MINUTES OF 41st MEETING OF THE TECHNICAL COMMITTEE HELD ON 31.05.2017 UNDER THE CHAIRMANSHIP OF DGHS FOR SUPERVISING CLINICAL TRIALS ON NEW CHEMICAL ENTITIES IN THE LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME COURT OF INDIA ON 03.01.2013.

Present:

1.	Dr. Jagdish Prasad, Director General of Health Services, Nirman Bhawan, New Delhi	Chairman
2.	Dr. Kamlakar Tripathi, Prof. Department of Medicine, Institute of Medical Sciences, Banaras Hindu University, Varanasi.	Member
3.	Dr. Nandini Kumar, Former Dy. Dire. Gen. Sr. Grade, Adjunct Professor, KMC, Manipal, 5/1 (New) Padmalaye Apt. Chennai.	Member
4.	Dr. Rajutitus Chacko, Prof. & Head, Dept. of Medical Oncology, CMC, Vellore.	Member
5.	Dr. Yash Paul, Prof. & Head, Dept. of Cardiology, PGIMER, Chandigarh.	Member

From CDSCO:

1. Dr.G.N. Singh
   Drugs Controller General (India)
2. Dr. V.G. Somani,
   Joint Drug Controller (India)
3. Mr. R. Chandrashekar
   Deputy Drugs Controller (India)
4. Mrs. Rubina Bose
   Deputy Drugs Controller (India)
5. Mrs. Annam Visala
   Deputy Drugs Controller (India)

The Chairman welcomed the members of the Committee for the 41st technical committee meeting. Thereafter, the Committee discussed the clinical trial proposals and other agenda one after another as under:

The Committee deliberated 19 cases related to approval of clinical trials. Out of these 19 cases, 06 cases were related to clinical trials of NCEs, 07 cases were related to Global Clinical Trials (GCT), remaining 06 cases were related to clinical trials for approval of New Drugs and Biologicals.

1. **Proposals of Clinical Trials of NCEs recommended by SECs.**

The Committee evaluated six cases related to clinical trials of NCEs and made recommendations considering all aspects of safety, efficacy especially in terms of the three parameters viz. risk versus benefit to the patients, innovation vis-a-vis existing therapeutic option and unmet medical need in the country. After detailed deliberations, the Committee recommended approval for six proposals of Clinical Trial. The recommendations of the Committee are enclosed at **Annexure-I.**

2. **Proposals of Clinical Trials of GCT recommended by SECs.**

The Committee evaluated six cases related to global clinical trials. After detailed deliberations, the Committee recommended approval for six proposals of clinical trials. The recommendations of the Committee are enclosed at **Annexure-II.**

3. **Proposals of Clinical Trials other than GCT/ NCEs recommended by SECs.**

The Committee evaluated six cases of other than GCT/clinical trial of NCEs. After detailed deliberations, the Committee recommended approval for 05 proposals. For the remaining proposal (Proposal No 06 of **Annexure-III**), the committee has not recommended and asked to present the proposal by the firm before the committee for certain clarification. The recommendation of the Committee is enclosed as **Annexure-III.**

4. **Others:**

Proposal for waiver of local clinical trial for wound care products manufactured in Switzerland by M/s B, Braun Medical AG, for import and market by M/s B, Braun Medical, India Pvt., Ltd., Bhiwandi under the provision of Drugs and Cosmetics Act and Rules.

Recommendation of the Technical Committee: The committee reviewed the recommendation of the SEC and as desired by the DCG (I) and Chairman of Technical committee, the proposal was deliberated in the technical committee. After detailed deliberation, the Committee has recommended for waiver of local clinical trial as the product is already approved in USA by USFDA, and EU and it is a relatively useful non risky wound dressing. Further, the committee recommended that the firm shall conduct the post marketing surveillance studies.

Annexure I

Proposals of clinical trial of NCEs along with their evaluations and recommendations of the Technical Committee in its 41st Meeting held on 31.05.2017:

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:** K-877 (PEMAFIBRATE) **Date of Application:** 03/02/17 (Online Submission) **Protocol No**: K-877-302 Version 1.0, dated 16/Nov/16 **Phase of the trial:** Phase III **Name of the Applicant:** M/s Quintiles Research India Private Limited **Name of the Sponsor:** Kowa Company Ltd, Japan **Name of the Manufacturer:** Kowa Company Ltd Nagoya Factory 2-18-57 Hatooka, Kita-ku Nagoya City Aichi 462-0024 Japan **Protocol Title:** Pemafibrate To Reduce Cardiovascular Outcomes By Reducing Triglycerides In Patients With Diabetes (Prominent)	**Assessment of Risk vs. Benefit to the patients:** The pre-clinical including repeat dose studies and Phase I, Phase II, Phase III studies justify the conduct of this study. **Innovation vis-à-vis Existing Therapeutic Option:** The primary scientific aim of this study is to assess whether treatment with selective peroxisome proliferator activated receptor modulator alpha (SPPARM-alpha) IMP, will prevent myocardial infarction (MI), ischemic stroke, unstable angina requiring unplanned revascularization and cardiovascular death in adults with T2D who have elevated TG and low HDLC levels and are at high risk for future CV events. **Unmet Medical Need in the country:** Reducing the rate of diabetes related complications requires more than just adequate glycemic control, and to ameliorate residual macrovascular risk, lipid management may require more than statins alone. The specificity of increased CV risk due to metabolic syndrome, T2D, increased TG and decreased HDL-C make South Asian populations in need of new effective treatments for these conditions as well as an ideal clinical setting to address the scientific hypothesis tested with IMP.	**1. Recommendation of SEC (Cardiology & Renal) on 18/April/17** After detailed deliberation the committee recommended the conduct of the Phase 3 clinical trial as per the protocol presented. **SEC Experts List** 1. Dr. Sandeep Bansal, Professor & Head of Department of Cardiology, Vardhman Mahavir Medical College, New Delhi- 110029. 2. Dr. K.M.K Reddy, DM Cardio, Osmania Medical College, Secunderabad, Andhra Pradesh. 3. Dr. S.K. Agrawal, Professor & Head of the department, Dept. Of Nephrology AIIMS, New Delhi. 4. Dr. Saibal Mukhopadhyay, Professor, Dept. Of Cardiology, G B Pant Hospital, Delhi. **2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

