N. SINGH**
   DCG (I), FDA Bhavan, New Delhi

Initiating the discussion, Chairman, Apex Committee welcomed the members of the Committee and special invitees to the meeting. Thereafter, the Committee deliberated upon each of the agenda items and recommended as following:

A: Proposals of Clinical Trials related to New Chemical Entities (NCEs) recommended by Technical Committee:

Proposal No.01:

Phase III, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active ulcerative colitis who are naive to TNF inhibitors.

The Committee, after detailed deliberations, concurred with the recommendations of the Technical Committee for approval of clinical trial protocol for conduct of the study. (Details at **Annexure-I**)

Proposal No.02:

An open-label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Etrolizumab phase II/III Studies.

The Committee, after detailed deliberations, concurred with the recommendations of the Technical Committee for approval of clinical trial protocol for conduct of the study. (Details at **Annexure-I**)

Proposal No.03:

A Phase Ib, Multi-center, Multi- stage Study of METREXASSIST™ (Parenteral TK-112690) administered in Combination with Methotrexate as a Weekly Infusion to Subjects with SCCHN Undergoing Treatment with Methotrexate - A Dose Escalation/Safety study with No Control.

The Committee, after detailed deliberations, concurred with the recommendations of the Technical Committee for approval of clinical trial protocol for conduct of the study (Details at **Annexure-I**).

Proposal No.04:

Phase III, Randomized, Observer-Masked, Active-Controlled, Parallel-Group, Multinational and Multicenter Study Assessing the Safety and Efficacy of DE-117 Ophthalmic Solution 0.002% Compared with Latanoprost Ophthalmic Solution 0.005% in Subjects with Open-Angle Glaucoma or Ocular Hypertension- PEONY Study).

The Committee, after detailed deliberations, concurred with the recommendations of the Technical Committee for approval of clinical trial protocol for conduct of the study. (Details at **Annexure-I**)

B: Proposals of Clinical Trials related to IND's recommended by IND Committee:

Proposal No.01:

A Phase I open label, multicentric trial to evaluate safety and tolerability of the poly ADP Ribose Polymerase (PARP) inhibitor, ZYTP1 in patients with advanced solid tumors.

The Committee, after detailed deliberations, concurred with the recommendations of the IND Committee for approval of clinical trial protocol for conduct of the study.

Proposal No.02:

A Phase 1/2 Study to Determine Safety, Tolerability, Pharmacokinetics, and Activity of K0706, a Novel Tyrosine Kinase Inhibitor (TKI), in Subjects with Chronic Myeloid Leukemia (CML) or Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia (Ph+ ALL)

The Committee after detailed deliberations concurred with the recommendations of the IND Committee for approval of clinical trial protocol for conduct of the study.

Proposal No.03:

A Prospective, Randomized, Parallel group Study to Evaluate the Safety and Efficacy of FDC of Mupirocin calcium, Neomycin Sulfate & HT61 HCl in Patients with infected skin lesions by Staphylococcus aureus including Methicillin-resistant Staphylococcus aureus (MRSA) and/or S. Pyogenes.

The Committee after detailed deliberations concurred with the recommendations of the IND Committee for approval of clinical trial protocol for conduct of the study.

Proposal No.04:

A randomized, double-blind, placebo controlled, parallel group, Phase II multi-centric trial to assess safety, tolerability and efficacy of PHD- 2 Inhibitor, ZYAN1 in the treatment of anemia in pre-dialysis chronic kidney disease patients.

The Committee, after detailed deliberations, concurred with the recommendations of the IND Committee for approval of clinical trial protocol for conduct of the study.

Proposal No.05:

A Phase 1, Randomized, Double-blind, Placebo-Controlled, Multiple Ascending Dose, Safety, Tolerability and Pharmacokinetics Study of Novel antimalarial CDRI compound 97/78 in healthy Volunteers.

