MINUTES OF 33rd MEETING OF THE TECHNICAL COMMITTEE HELD ON 20.05.2016 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. Raju Titus Chacko, Prof. & Head, Dept. of Medical Oncology, CMC, Vellore	Member
3.	Dr. Yash Paul Sharma, Prof. & Head, Department of Cardiology, PGIMER, Chandigarh.	Member
4.	Dr. Kamlakar Tripathi, Professor, Department of Medicine, Banaras Hindu University, Varanasi.	Member
5.	Dr. Nandini Kumar, Dr. TMA Pai Endowment Chair, Manipal University, Manipal.	Member

From CDSCO:

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

The Chairman welcomed the members of the Committee for the 33rd meeting. Thereafter, the Committee discussed the clinical trial proposals and other agenda one after another as under:

The Committee deliberated 17 cases related to recommendation for approval of clinical trials. Out of these 17 cases, 06 cases were related to clinical trials of NCEs, 05 cases were related to global clinical trials (GCT) and remaining 06 cases were related to clinical trials for approval of New Drugs, FDC and Biologicals.

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

The Committee evaluated 06 proposals 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 all 06 proposals of NCEs. The recommendations of the Committee are enclosed at **Annexure-I.**

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

The Committee evaluated 05 proposals related to global clinical trials. After detailed deliberations, the Committee recommended approval for 04 proposals of clinical trials, and referred one proposal to the SEC-Ophthalmology for reexamination. 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 06 proposals of other than GCT/clinical trial of NCEs. After detailed deliberations, the Committee recommended approval for 05 proposals, and has not recommended approval for one proposal. The recommendation of the Committee are enclosed at **Annexure-III.**

Thus, the Committee recommended approval for 15 out of 17 cases of clinical trial proposals, sought clarification on 01 and has not recommended for approval of one proposal.

4. **Waiver of Clinical Trial in Indian population for approval of New Drugs which have already been approved outside India.**

04 proposals were placed before the Committee for consideration of permission for manufacture/ import for marketing in the country with waiver of local clinical trial. After detailed deliberations, the committee recommended waiver of clinical trials for 03 proposals and has not recommended 01 proposal. The details of recommendations of the Committee along with recommendation of the SEC are annexed as **Annexure-IV.**

The meeting ended with vote of thanks to the Chair.

Annexure-I

List of 06 cases of clinical trial of NCEs along with their evaluations and recommendations of the Technical Committee in its 33rd Meeting.

Proposal No	Details of the proposal	Assessment of the Proposal *vis –a vis* specified Parameters	1. Recommendation of the Subject Expert Committee (SEC)/IND Committee 2. Recommendation of the Technical Committee
1.	**Name of the Drug:** NNC0195-0092 - novel long-acting human growth hormone (hGH) **Date of Application:** 21/Dec/2015 **Protocol No:** NN8640-4172 **Phase of the trial:** II **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	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drug from preclinical pharmacology, repeat dose toxicity, genotoxicity, reproductive toxicity and two phase I clinical studies justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** The purpose of the study is to evaluate the efficacy of multiple dose regimen of once weekly NNC0195-0092 after 26 weeks of treatment in growth hormone treatment naïve prepubertal children with growth hormone deficiency compared to once daily growth hormone administration (Norditropin® FlexPro®). **Unmet Medical Need in the country:** The test drug may provide alternate treatment option in children with growth hormone deficiency.	**1. Recommendation of the SEC (Endocrinology)** held on **05-04-2016** After detailed deliberation the committee recommended the conduct of the study with the following conditions- 1. High dose of glucocorticoids in children should be defined. (Dr. Rajesh Khadgawat did not participate in deliberation and decision making) **SEC Expert List:** **1.** Dr. Rajesh Khadgawat, Associate Professor, Dept. Of Endocrinology, AIIMS, New Delhi-29 **2.** Dr. Rajesh Rajput, Senior Professor & Head Dept. Of Endocrinology, PGIMS, Medical Road, Rohtak-124001. **3.** Dr. B Gupta, Dept. Of Medicine, NDMC & Hindu Rao Hospital, New Delhi. **4.** Dr. Y. K Gupta, Professor & Head Dept. Of

	Name of the Manufacturer: Novo Nordisk A/S, Novo Allé, DK-2880, Bagsværd, Denmark **Title:** A randomised, multinational, active-controlled,(open-labelled), dose finding, (double-blinded), parallel group trial investigating efficacy and safety of once-weekly NNC0195-0092 treatment compared to daily growth hormone treatment (Norditropin® FlexPro®) in growth hormone treatment naïve pre-pubertal children with growth hormone deficiency.		Pharmacology, AIIMS, New Delhi. **2.Recommendation of the Technical Committee:** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for the approval of the study.
2.	**Name of the Drug:** **MEDI4736** (Immunoglobulin G1, anti-(human CD antigen CD274) (human monoclonal MEDI4736 heavy chain) **Tremelimumab** (Human monoclonal antibody from the immunoglobulin (Ig)G2a subclass) **Date of Application:** 22/Jan/2016	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical safety pharmacology and toxicology studies including repeat dose toxicity, reproductive toxicity and phase I, II clinical studies justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** The primary objective of the study is to assess the efficacy of MEDI4736 + Tremelimumab combination therapy compared to standard of care in terms of Progression Free Survival (PFS)	**1. Recommendation of the SEC (Oncology) held on 07-04-2016** After detailed deliberation the Committee recommended the conduct of the study (Protocol version 01). In view of the potential toxicities of combining two immunotherapeutic monoclonal antibodies, the following safeguards were recommended: 1. Comprehensive training of Investigators especially