2.	**Name of the Drug:** LNP1892 **Date of Application:** 16.12.2016 **Protocol No**: LRP/LNP1892/2016/007, Version 1.2 Dated 15/Dec/16 **Phase of the trial:** Phase II **Name of the Applicant:** Lupin Limited, Lupin Research Park, Survey No. 46A/47A, Village - Nande, Taluka - Mulshi, Pune - 412 155, Maharashtra, India **Name of the Sponsor:** Lupin Atlantis Holdings SA Landis + Gyr Strasse 1 6300 Zug, Switzerland **Name of the Manufacturer:** Catalent Pharma Solutions 14 School house Rd. Somerset, New Jersey, NJ 08873 USA **Protocol Title:** A randomized, double-blind, placebo-controlled, phase ii study to assess the efficacy, pharmacokinetics, pharmacodynamics and safety of LNP1892 (Monotherapy) in Chronic Kidney Disease (CKD) Patients with Secondary Hyperparathyroidism (SHPT), On Dialysis and not on Dialysis	**Assessment of Risk vs. Benefit to the patients:** In Phase 1 first in human study, IMP was found to be safe and well tolerated up to the highest doses tested (up to 50 mg in single dose and 25 mg in multiple dose study). IMP has potential to decrease iPTH without significant hypocalcaemia. The observation of preclinical and Phase I clinical study justify the conduct of study. **Innovation vis-à-vis Existing Therapeutic Option:** In current available therapies for SHPT, phosphate binders have a risk of cardiovascular diseases (CVD), and newer vitamin D sterols have a risk of hypercalcemia and provide inefficient control. It is expected that the property of IMP of reducing iPTH without change in serum phosphate or calcium levels will benefit in SHPT patients who are on dialysis as well as not on dialysis. **Unmet Medical Need in the country:** In India, prevalence of SHPT is very common varying from 72.7% to 92.5%, increasing with CKD stage, and maximum seen in CKD Stage 5. Cinacalcet is the first US FDA approved calcimimetic for treating SHPT in CKD patients receiving dialysis (stage 5 CKD) and hypercalcemia in patients with parathyroid carcinoma. Cinacalcetis also not recommended in patients with intact parathyroid hormone (iPTH) values above 800 pg/mL and who are 'Not on Dialysis'. There is therefore, an urgent need for new pharmacologic therapies that achieve a balanced control of mineral metabolism and PTH secretion in SHPT in Dialysis as well as Not on Dialysis patients.	**1. Recommendation of SEC (Cardiology & Renal) on 18/April/17** After detailed deliberation the committee has recommended the conduct of the Phase II study. **SEC Experts List:** 1. Dr. Sandeep Bansal, Professor & Head of Department of Cardiology, Vardhman Mahavir Medical College, New Delhi- 110029. 2. Dr. K.M.K Reddy, DM Cardio, Osmania Medical College, Secunderabad, Andhra Pradesh. 3. Dr. S.K. Agrawal, Professor & Head of the department, Dept. Of Nephrology AIIMS, New Delhi. 4. Dr. Saibal Mukhopadhyay, Professor, Dept. Of Cardiology, G B Pant Hospital, Delhi. **2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