The Committee, after detailed deliberations, concurred with the recommendations of the IND Committee for approval of clinical trial protocol for conduct of the study.

Proposal No.06:

A Phase 1, Randomized, Double-blind, Placebo-Controlled, Single dose & Multiple Ascending Dose, Safety, Tolerability and Pharmacokinetics Study of Novel antiosteoporotic CDRI compound 99/373 in healthy Volunteers.

The Committee after detailed deliberations concurred with the recommendations of the IND Committee for approval of clinical trial protocol for conduct of the study.

Proposal No.07:

A phase 1, multicenter, double-blind, placebo-controlled, randomized (intra-group) clinical trial to evaluate two doses of three sequentially escalating cohort of ZIKA virus vaccine, inactivated (adsorbed) (BBV121) in healthy adult dengue sero-negative and dengue sero-positive volunteers.

The Committee after detailed deliberations concurred with the recommendations of the IND Committee for approval of clinical trial protocol for conduct of the study.

Proposal No.08:

An Open-Label, Single-Treatment, Single-Period, Single Dose, Clinical Phase 1 Study To Assess the Safety and Tolerability of Bivalent Human Papillomavirus (Types 16 L1 & 18 L1) of M/s Cadila Healthcare Ltd., India in Healthy, Adult, Female, Human Subjects.

The Committee after detailed deliberations concurred with the recommendations of the IND Committee for approval of clinical trial protocol for conduct of the study.

Proposal No.09:

Randomized, Multi-centric, Open-label, Comparator-controlled Study to evaluate the efficacy and safety of RABIMABs administered in conjunction with Vaxirab N for Post-exposure Prophylaxis in Patients following Potential Rabies Exposure.

The Committee after detailed deliberations concurred with the recommendations of the IND Committee for approval of clinical trial protocol for conduct of the study.

Proposal No.10:

Efficacy and safety of bolus injection of a novel thrombolytic agent (SMRX-11) in patients with acute ST-segment elevation Myocardial Infarction (STEMI): A phase II open label, dose escalation, multi center, angiographic trial.

The committee after detailed deliberations concurred with the recommendations of the IND Committee for approval of clinical trial protocol for conduct of the study.

OTHERS:

A:

I. **Application from M/s Regenerative Medical Services, Mumbai for grant of Marketing Authorization of Autologous Adult Live Cultured Chondrocytes (CHONDRON®)**

The Committee agreed with the recommendations of the CBBTDEC regarding grant of Marketing Authorization of "Autologous Adult Live Cultured Chondrocytes" for subjects with Articular Cartilage Defects of the Articulating joints, subject to the condition that the firm shall conduct Post Marketing Surveillance of first 50 subjects and the protocol for this will be submitted to CDSCO for approval

Application from M/s Regenerative Medical Services, Mumbai for grant of Marketing Authorization of Autologous adult live cultured Osteoblasts (OSSRON™).

The Committee agreed with the recommendations of the CBBTDEC regarding grant of Marketing Authorization of "Autologous Adult Live Cultured Osteoblasts" for subjects with Avascular Necrosis of the hip joint, subject to the condition that the firm shall conduct Post Marketing Surveillance of first 50 subjects and the protocol for this will be submitted to CDSCO for approval.

II. **Representation of M/s APAC Biotech Pvt. Ltd, Gurgaon for Marketing Authorization of APCEDEN™ [Dendritic Cell (DC) product].**

The Committee deliberated upon the points raised in the representation of the firm along with the Inspection report and agreed to the proposal contained in agenda for Marketing Authorization of the product subject to the condition that firm shall conduct the well structured post marketing surveillance study in adequate number of cases of prostate, ovarian, colorectal and Lung Cancers as per protocol approved by the Licensing Authority in consultation with the

CBBTDEC involving clinical specialists and oncologists or relevant experts for each category. Further, the Committee agreed that the marketing approval shall be limited to manufacturing for PMS study and after completion of PMS study, the firm shall submit results for evaluation to CDSCO. Further continued marketing may be permitted only if results are found to be satisfactory.