	Protocol No: D419LC00001 **Phase of the trial:** III **Name of the Applicant:** Astra Zenenca Pharma India Ltd., Block N1, 12th Floor, Manyata Embassy Business park Rachenahalli, Outer Ring Road, Bangalore – 560045, Karnataka, India **Name of the Sponsor:** AstraZeneca AB, 151 85 Sodertalje, Sweden **Name of the Manufacturer:** **<u>MEDI4736</u>** Cook Pharmica LLC, 1300 South Patterson Drive Bloomington, IN 47403 United States **<u>Tremelimumab</u>** Boehringer Ingelheim Pharma GmbH & Co KG (BIP) Birkendorfer Strasse 65 88397 Biberach/Riss Germany **Title:** A Phase III Randomized, Open-label, Multi-center,	and Overall Survival (OS). **Unmet Medical Need in the country:** The test drug may potentially provide alternative treatment option for patients with Recurrent or Metastatic Squamous Cell Head and Neck Cancer.	with regards to immunological toxicities must be provided. 2. Patients/attendants should be provided with instant electronic communication devices to ensure prompt adverse event management. **(Dr. Hemant Malhotra did not participate in deliberation and decision making)** **SEC Expert List:** 1. Dr. Sameer Bakshi, Professor, Dept. of Medical Oncology, AIIMS, New Delhi. 2. Dr. Hemant Malhotra, Head, Division of Medical Oncology, SMS Medical College, Jaipur. 3. Dr. C. K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. 4. Dr. (Big) Ajay Sharma, Professor, Dept. of Hematology, Army Hospital (Research & Referral), Dhaula Kuan, New Delhi-110010. 5. Dr. H.P Pati, Dept. of Oncology, AIIMS, New Delhi. 6. Dr. D. S Arya, Prof., Dept. of Pharmacology, AIIMS, New Delhi. 7. Dr. Raju Titus Chacko, Professor & Head, Dept. of Medical Oncology, Christian Medical, College, Vellore-632004. 8. Dr. V Anand, HOD, Dept. of Vascular Surgery, Army hospital, New Delhi.

	Global Study of MEDI4736 Alone or in Combination with Tremelimumab versus Standard of Care in the Treatment of First-line Recurrent or Metastatic Squamous Cell Head and Neck Cancer Patients.		9. Dr. Anurag Srivastava, Prof & Head Dept. of Surgical Disciplines, AIIMS, New Delhi **2. Recommendation of the Technical Committee** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for the approval of the study.
3.	**Name of the Drug: MEDI4736** (Immunoglobulin G1, anti-(human CD antigen CD274) (human monoclonal MEDI4736 heavy chain) **Tremelimumab** (Human monoclonal antibody from the immunoglobulin (Ig)G2a subclass) **Date of Application:** 21/Oct/2015 **Protocol No:** D419AC00003 **Phase of the trial:** III **Name of the Applicant:** Astra Zenenca Pharma India Ltd., Block N1, 12th Floor, Manyata Embassy Business park Rachenahalli, Outer Ring Road, Bangalore – 560045,	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drug from preclinical safety pharmacology and toxicology studies including repeat dose toxicity, reproductive toxicity and phase I, II clinical studies justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** The primary objective of the study is to assess the efficacy of MEDI4736 + Tremelimumab combination therapy compared to standard of care in terms of overall survival in patients with Non-Small Cell Lung Cancer (NSCLC). **Unmet Medical Need in the country:** The test drug may potentially provide alternate treatment option in patients with advanced or metastatic Non-Small Cell Lung Cancer (NSCLC).	**1.Recommendation of the SEC (Oncology)** held on **23-02-2016** After detailed deliberation the committee recommended conduct of the study as per submitted protocol. The committee has concerns about toxicity of two immunotherapeutic monoclonal antibodies as first line treatment in NSCLC and recommended instant electronic communication between subjects and study sites to ensure prompt adverse event management. **(Dr. C. K. Bose and Dr. Hemant Malhotra did not participate in decision making).** **SEC Expert List:** 1. Dr. Sameer Bakshi, professor, Dept. of Medical Oncology, AIIMS, New Delhi. 2. Dr. Hemant Malhotra, Head, Division of Medical Oncology, SMS Medical

	Karnataka, India. **Name of the Sponsor:** AstraZeneca AB, 151 85 Sodertalje, Sweden **Name of the Manufacturer:** **<u>MEDI4736</u>** Cook Pharmica LLC 1300 South Patterson Drive Bloomington, IN 47403 United States **<u>Tremelimumab</u>** Boehringer Ingelheim Pharma GmbH & Co KG (BIP) Birkendorfer Strasse 6588397 Biberach/Riss Germany **Title:** A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 in Combination with Tremelimumab Therapy Versus Standard of Care Platinum-Based Chemotherapy in First-Line Treatment of Patients with Advanced or Metastatic Non-Small-Cell Lung Cancer (NSCLC)		College, Jaipur. 3. Dr. C. K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. 4. Dr. (Big) Ajay Sharma, Professor, Dept. of Hematology, Army Hospital (Research & Referral), Dhaula Kuan, New Delhi-110010. 5. Dr. Renu Saxena, Prof. & Head AIIMS, Ansari Nagar Delhi. 6. Dr. D.S. Arya, 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 for the approval of the study.