3.	**Name of the Drug:** Semaglutide **Date of Application:** 28/12/16 (Online Submission) **Protocol No**: NN9535-4270, Version 3.0, dated 19/Dec/16 **Phase of the trial:** Phase IIIb **Name of the Applicant:** Novo Nordisk India Private Ltd, Plot No. 32, 47 - 50, EPIP Area, Whitefield, Bangalore - 560 066, India **Name of the Sponsor:** Novo Nordisk India Private Ltd, Plot No. 32, 47 - 50, EPIP Area, Whitefield, Bangalore - 560 066, India **Name of the Manufacturer:** Novo Nordisk A/S, Clinical Supplies Packaging, Novo Nordisk Park, B5.S.09. DK-2760, Måløv, Denmark. **Protocol Title:** Efficacy and safety of Semaglutide versus Canagliflozin as add-on to Metformin in subjects with type 2 diabetes.	**Assessment of Risk versus benefit to the patients**: The safety profile of the test drug from various preclinical pharmacology and toxicity studies including single dose toxicity, repeat dose toxicity studies and phase I, phase II, phase III clinical study justifies the conduct of the trial. **Innovation Vis-à- Vis existing therapeutic option**: The aim for the present trial is to compare the effect of IMP versus canagliflozin, in subjects with T2D inadequately controlled with metformin, in terms of glycaemic control, weight management and other efficacy parameters. **Unmet medical need in the country** Type 2 diabetes is a progressive disease and continuous treatment intensification is required in order to provide optimum glycaemic control. The currently available treatment modalities for T2D are still not satisfactory and there is a significant proportion of patients not reaching the treatment targets.	**1. Recommendation of SEC (Endocrinology & Metabolism) on 25/April/17** After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial. **SEC Experts List** 1. Dr. B. Gupta, Prof & Head Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi. 2. Dr. Deepak Khandelwal, Maharja Agrasen Hospital, Punjabi Bhagh, New Delhi. 3. Dr. K. H. Reeta, Dept. of Pharmacology, AIIMS, New Delhi. 4. Dr. Rajesh Khadgawat, Assoc. Prof., AIIMS, New Delhi. **2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
4.	**Name of the Drug:** MOD-4023 **Date of Application:** 10/12/16 (Online Submission) **Protocol No**: CP-4-006, Version No. 1.0, dated 05/Oct/16	**Risk vs Benefit to the patients:** The safety profile of the test drug from various preclinical pharmacology and toxicity studies including single dose toxicity, repeat dose toxicity, Male fertility studies, female reproduction and developmental toxicity Studies, Carcinogenicity, Genotoxicity	**1. Recommendation of SEC (Endocrinology & Metabolism) on 25/April/17** After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial. Dr. Rajesh Khadgawat did not

	Phase of the trial: Phase III **Name of the Applicant:** JSS Medical Research India Private Limited 6th Floor, Plot 12/2, Sector 27 D, Haryana, India **Name of the Sponsor:** OPKO Biologics Ltd. Ashlagan 16 Kiryat Gat, Israel **Name of the Manufacturer:** Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870, Puurs, Belgium **Protocol Title:** A phase III, open-label, randomized, multicenter, 12 months, efficacy and safety study of weekly MOD-4023 compared to daily Genotropin - therapy in pre-pubertal children with growth hormone deficiency.	studies and phase I, phase II, phase III clinical study justifies the conduction of the trial. **Innovation vis a vis against existing therapy:** The purpose of the study is to demonstrate that weekly MOD-4023 administration is non-inferior to daily Genotropin administration in terms of safety and efficacy outcomes **Unmet need-** The test drugs may provide treatment option in pre-pubertal children with growth hormone deficiency.	participate in the deliberation. **SEC Experts List** 1. Dr. B. Gupta, Prof & Head Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi. 2. Dr. Deepak Khandelwal, Maharja Agrasen Hospital, Punjabi Bhagh, New Delhi. 3. Dr. K. H. Reeta, Dept. of Pharmacology, AIIMS, New Delhi. 4. Dr. Rajesh Khadgawat, Assoc. Prof., AIIMS, New Delhi. **2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
5.	**Name of the Drug:** LNP3794 **Date of Application:** 17/03/17 (Online Submission) **Protocol No**: LRP/LNP3794/2016/006 **Phase of the trial:** II/III **Name of the Applicant:** Lupin Limited, Lupin Research Park, Survey No. 46A/47A, Village - Nande, Taluka -Mulshi, Pune - 412 155, India **Name of the Sponsor:** Lupin Limited, Lupin Research Park, Survey No. 46A/47A, Village - Nande, Taluka -Mulshi, Pune - 412 155, India	**Risk/Benefit Assessment for the Study:** The safety profile of the test drug from various preclinical pharmacology, toxicity studies and phase I clinical studies justifies the conduct of the trial. **Innovation Vs existing therapeutic Option** The study drug is an innovative targeted therapy for treatment of RAS mutant NSCLC patients. **Unmet medical need in the country:** LNP3794 in the treatment of RAS positive NSCLC would be a great advantage in scientific advancement and management of the disease.	**1. Recommendation of SEC (Oncology & Hematology) on 16.05.2017** After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial as per the protocol submitted. **SEC Experts:** 1. Dr. P.K Gogoi, Professor & Head, Guwahati Medical College and Hospital, Guwahati. 2. Dr. (Brig) Ajay Sharma, Professor & Sr. Advisor Army Hospital (Research & Referral) New Delhi 3. Dr. H.P. Pati, Professor, Dept. of Hematology, AIIMS, New Delhi. 4. Dr. Sameer Bakshi, Professor, Dept. of Oncology, AIIMS, New Delhi. 5. Dr. K. H. Reeta, Professor, Dept. of Pharmacology, AIIMS, New Delhi.