III. **Representation of M/s Stempeutics Research Private Limited, Bangalore for grant of Form 46 for Manufacturing and Marketing of Stempeucel®**

The Committee deliberated upon the points raised in the representation and agreed to the proposal contained in agenda for Marketing Authorization of the product subject to the condition that firm shall conduct the well structured post marketing surveillance study in 200 patients as per the recommendations of the CBBTDEC, and that the marketing approval shall be limited to manufacturing for PMS study. After completion of PMS study, the firm shall submit results for evaluation to CDSCO and further continued marketing shall be permitted only if results are found to be satisfactory.

B: Regulatory Approvals relating to combination products for HIV (ARV), Hepatitis, Tuberculosis and such infectious diseases with focus on exports.

The Committee noted the deliberations held at the level of Joint Secretary and agreed proposed course of action for regulatory approvals to such combination products, which have been recommended by WHO for concomitant administration.

C: Timely disposal of clinical trial related applications

(1) System is CDSCO to be strengthened so that need of supervisions of clinical trials by Apex Committee is minimized.

(2) The Committee desired that the details of time-lines for appraisal/disposal of proposals relating to clinical trials be placed on the website of CDSCO within two weeks.

(3) The Committee also directed that a Special Cell be created for appraisal and processing of clinical trials related work in CDSCO, if needed.

(4) The Committee was assured that no proposals for Apex Committee are pending as on date.

2. The meeting ended with vote of thanks to and from the Chairman

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Annexure-I

Proposal of clinical trial of NCEs along with their evaluations and recommendations of the Technical Committee in its 37th, 38th, and 39th Technical Committee Meetings held on 28.11.2016, 22.12.2016 and 06.02.2017 respectively.

Proposal No.	Details of the proposal	Assessment of the Proposal *vis – a vis* specified Parameters	Recommendations 1. Subject Expert Committee 2. Technical Committee
1.	**Name of the Drug:** Etrolizumab Solution for Injection [105 mg/0.7mL Pre-filled Syringe] (rhuMAb Beta7) **Date of Application:** 24/06/2016 **Protocol No**: GA29102 **Phase of the trial:** Open Label Extension (OLE) **Name of the Applicant:** Roche Products (India) Pvt. Ltd. 1503, 15th Floor, The Capital, Plot No. C-70, Bandra Kurla Complex, Bandra East, Mumbai – 400051, India **Name of the Sponsor:** F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel, Switzerland **Name of the Manufacturer:** F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel, Switzerland. **Title:** An open-label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical safety pharmacological toxicology studies and clinical studies justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option: Protocol No GA29102:** To evaluate the efficacy of Etrolizumab (105mg) subcutaneous every 4 weeks (Q4W) compared with placebo for maintenance of remission at week 62 for randomized patients in remission at week 10, as determined by the mayo clinic score. **Protocol No GA28951:** To assess the long-term safety and efficacy of Etrolizumab in patients eligible for OLE. For progressive multifocal leukoencephalopathy (PML) safety monitoring. **Unmet Medical Need in the country:** The test drug may potentially provide alternative treatment of subjects with moderate to severe Active Ulcerative Colitis who are naive to TNF inhibitors.	**1. The proposal was deliberated in SEC (Gastroenterology) held on 09/09/2016.** After detailed deliberation, the committee found merit in the phase III study (Protocol GA29102). However, for protocol GA28951, the committee recommended that inclusion criteria should be modified such that those who do NOT respond to the initial 10 weeks of induction therapy are not given the investigation product in an open label manner. This is because these patients are TNF alpha inhibitor naïve and hence it is ethically not correct to not offer them TNF-alpha inhibitors. A suitably modified form of these protocols for India should be submitted for further review. These should include long-term safety monitoring (including PML) for all patient exposed to the investigational product. **The proposal was re-deliberated in SEC (Gastroenterology) held on 26/10/2016** The firm now provided data showing that extension of Etrolizumab beyond 10 weeks results in a similar degree of response as compared to TNF-α inhibitor therapy. The firm has