	(NEPTUNE)		
4.	**Name of the Drug:** INC280 (Capmatinib) **Date of Application:** 20/Jan/2016 **Protocol No:** CINC280B2201 **Phase of the trial:** II **Name of the Applicant:** Novartis Healthcare Private Limited, Dr. Annie Besant Road, Worli Mumbai - 400 018. **Name of the Sponsor:** Novartis Healthcare Private Limited, Dr. Annie Besant Road, Worli Mumbai - 400 018. **Name of the Manufacturer:** Novartis Pharma AG Lichtstrasse 35 CH-4056 Basel, Switzerland **Title:** Phase II, open-label, multicenter trial with oral cMET inhibitor INC280 alone and in combination with erlotinib versus platinum/pemetrexed in adult patients with EGFR mutated,	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drug from preclinical toxicity studies including single dose, repeat dose, genotoxicity, reproductive toxicity and phase I clinical study justify the conduct of this study. **Innovation vis-à-vis Existing Therapeutic Option:** The purpose of the study is to compare the antitumor activity of INC280 alone, and INC280 in combination with erlotinib, vs platinum with pemetrexed, as measured by Progression Free Survival (PFS) per investigator's assessment. **Unmet Medical Need in the country:** The test drug may potentially provide alternate option for the treatment in adult patients with EGFR mutated, cMET amplified, locally advanced/metastatic non-small cell lung cancer (NSCLC) with acquired resistance to prior EGFR tyrosine kinase inhibitor.	**1.Recommendation of the SEC (Oncology)** held on **07-04-2016** After detailed deliberation, the Committee recommended conduct of the trial as proposed by the firm with the following additional condition: As the phase I study has not been done in India and PK /PD data of the new molecule (INC280) is not available in Indian patients, the firm should conduct additional PK/PD studies in the enrolled patients in India who are on the Investigational product arm (INC280). **SEC Expert List:** 1. Dr. Sameer Bakshi, Professor, Dept. of Medical Oncology, AIIMS, New Delhi. 2. Dr. Hemant Malhotra, Head , Division of Medical Oncology, SMS Medical College, Jaipur. 3. Dr. C. K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. 4. Dr. (Big) Ajay Sharma, Professor, Dept. of Hematology, Army Hospital (Research & Referral), Dhaula Kuan,

	cMET-amplified, locally advanced/ metastatic non-small cell lung cancer (NSCLC) with acquired resistance to prior EGFR tyrosine kinase inhibitor (EGFR TKI)		New Delhi-110010. 5. Dr. H.P Pati, Dept. of Oncology, AIIMS, New Delhi. 6. Dr. D. S Arya, Prof., Dept. of Pharmacology, AIIMS, New Delhi. 7. Dr. Raju Titus Chacko, Professor & Head, Dept. of Medical Oncology, Christian Medical, College, Vvellore-632004. 8. Dr. V Anand, HOD, Dept. of Vascular Surgery, Army hospital, New Delhi. 9. Dr. Anurag Srivastava, Prof & Head Dept. of Surgical Disciplines, AIIMS, New Delhi. **2.Recommendation of the Technical Committee** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for the approval of the study.
5.	**Name of the Drug:** GS-5745 is a humanized monoclonal antibody (mAb). **Date of Application:** 02/March/2016 **Protocol No:** GS-US-326-1100 **Phase of the trial:II/III** **Name of the Applicant:** KlinEra	**Risk vs Benefit to the patients:** The safety profile of the test drug from various preclinical toxicity studies including repeat dose toxicity, reproductive studies and phase I clinical study justifies the conduction of the trial. **Innovation vis-a-vis against existing therapy:** The purpose of the study is to evaluate the safety and efficacy of GS-5745 in subjects with moderately to severe active Ulcerative Colitis. **Unmet need:** The test drugs may	**1. Recommendation of the SEC (Gastro) held on 19-04-201** After detailed deliberation the committee recommended the conduct of the study. **SEC Expert List:** 1. Dr. Nihar Ranjan Dash, Additonal Professor, Dept. of GI Surgery, AIIM, New Delhi-110029 2. Dr. A. Saraya Bhatia, Professor, Dept. of

	Corporation India 801, Neelkanth Corporate Park, Near Vidyavihar Station, Vidyavihar West, Mumbai 400 086: T: +91-22 25091470 **Name of the Sponsor:** Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA **Name of the Manufacturer:** Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA **Title** A Combined Phase 2/3, Double-Blind, Randomized, Placebo-Controlled, Induction and Maintenance Study Evaluating the Safety and Efficacy of GS-5745 in Subjects with Moderately to Severely Active Ulcerative Colitis.	provide alternate treatment option for subjects with moderately to severe active Ulcerative Colitis not responding clinically to at least one drug of the regimen	Gastroenterology AIIMS, New Delhi-29 3. Dr. Shobna Bhatia, Professor, Dept. of Gastroenterology & Hepatology Seth GS Medical College and KEM Hospital, Parel, Mumbai-400012 4. Dr. Rakhi Maiwal, Professor, Institute of Liver and Biliary Science, D-1, Vasant Kunj, New Delhi-10 5. Dr. Rakesh Aggarwal, Professor of Gastroenterology, SGPGI, Luncknow. 6. Dr. Jyotsna Bhargava, Professor, Dept. of Pharmacplogy, SMS Medical College, Jaipur **2.Recommendation of the Technical Committee** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for the approval of the study.
6.	**Name of the Drug:** QAW039 is a competitive reversible antagonist at the human CRTh2 receptor. **Date of Application:**	**Risk versus benefit to the patients-** The safety profile of the test drug from various pre clinical toxicities including single dose, repeat dose, genotoxicity and clinical phase I, II studies justify the conduct of the study.	**1. Recommendation of the SEC (Pulmonary) held on 29-03-2016** After detailed deliberation the committee recommend the conduct of the study subject to the following