	Name of the Manufacturer: Catalent Pharma Solutions, New Jersey, NJ 08873 USA. **Protocol Title:** A Phase II/III Pivotal, Open-label, Randomized, 3 Arm Study to Assess the Efficacy of LNP3794 Monotherapy or in Combination with Docetaxel, Compared with Docetaxel Alone, in Patients with RAS Mutation Positive Locally Advanced and Metastatic Non-Small Cell Lung Cancer		6. Dr. C. k Bose, Assisstant Professor, Netaji Subhash Chander Bose Cancer Research Institutie. 7. Dr. Sanjay Kumar Singh, Assistant Professor, Gajara Raja Medical College, Gwalior. 8. Dr. P. K Julka, Director Max Oncology, Day Care Centre, Lajpat Nagar. **2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
6.	**Name of the Drug**: SPI-2012 (Eflapegrastim) **Date of Application**: 20/04/17 (Online Submission) Protocol No: SPI-GCF-302 Version: Original dated 27/Sep/2016 Phase of the trial: III **Name of the Applicant**: Spectrum Oncology Pvt Ltd., 71, Free Press House, Journal Marg, Nariman Point, Mumbai, Maharashtra, India **Name of the Sponsor:** Spectrum Pharmaceuticals, Inc. 157 Technology Drive, Irvine, CA 92618 USA. **Name of the Manufacturer:** Hanmi Pharm. Co., Ltd., Chupalsandan-ro Paengseong-eup	**Assessment of Risk versus benefit to the patients**: The safety profile of the test drug from various preclinical pharmacology and toxicity studies including single dose toxicity, repeat dose toxicity, Female reproductive & developmental toxicity studies and phase I, phase II, phase III clinical study justifies the conduction of the trial. **Innovation Vis-à- Vis existing therapeutic option**: The study drug is a novel biologic that was designed to maximize the pharmacological activity of the granulocyte-colony stimulating factor (G-CSF) moiety of the molecule. **Unmet medical need in the country:** The study drug may provide an alternative treatment option in MBC patients receiving chemotherapy.	1. **Recommendation of SEC (Oncology & Hematology) on 16/05/17** After detailed deliberation committee recommended for grant of permission to conduct the clinical trial as per the protocol submitted. SEC Experts: 1. Dr. P.K Gogoi, Professor & Head, Guwahati Medical College and Hospital, Guwahati. 2. Dr. (Brig) Ajay Sharam, Professor & Sr. Advisor Army Hospital (Research & Referal) New Delhi 3. Dr. H.P Pati, Professor, Dept. of Hematology, AIIMS, New Delhi. 4. Dr. Sameer Bakshi, Professor, Dept. of Oncology, AIIMS, New Delhi. 5. Dr. K. H. Reeta, Professor, Dept. of Pharmacology, AIIMS, New Delhi. 6. Dr. C. k Bose, Assisstant Professor, Netaji Subhash Chander Bose Cancer Research Institutie. 7. Dr. Sanjay Kumar Singh, Assistant Professor, Gajara Raja Medical College, Gwalior. 8. Dr. P. K Julka, Director Max Oncology, Day Care Centre, Lajpat Nagar.

	Pyeongtaek -si, Gyeonggi-do 17998, Korea **Protocol Title**: A Randomized, Open-label, Active-control Trial of SPI-2012 (Eflapegrastim) versus Pegfilgrastim in the Management of Chemotherapy-Induced Neutropenia in Early stage Breast cancer patients receiving Docetaxel and Cyclophosphamide (TC).		**2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

Annexure-II

Proposals of clinical trial of GCTs along with their evaluations and recommendations of the Technical Committee in its 41st Meeting held on 31.05.2017:

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:** Dapagliflozin Propanediol. **Date of Application:** 23/Dec/16 **Protocol No**: D169AC0000, Version 1.0, dated 26/Oct/16 **Phase of the trial:** Phase III **Name of the Applicant:** AstraZeneca Pharma India Ltd, Block No N1, 12th Floor, Manyata Embassay Business Park, Bangalore. **Name of the Sponsor:** M/s. AstraZeneca AB, 151 85, Sodertalje, Sweden. **Name of the Manufacturer:** AstraZeneca AB, R&D Mölndal, Pepparedsleden 1431 83 Mölndal, Sweden (For Clinical Release). **Protocol Title:** A Study to Evaluate the Effect of Dapagliflozin on Renal Outcomes and Cardiovascular Mortality in Patients with Chronic Kidney Disease.	**Assessment of Risk vs. Benefit to the patients:** In light of the fact that the test drug is approved and marketed in India, the safety profile of the test drug justifies the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** IMP mechanism of action results in a direct and insulin independent elimination of glucose by the kidneys, which results in reduced blood glucose levels in type 2 diabetes (T2D) patients. In addition, IMP has a mild diuretic and natriuretic effect. Moreover, IMP has also been shown to reduce BP and albuminuria, two essential prognostic risk factors for progression of CKD. **Unmet Medical Need in the country:** The incidence of Chronic kidney disease is suggested to increase due to increase in the prevalence of Diabetes, Hypertension and other related disorders.	**1. Recommendation of SEC (Endocrinology & Metabolism) on 25/April/17** After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial subject to the condition that there must be a Nephrologist in the Investigator's team at all study centers. **SEC Experts:** 1. Dr. B. Gupta, Prof & Head Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi. 2. Dr. Deepak Khandelwal, Maharja Agrasen Hospital, Punjabi Bhagh, New Delhi. 3. Dr. K. H. Reeta, Dept. of Pharmacology, AIIMS, New Delhi. 4. Dr. Rajesh Khadgawat, Assoc. Prof., AIIMS, New Delhi. **2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study subject to condition that females with history of mycotic infection shall be excluded.