	Etrolizumab phase II/III Studies.		provided satisfactory explanation; therefore the committee recommended the conduct of the study in its presented form. **SEC Expert List:** 1. Dr. A. Saraya, Professor, Dept. of Gastroenterology AIIMS, New delhi-110029. 2. Dr. P. Shravan Kumar, Professor, HOD of Gastroenterology, Gandhi Medical College and Hospital, Secunderabad, Telangana. 3. Dr. Shalini Chawla, Professor, Dept. of Pharmacology, MAMC, New Delhi. 4. Dr. Shobha Bhatia, Professor, Dept. of Gastroenterology and Hepatology Seth GS Medical College and KEM Hospital, Parel, Mumbai-400012. 5. Dr. Sudhir Gupta, Prof. and Head, Government Medical College and Super speciality, Nagpur. 6. Dr. Sandeep Nijhawan, Sr. Professor, SMS Medical College, Jaipur. 7. Dr. Manoj Kumar Sharma, Associate Prof., Institute of Liver and Biliary Sciences, D-1 Vasant Kunj, New Delhi **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
2.	**Name of the Drug:** Etrolizumab Solution for Injection [105 mg/0.7mL Pre-filled Syringe] (rhuMAb Beta7)	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical safety pharmacological toxicology studies and clinical studies justify the conduct of the	**1. The proposal was deliberated in SEC (Gastroenterology) held on 09/09/2016.** After detailed deliberation, the committee found merit in the

	Date of Application: 24/06/2016 **Protocol No**: GA28951 **Phase of the trial:** Open Label Extension (OLE) **Name of the Applicant:** Roche Products (India) Pvt. Ltd. 1503, 15th Floor, The Capital, Plot No. C-70, Bandra Kurla Complex, Bandra East, Mumbai – 400051, India **Name of the Sponsor:** F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel, Switzerland **Name of the Manufacturer:** F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel, Switzerland. **Title:** An open-label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Etrolizumab phase II/III Studies.	trial. **Innovation vis-à-vis Existing Therapeutic Option: Protocol No GA29102:** To evaluate the efficacy of Etrolizumab (105mg) subcutaneous every 4 weeks (Q4W) compared with placebo for maintenance of remission at week 62 for randomized patients in remission at week 10, as determined by the mayo clinic score. **Protocol No GA28951:** To assess the long-term safety and efficacy of Etrolizumab in patients eligible for OLE. For progressive multifocal leukoencephalopathy (PML) safety monitoring. **Unmet Medical Need in the country:** The test drug may potentially provide alternative treatment of subjects with moderate to severe Active Ulcerative Colitis who are naive to TNF inhibitors.	phase III study (Protocol GA29102). However, for protocol GA28951, the committee recommended that inclusion criteria should be modified such that those who do NOT respond to the initial 10 weeks of induction therapy are not given the investigation product in an open label manner. This is because these patients are TNF alpha inhibitor naïve and hence it is ethically not correct to not offer them TNF-alpha inhibitors. A suitably modified form of these protocols for India should be submitted for further review. These should include long-term safety monitoring (including PML) for all patient exposed to the investigational product. **The proposal was re-deliberated in SEC (Gastroenterology) held on 26/10/2016** The firm now provided data showing that extension of Etrolizumab beyond 10 weeks results in a similar degree of response as compared to TNFα inhibitor therapy. The firm has provided satisfactory explanation; therefore the committee recommended the conduct of the study in its presented form. **SEC Expert List:** 1. Dr. A. Saraya, Professor, Dept. of Gastroenterology AIIMS, New delhi-110029. 2. Dr. P. Shravan Kumar, Professor, HOD of Gastroenterology, Gandhi Medical College and Hospital,