	20/Oct/2015 **Protocol No:** CQAW039A2314 **Phase of the trial: III** **Name of the Applicant:** Novartis Healthcare Private Limited, Sandoz House, Dr. Annie Besant Road, Worli, Mumbai - 400 018. **Name of the Sponsor:** Novartis Healthcare Private Limited, Sandoz House, Dr. Annie Besant Road, Worli, Mumbai - 400 018. **Name of the Manufacturer:** Novartis Pharma AG Lichtstrasse 35 CH-4056 Basel, Switzerland **Title:** A 52-week, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of QAW039 when added to existing asthma therapy in patients with uncontrolled severe asthma.	**Innovation vis-a-vis existing therapeutic option** The purpose of study is to assess the efficacy and safety of QAW039 when added to existing asthma therapy in patients with uncontrolled severe asthma. **Unmet need in the country-** The test drug may be an alternative treatment option in patients with uncontrolled severe asthma.	conditions; 1. All the preclinical data should be submitted as per the requirements of the Sch Y and the justification for the non performance of the carcinogenicity study must be explained. 2. Patient with eosinophilic lung disorder through appropriate laboratory assessment must be excluded. **SEC Expert List:** 1. Dr. Subodh Kumar, Assistant Professor, AIIMS Rishikesh, Dehradun. 2. Dr. Sushant H. Meshram Professor, Govt. Medical College & Hospital, Nagpur. 3. Dr. J.C. Suri, Professor, VMMC & Sadurjung Hospital, New delhi. 4. Dr. Shalini Chawala, Professor, Dept. Pharmacology, MAMC, New Delhi. **2.Recommendation of the Technical Committee** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for the approval of the study.

Annexure-II

List of 05 case of Clinical Trial proposal of GCT along with evaluations and recommendations of the Technical Committee in 33rd Meeting.

Proposal No.	Details of the proposal	Assessment of the Proposal *vis – a vis* specified Parameters	Recommendation 1. Subject Expert Committee 2. Technical Committee
1.	**Name of the Drug:** Faster Acting Insulin Aspart (FIAsp) **Date of Application:** 21/Aug/2015 **Protocol No:** NN1218-4131 **Phase of the trial:** 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, Novo Allé DK-2880, Bagsværd, Denmark **Title:** Efficacy and Safety of Faster-acting Insulin Aspart compared to NovoRapid® both in combination with Insulin	**Assessment of Risk vs. Benefit to the patients:** In light of the fact that the Fast Acting Insulin Aspart is already approved and marketed in India, the safety profiles of the test drugs justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** The purpose of the study is to confirm efficacy in terms of glycaemic control of treatment with mealtime fasteracting insulin aspart in combination with insulin degludec in adults with type 1 diabetes mellitus. . **Unmet Medical Need in the country:** The test drug may provide better treatment option in subjects with type 1 diabetes.	**1. Recommendation of the SEC (Endocrinology) held on 05-04-2016:** After detailed deliberation the Committee recommended the conduct of the study with the revised protocol. (Protocol Amendment no. 01 Version 4). **(Dr. Rajesh Rajput did not participate in deliberation and decision making).** **SEC Expert List:** 1. Dr. Rajesh Khadgawat, Associate Professor, Dept. Of Endocrinology, AIIMS, New Delhi-29 2. Dr. Rajesh Rajput, Senior Professor & Head Dept. Of Endocrinology, PGIMS, Medical Road, Rohtak-124001. 3. Dr. B Gupta, Dept. Of Medicine, NDMC & hindu Rao Hospital, New Delhi. 4. Dr. Y. K Gupta, Professor & Head Dept. Of Pharmacology, AIIMS, New Delhi. **2.Recommendation of the Technical Committee** After detailed deliberation, the Committee agreed with the