2.	**Name of the Drug:** Liraglutide **Date of Application:** 27/12/16 (Online Submission) **Protocol No**: NN2211-4315, Version 1.0, dated 16/Sept/16 **Phase of the trial:** Phase IIIb **Name of the Applicant:** Novo Nordisk India Private Ltd, Plot No. 32, 47 - 50, EPIP Area, Whitefield, Bangalore -560 066, Karnataka, India **Name of the Sponsor:** Novo Nordisk India Private Ltd, Plot No. 32, 47 - 50, EPIP Area, Whitefield, Bangalore -560 066, Karnataka, India **Name of the Manufacturer:** Novo Nordisk A/S, Clinical Supplies Packaging, Novo Nordisk Park, B5.S.09. DK-2760, Malov Denmark. **Protocol Title:** LIRA-ADD2SGLT2i – Liraglutide versus placebo as add-on to SGLT2 inhibitors.	**Assessment of Risk vs. Benefit to the patients:** In light of the fact that the test drug is approved and marketed in India, the safety profile of the test drug justifies the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option**: : In patients with T2DM who have not achieved glycaemic control on an SGLT2 inhibitor (with or without Metformin), adding Liraglutide to their treatment may achieve a better glycaemic control reflected in HbA1c reduction with associated decrease in body weight and no increase of hypoglycaemic events. **Unmet Medical Need in the country:** T2DM is increasing in incidence and prevalence. Despite compliance with their treatment regimens, a large proportion of patients do not reach treatment targets, indicating that the current available treatment modalities are not satisfactory and more treatment options need to be explored.	**1. Recommendation of SEC (Endocrinology & Metabolism) on 25/April/17.** After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial. **SEC Experts:** 1. Dr. B. Gupta, Prof & Head Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi. 2. Dr. Deepak Khandelwal, Maharja Agrasen Hospital, Punjabi Bhagh, New Delhi. 3. Dr. K. H. Reeta, Dept. of Pharmacology, AIIMS, New Delhi. 4. Dr. Rajesh Khadgawat, Assoc. Prof., AIIMS, New Delhi. **2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
3.	**Name of the Drug:** Exenatide **Date of Application:** 03/Mar/17 **Protocol No**: H8O-MC-	**Assessment of Risk vs. Benefit to the patients:** In light of the fact that the test drug is approved and marketed in India, the safety profile of the test drug justify the conduct of	**1. Recommendation of SEC (Endocrinology & Metabolism) on 25/April/17** After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial.

	GWBQ(d) **Phase of the trial:** Phase III **Name of the Applicant:** AstraZeneca Pharma India Pvt. Ltd, Manayata Business Park, Block N1, Bangalore. **Name of the Sponsor:** Amylin LLC (a wholly owned subsidiary of AstraZeneca) AstraZeneca AB, SE 15185, Sodertalje, Sweden. **Name of the Manufacturer:** CP Pharmaceuticals Ltd. Ash Road North Wrexham Industrial Estate Wrexham LL13 9UF UK. **Protocol Title:** Safety and efficacy of Exenatide as monotherapy and adjunctive therapy to oral antidiabetic agents in adolescents with type 2 diabetes.	the trial. **Innovation vis-à-vis Existing Therapeutic Option:** The primary objective of this study is to test the hypothesis that glycemic control, as measured by change in hemoglobin A1c (HbA1c) from baseline to endpoint, with Exenatide is superior (in at least 1 of the Exenatide treatment arms), to that of placebo after 28 weeks of treatment in adolescent patients with type 2 diabetes who are naïve to antidiabetic agents, or patients who are being treated with Metformin, an SU, or a combination of Metformin and an SU. **Unmet Medical Need in the country:** - The test drug may be a better treatment option in Type 2 Diabetes Mellitus.	Dr. Rajesh Khadgawat did not participate in the deliberation. **SEC Experts:** 1. Dr. B. Gupta, Prof & Head Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi. 2. Dr. Deepak Khandelwal, Maharja Agrasen Hospital, Punjabi Bhagh, New Delhi. 3. Dr. K. H. Reeta, Dept. of Pharmacology, AIIMS, New Delhi. 4. Dr. Rajesh Khadgawat, Assoc. Prof., AIIMS, New Delhi. **2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
4.	**Name of the Drug:** Dulaglutide **Date of Application:** 01/12/16 (Online Submission) **Protocol No** H9X-MC-GBGC (c) **Phase of the trial:** III **Name of the Applicant:** Eli Lilly and Company (India) Pvt. Ltd. Sector – 32, Gurgaon – 122001, Haryana, India **Name of the Sponsor: :** Eli Lilly and Company (India) Pvt. Ltd. Sector – 32, Gurgaon – 122001, Haryana, India	**Risk versus benefit to the patients-** In light of the fact that the test drug is old drug and marketed in India, the safety profile of the test drug justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic option:** The primary objective of this study is to test the hypothesis that Dulaglutide (0.75 mg and 1.5mg, pooled) given subcutaneously (SC) once a week for 26 weeks to children and adolescents with T2DM who have inadequate glycemic control, despite diet and exercise, with or without	**1. Recommendation of SEC (Endocrinology & Metabolism) on 25/April/17.** After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial. **SEC Experts List:** 1. Dr. B. Gupta, Prof & Head Dept. of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi. 2. Dr. Deepak Khandelwal, Maharja Agrasen Hospital, Punjabi Bhagh, New Delhi. **3.** Dr. K. H. Reeta, Dept. of Pharmacology, AIIMS, New Delhi.