			Secunderabad, Telangana. 3. Dr. Shalini Chawla, Professor, Dept. of Pharmacology, MAMC, New Delhi. 4. Dr. Shobha Bhatia, Professor, Dept. of Gastroenterology and Hepatology Seth GS Medical College and KEM Hospital, Parel, Mumbai-400012. 5. Dr. Sudhir Gupta, Prof. and Head, Government Medical College and Super speciality, Nagpur. 6. Dr. Sandeep Nijhawan, Sr. Professor, SMS Medical College, Jaipur. 7. Dr. Manoj Kumar Sharma, Associate Prof., Institute of Liver and Biliary Sciences, D-1 Vasant Kunj, New Delhi **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
3.	**Name of the Drug:** Parenteral TK-112690 (METREXASSIST™) **Date of Application:** 17/2/2016 **Protocol No**: CLP-2690-0002 **Phase of the trial:** Ib **Name of the Applicant:** M/s R A Chem Pharma Limited India **Name of the Sponsor:** Tosk, Inc., 2672 Bayshore Parkway, Suite	**Risk versus Benefit to the patients**- The safety profile of the test drug from preclinical studies including single dose toxicity, repeat dose toxicity; genotoxicity and Clinical Phase I study justify the conduct of the study. **Innovation vis a vis existing therapeutic option**- The purpose of the study is to assess the efficacy Metrexassist administered weekly to subjects with locally advanced or recurrent or metastatic SCCHN scheduled to receive MTX as chemotherapy. **Unmet need**- The test drug may	**1. Recommendation of SEC (Oncology) held on 03/05/2016.** After detailed deliberation the committee noted the following 1. The rationale of using of the trial drugs for the mucoprotection of patients on Methotrexate is not clear and not substantiated by available published literature, specifically the role of Uridine in reducing mucositosis and not interfering with the action of Methotrexate on cancer cells was not substantiated with

	507, Mountain View, CA 94043 **Name of the Manufacturer:** M/s R A Chem Pharma Ltd, India for Drug Substance and M/s Ther Dose Pharma Pvt. Ltd., Hyderabad, India **Title:** A Phase Ib, Multi-center, Study of METREXASSIST™ (Parenteral TK-112690) Administered in Combination with Methotrexate as a Weekly Infusion to Subjects with SCCHN Undergoing Treatment with Methotrexate. A Dose Escalation/Safety study with No Control.	be alterative option in the treatment of patients locally advanced or recurrent or metastatic SCCHN	evidences 2. They have not presented in vitro pre clinical or animal studies showing that the trial drug does not interfere with the efficacy of Methotrexate 3. The rationale for addition of Uridine supplement in the trial will confound the outcome of the trial. **The Proposal was Re-deliberated in SEC (Oncology) held on 19/7/2016** The firm presented protocol and the following clarifications still need to be addressed: 1. Only the summary version of non clinical pharmacological and toxicological data of the study drug was presented. The same need to be presented in full detail including the data for the combination of Uridine with Metrexassist. 2. The committee was informed that the protocol was approved in US in 2011 ; however no patients were recruited ,the reason for non recruitment for a period of five years is unclear. Hence the committee did not recommend the approval to conduct the study **The Proposal was Re-deliberated in SEC (Oncology) held on 23/8/206** After detailed deliberation the committee has recommended the conduct of phase Ib trial in at least 25 patients. Accordingly modified protocol for phase Ib is submitted to DCGI office.