	Degludec in Adults with Type 1 Diabetes		recommendation of the SEC and recommended for the approval of the study.
2.	**Name of the Drug:** Ticagrelor and Acetyl Salicylic Acid **Date of Application:** 21/Dec/2015 **Protocol No:** ISSBRIL0345 **Phase of the trial:** IV **Name of the Applicant:** Mr. Saleem, Operation-Manager IProcess Clinical Marketing (Pvt) Ltd, Malik's Building, 2nd Floor, No 29, Hospital Road, Bangalore - 560051 **Name of the Sponsor:** Icahn School of Medical at Mount Sinai **Name of the Manufacturer:** Astra Zeneca, USA for Ticagrelor and Pharma Science Inc. for Aspirin, Canada **Title:** TWILIGHT-Ticagrelor with Aspirin or Alone in High Risk Patients After Coronary Intervention	**Assessment of Risk vs. Benefit to the patients:** In light of the fact that the test drugs are old drugs and marketed in India, the safety profile of the test drugs justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** The purpose of the study is to determine the impact of antiplatelet monotherapy with ticagrelor alone versus DAPT with ticagrelor plus aspirin for 12 months in reducing clinically relevant bleeding among high risk patients undergoing PCI who have completed a 3- months course of aspirin plus ticagrelor. **Unmet Medical Need in the country:** The test drugs may provide alternate treatment option in high risk patients after coronary intervention.	**1. Recommendation of the SEC (Cardiology) held on 12-04-2016:** After detailed deliberation the committee recommended the approval of the protocol in its presented form. The committee noted that one PI has been proposed to conduct the trial at two sites which is not acceptable. **SEC Expert List:** 1. Dr. P.R. Gupta Professor of Cardiology, Institute of Medical Sciences, Varanasi, UP 2. Dr. Shyam Sunder Kothari, Prof. Dept. of Cardiology, AIIMS, New delhi. 3. Dr. Lalit Kumar Gupta, Professor, Dept. of Pharmacology, LHMC, New Delhi. 4. Dr. Sandeep Bansal HOD, Dept. of Cardiovascular, VMMC & Safdurjung Hospital, New delhi. 5. Dr. S. K aggrawal, Professor & Head of the dept., Dept. of Nephrology, AIIMS, New Delhi. 6. Dr. A.H.Ansari, Assistant Professor, Vardhman Mahavir Medical College, New Delhi

			2.Recommendation of the Technical Committee: The committee noted that both the drugs are individually approved for marketing in the country and are also concomitantly used in clinical practice. Therefore after detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for approval of the study.
3.	**Name of the Drug:** Triamcinolone Acetonide Injectable Suspension (CLS-TA) **Date of Application:** 05/Jan/2016 **Protocol No:** CLS1001-301 **Phase of the trial:** III **Name of the Applicant:** Excel Life Sciences Pvt. Ltd. D-62, 1st Floor, Sector-2, Noida, Uttar Pradesh 201301, India **Name of the Sponsor:** Clearside Biomedical, Inc.1220 Old Alpharetta Rd., Suite 300 Alpharetta, GA 30005, USA **Name of the Manufacturer:** Aviro Biopharmaceuticals, LLC 4 Chrysler Irvine, CA 92618 FDA Registration	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical safety pharmacology and toxicology studies including Single dose toxicity, repeat dose toxicity, reproductive toxicity, Carcinogenicity and phase I/II, II clinical studies justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** The primary objective of the study is to demonstrate the efficacy of CLS-TA as shown by the change from baseline in BCVA (Best corrected Visual Acuity) in subjects with macular edema associated with noninfectious uveitis. **Unmet Medical Need in the country:** The test drug may potentially provide alternative treatment of subjects with macular edema associated with	**1. Recommendation of the SEC (Ophthalmology) held on 21-04-2016** After detailed deliberation the Committee has recommended the conduct of the trial subject to the following condition: Patients of known glaucoma, in spite of controlled IOP on medication and high myopes (more than -6D) should be excluded from the study. **SEC Expert List:** 1. Dr. Renuka Srinivasan Professor JIPMER, Dhanvantri Nagar, Pondicherry-605006. 2. Dr. Rohit Saxena Associate, Prof. AIIMS, New delhi-110029. 3. Dr. R.K. Jain, Professor, Lady Hardinge Medical College, New Delhi.. 4. Dr. Vandana Roy, Professor, Department of Pharmacology, MAMC, New Delhi-302004.

	Number: 3007526273 **Title: PEACHTREE**: A **P**hase 3, Randomiz**E**d, M**A**sked, **C**ontrolled Clinical Trial to Study the Safety and Efficacy of Triamcinolone Acetonide Injectable Suspension (CLS-TA) for t**H**e **TR**eatment of Subjects with Macular **E**dema associated with Non-Infectious Uv**E**itis.	Non- Infectious Uveitis.	5. Dr. Arjun Ahuja Professor & Head Seth G.S. Medical College & KEM Hospital, Mumbai. **2.Recommendation of the Technical Committee** The committee noted that a sham injection is given in the control arm. It is an invasive procedure in patients with macular odema with some risks. The members of the committee referred to the SEC for re-examination of the proposal with regards to the following points: **1.** Is the comparative arm with a sham procedure required in this protocol **2.** If required, what are the likely risks/ benefits to subjects randomized to the sham injection/ control arm of the study? **3.** What risk mitigation strategies are in place to protect patients in the sham injection arm **4.** Adverse events have been reported in the Phase I/II study, one of them serious besides the ocular pain in some. Due to invasive nature of sham procedure in control group which could also lead to severe adverse events, SEC may re-examine to see if the design can be modified to exclude this arm for risk minimization management? Proposal will be examined after receiving the recommendation.