	Name of the Manufacturer: Eli Lilly and Company Lilly Technology Center Indianapolis, Indiana 46221 USA **Protocol Title:** A Randomized, Double-Blind Study with an Open-Label Extension Comparing the Effect of Once- Weekly Dulaglutide with Placebo in Pediatric Patients with Type 2 Diabetes Mellitus	Metformin and/or basal insulin is superior to placebo in the treatment of T2DM, as measured by baseline to Week 26 change in HbA1c. **Unmet need in the country**- The test drug may be treatment option in Pediatric Patients with Type 2 Diabetes Mellitus	**4.** Dr. Rajesh Khadgawat, Assoc. Prof., AIIMS, New Delhi. **2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
5.	**Name of the Drug:** Ribociclib (LEE011) **Date of Application:** 17/02/17 (Online Submission) **Protocol No**: CLEE011A2404, Version 01, dated 19/Dec/16 **Phase of the trial:** IIIb **Name of the Applicant:** M/s Novartis Healthcare Pvt. Ltd., Mumbai **Name of the Sponsor:** M/s Novartis Healthcare Pvt. Ltd., Mumbai **Name of the Manufacturer:** M/s Novartis Singapore Pharmaceutical Manufacturing Pvt. Ltd., Singapore **Protocol Title:** An open-label, multicenter, Phase IIIb study to assess the safety and efficacy of	**Risk versus benefit to the patient:** The pre-clinical including repeat dose toxicity studies and Phase I, Phase II, Phase III studies justify the conduct of this study. **Innovations Vs existing therapeutic option:** CDK4/6 inhibitor such as Ribociclib in combination with endocrine treatment has the potential to have a positive influence on breast cancer. The purpose of this study is to further evaluate the overall safety and tolerability and clinical efficacy of Ribociclib in combination with Letrozole in a large cohort of patients with HR+, HER2- advanced breast cancer, who has not received prior hormonal treatment for advanced disease. **Unmet medical need in the country:** Despite endocrine therapy being the mainstay of the first several lines of therapy in patients with HR+, HER2- breast cancer, resistance to endocrine therapy and disease progression occur	**1. Recommendation of SEC (Oncology & Hematology) on 13/April/17** After detailed deliberation the committee recommended conduct of the study with a suggestion that the number of trial participants from India be increased from 50. **SEC Experts List:** 1. Dr. H.P. Pati, Professor, Dept. of hematology, AIIMS, New Delhi 2. Dr. Sameer Bakshi, Professor, Dept. of Oncology, AIIMS, New Delhi. 3. Dr. Renu Saxena, Professor & HOD, Dept. of Hematology, AIIMS, New Delhi. 4. Dr. D S Arya, Professor, Dept. of Pharmacology, AIIMS, New Delhi. 5. Dr. C K Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. **2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

	ribociclib (LEE011) in combination with letrozole for the treatment of men and pre/postmenopausal women with hormone receptor-positive (HR+) HER2-negative (HER2-) advanced breast cancer (ABC) with no prior hormonal therapy for advanced disease	creating a significant unmet medical need.	
6.	**Name of the Drug:** Atezolizumab **Date of Application:** 29/03/17 (Online Submission) **Protocol No**: MO29983, Version 3.0, dated 22/Nov/16 **Phase of the trial:** IIIb **Name of the Applicant:** Roche Products (India) Pvt. Ltd "Bandra Kurla Complex, Bandra (East), Mumbai 400 051 **Name of the Sponsor:** F. Hoffmann-La Roche Ltd, Switzerland **Name of the Manufacturer:** F. Hoffmann-La Roche Ltd, Basel, Switzerland at Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim, Germany. **Protocol Title:** An open label, single arm, multicenter, Safety study of Atezolizumab in locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract.	**Risk vs Benefit to the patients:** The safety profile of the test drug from various preclinical pharmacology, toxicity studies, phase I, II and III clinical studies justifies the conduct of the trial. **Innovation vis-à- vis available treatment** Atezolizumab, a humanized immunoglobulin (Ig) G1 monoclonal antibody targets human PD-L1 on ICs and tumor cells (TCs), resulting in improved anti-tumor activity in contrast to the chemotherapeutic agents which acts by direct elimination of tumor cells by producing cytotoxicity. **Unmet medical need:** The study drug may provide additional data on safety and efficacy in patients of both urothelial and non urothelial cancers of the urinary tract who progress on first line platinum based chemotherapy.	**1. Recommendation of SEC (Oncology & Hematology) on 16.05.2017** After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial as per the protocol submitted **SEC Experts:** 1. Dr. P.K Gogoi, Professor & Head, Guwahati Medical College and Hospital, Guwahati. 2. Dr. (Brig) Ajay Sharma, Professor & Sr. Advisor Army Hospital (Research & Referal) New Delhi 3. Dr. H.P Pati, Professor, Dept. of Hematology, AIIMS, New Delhi. 4. Dr. Sameer Bakshi, Professor, Dept. of Oncology, AIIMS, New Delhi. 5. Dr. K. H. Reeta, Professor, Dept. of Pharmacology, AIIMS, New Delhi. 6. Dr. C. k Bose, Assisstant Professor, Netaji Subhash Chander Bose Cancer Research Institutie. 7. Dr. Sanjay Kumar Singh, Assistant Professor, Gajara Raja Medical College, Gwalior. 8. Dr. P. K Julka, Director Max Oncology, Day Care Centre, Lajpat Nagar. **2. Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