			List of SEC Experts: 1. Dr. Sameer Bakshi, Professor, Dept. of Medical Oncology, AIIMS, New Delhi 2. Dr. H.P Pati, Prof, Dept of Hematology, AIIMS, New Delhi. 3. Dr. Prantar Chakraborty, Dept. of Haematology, NKS Medical College, Kolkata. 4. Dr. C.K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. 5. Dr. H.S Rehan , Prof & Head of Dept. of Pharmacology, Lady Harding Medical College, New Delhi 6. Dr. Renu Saxena, Prof & Head, Dept. of Hematology, AIIMS, New Delhi. **2. Recommendation of the Technical Committee meeting held on 22.12.2016:** The committee opined that the clinical trial with the NCE is proposed to be India centric, with no other participating countries. After detailed deliberation, the committee has requested the applicant to make a detailed protocol presentation before it in the next meeting and an expert in Pharmacology and Toxicology should also be invited. Accordingly, the firm has presented the proposal before the Committee. **Recommendation of the Technical Committee meeting held on 06.02.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the

			study.
4.	**Name of the Drug:** DE-117 **Date of Application:** 31/08/2016 **Protocol No:** 01171505 **Phase of the trial:** III **Name of the Applicant:** M/S. Covance India Pharmaceutical Services Private Limited Company, Japan. **Name of the Manufacturer:** M/s. Santen Pharmaceutical Co. Ltd., Japan. **Title:** A Phase III, Randomized, Observer-Marked, Active-Controlled, Parallel-Group, Multinational and Multicenter Study Assessing the Safety and Efficacy of DE-117 Ophthalmic Solution 0.002% compared with Latanoprost Ophthalmic Solution 0.005% in Subjects with Open-Angle Glaucoma or Ocular Hypertension-PEONY Study.	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the test drug from preclinical studies including single dose toxicity, repeat dose toxicity, genotoxicity, reproductive and development toxicity studies and Clinical Phase I & II studies justify the conduct of the study. **Innovation vis-à-vis Existing Therapeutic Option:** The objective of the study is to determine if the mean diurnal intraocular pressure (IOP) reduction with DE-117 ophthalmic solution 0.002% is non-inferior to Latanoprost ophthalmic solution 0.005% at Month 3 in subjects with open-angle glaucoma (OAG) or ocular hypertension (OHT). **Unmet Medical Need in the country:** The test drug may provide alternative treatment option for subjects with Open-Angle Glaucoma or Ocular Hypertension.	**1. Recommendations of Subject Expert Committee (SEC) (Ophthalmology) held on 13/10/2016.** After detailed deliberation the committee opined that firm needs to modify the CT protocol with respect to - 1. Recruit only newly diagnosed cases since a 4 week wash out period is not safe. 2. The subjects should be over 40 years of age. 3. The visual field examination must be done on all subjects at the end of the study. **The firm has submitted response for above recommendation,** 1. 4 weeks washout is reasonable and the risk in this well controlled phase III study is minimal. 2. The firm has given the details of protocol trial accepted earlier by CDSCO and SEC in which the age of inclusion is ≥18 years. 3. The firm has stated that they would modify the protocol as per SEC recommendation to have the visual field examination at visit 1 (Screening) an visit 5 (month 3)/ early termination. **The proposal was Re-deliberated in (Ophthalmology) held on 13/01/2017.** After detailed re-deliberation the committee recommended the

			conduct of the study subject to the following conditions: **1.** Patient at the time of enrollment should not be using more than two topical drugs for control of glaucoma. **2.** Subjects with diagnosis of OAG (including Pigmentary Glaucoma) or OHT in both eyes are proposed to be included. Hence age group 18 and above is acceptable. **3.** The visual field examination at Visit 1 (Screening) and Visit 5 (Month must be done. **SEC Expert List:** **1.** Dr. Rohit Saxena, Prof. AIIMS, New Delhi. **2.** Dr. R.K. Jain, Professor, Lady Harding Medical College, New Delhi. **3.** Dr. Renuka Srinivasan Prof., JIPMER, Dhanvantri Nagar, Pondicherry-605006. **4.** Dr. Kamalesh Khilani Prof., SMS Medical College, Jaipur. **5.** Dr. Pooja Gupta, Asst. Prof, Dept. of Pharmacology, AIIMS, New Delhi. **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study

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