4.	**Name of the Drug:** QMF149 (Indacaterol acetate/Mometasone furoate) **Date of Application:** 06/Nov/2015 **Protocol No:** CQVM149B2301 **Phase of the trial:** III **Name of the Applicant:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli, Mumbai - 400 018. **Name of the Sponsor:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli, Mumbai - 400 018. **Name of the Manufacturer:** Novartis Pharma AG Lichtstrasse 35, CH-4056 Basel, Switzerland **Title:** "A multi-center, randomized, 52 week treatment, doubleblind, triple-dummy, parallel-group study to assess the efficacy and safety of QMF149 compared with mometasone furoate in patients with asthma."	**Risk versus benefit to the patients-** The safety profile of the test drug from pre clinical toxicities including 13-week inhalation toxicity studies and clinical phase I, II studies justify the conduct of the study. **Innovation vis-a-vis existing therapeutic option** The purpose of study is to assess the efficacy and safety of QMF149 compared with Mometasone Furoate in patients with asthma. **Unmet need in the country-** The test drug may be an alternative treatment for asthma patients.	**1. Recommendation of the SEC (Pulmonary) held on 29-03-2016** After detailed deliberation the committee recommended the conduct of the study in its presented form **SEC Expert List:** 1. Dr. Subodh Kumar, Assistant Professor, AIIMS Rishikesh, Dehradun. 2. Dr. Sushant H. Meshram Professor, Govt. Medical College & Hospital, Nagpur. 3. Dr. J.C. Suri, Professor, VMMC & Sadurjung Hospital, New delhi. 4. Dr. Shalini Chawala, Professor, Dept. Pharmacology, MAMC, New Delhi **2.Recommendation of the Technical Committee** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for the approval of the study.
5.	**Name of the Drug:** QVM149 is a fixed-dose	**Risk versus benefit to the patients** In light of the fact	**1. Recommendation of the SEC (Pulmonary) held on**

	combination of Indacaterol acetate (inhaled LABA), Glycopyrronium Bromide (inhaled LAMA), and Mometasone Furoate (MF, ICS) **Date of Application**: 17 December 2015 **Protocol No:** CQVM149B2302 **Phase of the trial:** III **Name of the Applicant:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli, Mumbai - 400 018. **Name of the Sponsor:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli, Mumbai - 400 018. **Name of the Manufacturer:** Novartis Pharma AG Lichtstrasse 35 CH-4056 Basel, Switzerland **Title:** A multicenter, randomized, 52-week, double-blind, parallel group, active controlled study to compare the efficacy and safety of QVM149 with QMF149 in patients with asthma	that the test drug as single agent is approved and marketed in India, the safety profile of these single drug justify the conduct of the study. **Innovation vis-a-vis existing therapeutic option** The primary objective is to demonstrate the superiority of either QVM 149 150/50/80 µg o.d. to QMF 149 150/160 µg o.d or QVM149 150/50/160 µg o.d. to QMF149 150/320 µg o.d. all delivered via concept 1 in terms of trough FEV1 after 26 weeks of treatment in patients with asthma. **Unmet need in the country-** The test drug may be an alternative treatment for asthma patients.	**29-03-2016.** After detailed deliberation the committee recommended the conduct of the study in its presented form. **SEC Expert List:** 1. Dr. Subodh Kumar, Assistant Professor, AIIMS Rishikesh, Dehradun. 2. Dr. Sushant H. Meshram Professor, Govt. Medical College & Hospital, Nagpur. 3. Dr. J.C. Suri, Professor, VMMC & Sadurjung Hospital, New delhi. 4. Dr. Shalini Chawala, Professor, Dept. Pharmacology, MAMC, New Delhi **2.Recommendation of the Technical Committee** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for the approval of the study.

Annexure III

List of 06 cases of clinical trial proposals other than GCT/NCEs along with evaluations and recommendations of 33rd Meeting.

S.No.	Name of the Drug	Firm Name	Recommendations: 1. Subject Expert Committee (SEC) 2. Technical Committee
1.	Measles-Rubella (MR)Vaccine, Live, Attenuated (Freeze-dried) I.P **Protocol No.** BECT036/MRV-PII/III/CTP-01 **Phase of Trial:** Phase II/III Trial **Name of the Sponsor:** Biological E. Limited, 18/1&3, Azamabad,Hyderabad – 500 020 Telangana, India **Protocol Title:** A Phase II/III, Randomised, Comparative, Multicentre Study to Evaluate the Safety and Immunogenicity of Biological E's Live, Attenuated Measles-Rubella (MR) Vaccine in 9-12 month old Healthy Infants	M/s Biological E. Limited	**1. Recommendation of the SEC dated 12.01.2016:** The committee deliberated the proposal and recommended to conduct the study subject to following amendments in the protocol: 1. The comparator vaccine shall be changed to an approved MR vaccine 2. Visit 1 and 2 to be combined 3. Omit routine lab testing for HCV, HIV and Hepatitis B. **SEC Expert List:** 1) Dr. A.P. Dubey, Prof & Head, Pediatrics, MAMC, New Delhi 2) Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi 3) Dr. P.P. Gupta, Professor & Head of Department of Pharmacology, AIIMS, Patna 4) Dr. Savita Verma, Professor, Pharmacology, PGIMS, Rohtak 5) Dr. Veena Verma, Professor, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. **2.Recommendation of the Technical Committee:** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for the approval of the study.
2.	Autologous Adult Live Cultured Buccal Epithelial cells in	M/s Regenerative Medical Services Pvt. Ltd.	**1. Recommendation of the SEC dated 14.07.2015:** After detailed deliberation and reviewing