7.	**Name of the Drug:** VBP-245; Topical Povidone - Iodine 2% Gel **(for the Treatment of Molluscum Contagiosum)** **Date of Application:** 29/12/2016 (Online Submission) **Protocol No:** VBP-245-MCV, Version 1.0, dated 15/11/16 **Phase of the trial:** II **Duration of trial:** 60 days **Name of the Applicant:** JSS Medical Research India Private Limited Vatika Mindscapes (Tower B), 6th Floor, Plot 12/2, Sector 27D, Faridabad – 121003, Haryana, India **Name of the Sponsor:** Veloce Bio Pharma LLC 1007 N Federal Hwy #E4 Fort Lauderdale, FL 33304 **Name of the Manufacturer:** Frontage Laboratories, Inc., 75 E. Uwchlan Ave Suite 100, Exton, Pennsylvania 19341. **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	**Risk versus benefit to the patient:** Povidone Iodine is approved as a broad spectrum antimicrobial with a known safety profile for 2% formulation which justifies the conduct of the study. **Innovations Vs existing therapeutic option:** There are no approved agents indicated for the treatment of MC in children or adults. Study drug may provide a treatment option for the treatment of Molluscum Contagiosum. **Unmet medical need in the country:** The study drug may provide a treatment option for the treatment of Molluscum Contagiosum in Pediatric patients.	**1. Recommendation of SEC (Dermatology) held on 28/March/2017.** After detailed deliberation committee recommended the conduct of the study subject to submission of safety data on DMSO used in the formulation for the topical preparation to CDSCO **SEC Experts:** 1. Dr. V.K. Sharma, Professor and Head, Dept. of Dermatology, AIIMS, New Delhi-110029. 2. Dr. D.M Thappa, Professor and Head, Dept. of Dermatology, JIPMER, Pondicherry-605006. 3. Dr. Sanjeev Handa, Professor and Head, Dept. of Dermatology, PGIMER, Sector 12, Chandigarh. 4. Dr. D.S. Arya, Professor, Dept. of Clinical Pharmacology, AIIMS, New Delhi. 5. Dr. Binod Khaitan, Professor and Head, Dept. of Dermatology, AIIMS, New Delhi. **2.Recommendation of the Technical Committee meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

Annexure III

Proposals of clinical trial of other than NCE/GCT along with their evaluations and recommendations of the Technical Committee in its 41st Meeting held on 31.05.2017:

S.No.	Name of the Drug	Recommendations: 1. Subject Expert Committee 2. Technical Committee
1.	Azilsartan Medoxomil 40 mg and Chlorthalidone 12.5 mg Tablets	**1. Recommendation of the SEC on 18.04.2017** The firm presented the proposed Phase III clinical trial protocol. After detailed deliberation the Committee recommended the study subject to the condition that the evaluable sample size should be minimum 300. Accordingly, firm should submit revised clinical trial protocol to the office of DCG (I). Firm shall complete Bioequivalence study before initiation of clinical trial. **Action Taken: Accordingly firm has submitted the revised clinical trial protocol with the sample size of 352.** **SEC Expert List:** 1. Dr.Sandeep Bansal, Professor & Head of Department of Cardiology, Vardhman Mahavir Medical College, New Delhi-110029 2. Dr. K.M.K Reddy, DM Cardio, Osmania Medical College, Secunderabad, Andhra Pradesh. 3. Dr. S.K. Agrawal, Professor & Head of the department, Dept. Of Nephrology AIIMS, New Delhi. 4. Dr. K. H. Reeta, Department of Pharmacology, AIIMS, New Delhi. 5. Dr.Saibal Mukhopadhyay, Assoc. Professor, Deptt. Of Cardiology, G B Pant Hospital, Delhi. **2. Recommendation of the Technical Committee on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
2.	Remifentanil Hydrochloride 1 mg and 2 mg injection	**1. Recommendation of the SEC on 18.05.2017** The firm has applied for the grant of permission for import and market of Remifentanil HCl 1mg and 2mg indicated as an analgesic agent for use during the

		induction and maintenance of general anesthesia for inpatient and outpatient procedures and proposed to conduct the phase III clinical trial entitled as "Prospective, observer blind, randomized, comparative, parallel group, study to evaluate safety and efficacy of Remifentanil versus Fentanyl for analgesia during the induction and maintenance of general anesthesia" with 200 subjects for 6 months of duration at 04 sites in India. The objective of the study is to evaluate the efficacy and safety of Remifentanil versus Fentanyl for analgesia during the induction and maintenance of general anesthesia. The firm presented the proposal before the committee. After detailed deliberation the committee noted that the proposed drug is not the innovator's product. Therefore, the Committee opined that the firm should conduct three arm study comparing the test product vis- a- vis Innovator's product and Fentanyl Injection. Accordingly, the firm shall submit the revised clinical trial protocol to the office of DCG (I) for approval. **Action Taken: The firm has submitted the revised clinical trial protocol accordingly with the three arm study comparing the test product vis- a- vis Innovator's product and Fentanyl Injection.** **SEC Expert List:** 1. Dr. Chadralekha, Professor & Head, NDMC Medical College & Hindurao Hospital. 2. Dr. R.K. Arya, RML Hospital, New Delhi 3. Dr. Lalit Kumar Gupta, Pharmacologist, Lady Hardinge medical College, New Delhi **2. Recommendation of the Technical Committee Meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
3.	Human Insulin	**1. Recommendation of the SEC held on 08.09.2016:** The firm presented the proposal for the PK/PD, safety and efficacy of soluble Insulin injection IP 40IU/mL. After detailed deliberation committee noted the following- 1. Sample size calculation needs to be based on the