	DMEM Suspension. **Protocol No.** RMS/UR/US/1502 **Phase of Trial:** Phase IIb **Name of the Sponsor:** Regenerative Medical Services Pvt. Ltd. 2-ABC, Acme Plaza, Opp. Big Cinema, Andheri-Kurla Road, Andheri (E), Mumbai-400059 Tel No: 022-37330300 Fax No: 022-28390556 **Protocol Title:** A Prospective, Open-label, Multicentric Study to Assess the Safety and Efficacy of Autologous Adult Live Cultured Buccal Epithelial Cells (Uregrow™) in Subjects with Urethral Stricture		the data presented by M/s RMS Pvt. Ltd, Mumbai, the committee recommended conducting Phase IIb clinical trial instead of Phase III clinical trial of Autologous Adult Live Cultured Buccal Epithelial cells (MUKOCELL) in subjects with urethral strictures. Accordingly, the firm should submit the revised protocol to the office of DCG (I). Accordingly, the firm has submitted the revised protocol as per the recommendation of CBBTDEC. **SEC Expert List:** **1.** Dr. Soumya Swaminathan, Secretary & Director General, ICMR, New Delhi - 110029 **2.** Prof. N. K. Mehra, Dr C.G. Pandit National Chair and Former Dean (Research) and Ex- Head Dept. of Transplant Immunology & Immunogentics, AIIMS, New Delhi. **3.** Prof. D. Balasubramanian, Director (Research), L.V. Prasad Eye Institute Banajara Hills, Hyderabad 500034. **4.** Dr. Rita Mulherkar, FNASc., ACTREC, Tata Memorial Centre, Navi Mumbai, 410210. **2.Recommendation of the Technical Committee** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for the approval of the study.
3.	Repaglinide and Voglibose Tablets 0.5mg + 0.2mg, 0.5mg + 0.3mg, 1mg + 0.2mg & 1mg + 0.3mg **Phase of Trial:** Clinical Trial: **Phase**	M/s Torrent Pharmaceuticals Limited	**1. Recommendation of the SEC dated 26.02.2016:** The firm presented the revised CT/BE study protocols as per the suggestions made by the SEC on 1.9.2015. Committee recommended the proposed study (CT/BE) with suggestion that the sentence "in situation of low (<70mg/dl) glucose

	III Comparative Bioavailability Study: **Phase I** **Name of the Sponsor:** Torrent Pharmaceuticals Limited Research Centre, Bhat- 382 428 Dist. Gandhinagar, (Gujarat) India **Protocol Title: Clinical Trial:** A Multicentric, Randomized, Open Label, Comparative, Parallel assignment Clinical Trial to Evaluate the Safety and Efficacy of Fixed Dose Combinations (FDC) of Repaglinide (0.5mg / 1mg) + Voglibose (0.2mg / 0.3mg) tablets Versus Repaglinide (0.5mg / 1mg) tablets in Patients with Type 2 Diabetes Mellitus. **Comparative Bioavailability Study:** An Open Label, Randomized, 2-Period, 2-Treatment, 2-Sequence, Crossover, Single-Dose Comparative Bioavailability Study of FDC of Repaglinide 1mg and Voglibose		level, patient will be instructed to take two consecutive glucometers reading at the interval of 15 minutes" should be replaced with the sentence that "in situation of low (<70mg/dl) glucose level, patient should be instructed to take necessary corrective steps as to be defined clearly in the protocol to prevent hypoglycemia. **SEC Expert List:** 1. Dr. C. D. Tripathi, Professor & Head Department of Pharmacology, VMMC, New Delhi. 2. Dr. Rajesh Khadgawat, Professor, Dept. of Endocrinology, AIIMS, New Delhi-110029. 3. Dr. Richa Dewan, Department of medicine, MAMC New Delhi. 4. Dr. Rajesh Rajput, Senior Professor & Head Department Endocrinology, PGIMS, Medical Road, Rohtak-124001. **2.Recommendation of the Technical Committee** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for the approval of the study, as both Repaglinide and Voglibose have been used for the treatment of post prandial hyperglycemia simultaneously in the same individuals.

	0.3mg tablet (Test, Torrent Pharmaceuticals Ltd., India) *versus* Prandin® tablet containing Repaglinide 1mg (Reference, Novo Nordisk Inc., Princeton, NJ 08540, USA) in Healthy Human Volunteers		
4.	Pneumococcal Polysaccharide Conjugate Vaccine (10-valent, Adsorbed) [NuCoVac® vaccine] with 3+1 vaccination schedule **Phase of Trial:** Phase III **Name of the Sponsor:** Panacea Biotec Limited B-1 Extn/G-3, Mohan Co-op. Indl. Estate, Mathura Road, New Delhi-110044 Ph No.: +91-11-41679000 Extn. 2491 Fax: +91-11-41578085 **Protocol Title:** A Randomized, Open labeled, Multicenter, Phase III study to assess and compare the immunogenicity and reactogenicity of 10-valent pneumococcal, with preservative polysaccharide conjugate vaccine	M/s Panacea Biotec Limited	**1. Recommendation of the SEC dated 18.02.2016:** The committee deliberated the proposal in detail and recommended for conduct of proposed studies with the following conditions: 1) The firm shall submit separate Form 44 and TR-6 challan for the proposed two study protocols. 2) To reconsider the amount of blood to be withdrawn. Action Taken: Accordingly, the Firm has submitted separate Form44 and TR-6 Challan. However, the protocol to be amended with respect to amount of blood withdrawn and will be submitted shortly. **SEC Expert List:** **1.** Dr. A. P. Dubey, Prof. & Head, Pediatrics, MAMC, New Delhi **2.** Dr. Ramesh aggrawal, Add. Professor, Vaccine & Neonatology, AIIMS, New Delhi **3.** Dr. P. P. Gupta, Prof. & Head, Department of Pharmacology, AIIMS, Patna **4.** Dr. B. L. Sherwal, Prof. Microbiology & Director, RIMS, Ranchi **5.** Dr. Savita Verma, Prof. Pharmacology, PGIMS, Rohtak