		literature of the PK/PD study conducted on regular soluble Human Insulin 2. Laboratory parameters for the various exclusion criteria need to be clearly defined in the CT protocol. 3. PI of the study should be MD (Internal/General Medicine) and needs to be mentioned in the study protocol. Accordingly, the revised protocol should be submitted to the DCGI office. CT Permission may be granted after compliance of the above mentioned points. **Action taken: The firm has submitted the revised clinical trial protocol**. **Expert Committee Members:** 1. Dr. Rajesh Rajput, PGIMS, Rohtak, Department of Medicine VI & Endocrinology, Rohtak. 2. Dr. Lalit Kumar Gupta, Pharmacologist, Lady Hardinge Medical College, Delhi. 3. Dr. Richa Diwan, Director & Prof of Medicine, MAMC, New Delhi **2. Recommendation of the Technical Committee Meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
4.	Trastuzumab Emtansine	**1. Recommendation of the SEC held on 13.04.2017:** After detail deliberation of the phase III clinical trial protocol, committee recommended for approval to conduct of the Phase III study. **Expert Committee Members:** 1. Dr. H. P. Pati, Professor, Dept. of hematology, AIIMS, New Delhi 2. Dr. Sameer Bakshi, Professor, Dept. of Oncology, AIIMS, New Delhi. 3. Dr. Renu Saxena, Professor & HOD, Dept. of Hematology, AIIMS, New Delhi. 4. Dr. D S Arya, Professor, Dept. of Pharmacology, AIIMS, New Delhi. 5. Dr. C K Bose, Assistant Professor, Netaji Subhash Chander Bose Cancer Research Institute, Kolkata **2. Recommendation of the Technical Committee**

		Meeting held on 31.05.2017: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
5.	Trastuzumab	1. **Recommendation of the SEC on 21.03.2017** After detailed deliberation, the committee recommended the conduct of Phase III clinical trial as presented with condition that there will be data of at least 100 evaluable subjects in the Test arm. **SEC Experts:** 1. Dr. Sameer Bakshi, Professor, Dept. of Oncology, AIIMS , New Delhi. 2. Dr. Renu Saxena, Professor & HOD, Dept. of Hematology, AIIMS New Delhi. 3. Dr. H.P.Pati, Professor, Dept. of Hematology, AIIMS New Delhi 4. Dr.Sanjay Kumar Singh, Dept. of Medical Oncology, Gajara Raja Medical College, Veer Savarkarlvlarz Gwalior 5. Dr. Raju Titus Chacko, Department of Medical Oncology, Christian Medical, College, Veilore-632004 6. Dr.S .D.Banaval i, Professor, Dept. of Oncology, KEM Mumbai. 7. Dr.P .K.Gogoi, Professor & HOD, Gauhati Medical College and Hospital, Guwahati. **8.** Dr.K.H Reeta, Professor, Dept. of Pharmacology, AIIMS, New Delhi **2. Recommendation of the Technical Committee Meeting held on 31.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
6.	Regen-D10, Epidermal Growth Factor 10µg / 100 gram	1. **Recommendation of the SEC :** After detailed deliberation, the committee recommended the phase II study protocol (Wrinkle) with the following changes to be made and submit the revised protocol:: 1) Placebo to be renamed as vehicle control. 2) Dermoscopy has to be standardized to have a objective scoring for assessing to minimize inter user variability. 3) Standardized photography with fixed distance, lighting, camera setting and subject position at every visit of the subject. **Expert Committee Members:** SEC Expert: 1. Dr. V. K. Sharma, Professor & Head, Dept. of Dermatology, New Delhi-110029

		2. Dr. Sanjeev Handa, Professor & Head, Dept. of Dermatology, PGIMER, Sector 12, Chandigarh 16001212 3. Dr. S. N. Bhattacharya, Professor & Head, Dept. of Dermatology, University of Medical College Science, New Delhi 4. Dr. Lalit Kumar Gupta, Prof. Dept. of Pharmacology, LHMC, New Delhi 5. Dr. Binod K Khaitan, Professor & Head, Dept. of Dermatology, AIIMS, New Delhi **2. Recommendation of the Technical Committee Meeting held on 22.12.2016:** After detailed deliberation, the committee recommended that the inclusion criteria should be amended such that the trial should be conducted on the subjects in the age group above 50 years. The NOC for conduct of clinical trial may be issued after submission of revised clinical protocol. Based on the Technical committee recommendation the firm has submitted a representation for reconsideration for the reduction of age group from 50 to 35. **3. Recommendation of the Technical Committee Meeting held on 31.05.2017:** After detailed deliberation, the committee did not recommend the proposal to reduce the age from 50 to 35 and called for represent the proposal before the committee.

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