	(adsorbed) NuCoVac® of Panacea Biotec Ltd. with SYNFLORIX® of GlaxoSmithKline Ltd in healthy Infants. (3+1 vaccination schedule)		6. Dr. Rahul Narang, Prof. Microbiology, MGIMS, Warud, Wardha, MH 7. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology, MAMC, New Delhi **2.Recommendation of the Technical Committee** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended for the approval of the study.
5.	Pneumococcal Polysaccharide Conjugate Vaccine (10-valent, Adsorbed) [NuCoVac® vaccine] with 2+1 vaccination schedule **Phase of Trail:** Phase III **Name of the Sponsor:** Panacea Biotec Limited, B-1 Extn/G-3, Mohan Co-op. Indl. Estate, Mathura Road, New Delhi-110044 Ph No.: +91-11-41679000 Extn. 2491 Fax: +91-11-41578085 **Protocol Title:** A Randomized, Open labeled, Multicenter, Phase III study to assess and compare the immunogenicity and reactogenicity of 10-valent pneumococcal, with preservative polysaccharide	M/s Panacea Biotec Limited	**1. Recommendation of the SEC dated 21.03.2016:** The committee deliberated the proposal in detail and recommended for conduct of proposed studies with the following conditions: 1) The firm shall submit separate Form 44 and TR-6 challan for the proposed two study protocols. 2) To reconsider the amount of blood to be withdrawn. **Action Taken**: The Firm has submitted separate Form44 and TR-6 Challan. However, the protocol to be amended with respect to amount of blood withdrawn and will be submitted shortly. **SEC Expert List:** 1. Dr. A. P. Dubey, Prof. & Head, Pediatrics, MAMC, New Delhi 2. Dr. Ramesh aggrawal, Add. Professor, Vaccine & Neonatology, AIIMS, New Delhi 3. Dr. P. P. Gupta, Prof. & Head, Department of Pharmacology, AIIMS, Patna 4. Dr. B. L. Sherwal, Prof. Microbiology & Director, RIMS, Ranchi 5. Dr. Savita Verma, Prof. Pharmacology, PGIMS, Rohtak 6. Dr. Rahul Narang, Prof. Microbiology, MGIMS, Warud, Wardha, MH

	conjugate vaccine (adsorbed) NuCoVac® of Panacea Biotec Ltd. with SYNFLORIX® of GlaxoSmithKline Ltd in healthy Infants. (2+1 vaccination schedule)		7. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology, MAMC, New Delhi **2. Recommendation of the Technical Committee** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended approval for the conduct of the study.
6.	Azelnidipine 16mg and Metoprolol Succinate extended release 50mg Capsules **Phase of Trial:** Phase III **Name of the Sponsor:** Glenmark Pharmaceutical Ltd. Andheri (E), Mumbai-400 099, India **Protocol Title:** A parallel group, double-blind, randomized, controlled multicenter study to assess the efficacy and safety of Fixed Dose combination of Azelnidipine and Metoprolol (Glenmark Pharmaceuticals Ltd) in comparison to monotherapy of Azelnidipine and Metoprolol ER given alone in patients of essential hypertension.	M/s Glenmark Pharmaceutical Ltd.	**1. Recommendation of the SEC dated 29.03.2016 :** The firm presented the revised protocol after incorporating the recommendation made by this Committee in its earlier meeting. The Committee deliberated the proposal in detail and observed that all the necessary changes have been made and therefore, recommended grant of permission for conduct of clinical trial as per the presented protocol. **SEC Expert List:** 1. Dr. Shashi Mohan Sharma, Professor, Department of Cardiology, SMS Medical College J.L.N. Marg, Jaipur 2. Dr. Sandeep Bansal, HOD, VMMC, Safdarjung Hospital, New Delhi 3. Dr. A.H.Ansari, CMO, VMCC, New Delhi 4. Dr. Shalini Chawla, Professor, Pharmacology, MAMC, Delhi The proposal was deliberated in the Technical Committee **Recommendation of the Technical Committee on 26.04.2016** After detailed deliberations, the Committee requested to place before it the approved indication for Azelnidipine and

			also clarification whether monotherapy is intended to be used in mild, moderate or severe hypertension for taking decision in this regard. **2. Recommendation of the Technical Committee :** The committee noted that the drug Azelnidipine is not approved for marketing in the country as a monotherapy. Further it is also noted that available safety and efficacy data in public domain is limited and Phase II clinical trials is being conducted in the country. Therefore after detailed deliberation, the Committee did not recommend the proposed Phase III clinical trial.

Recommendations of the 04 cases of Clinical trial waiver in Indian populations of 33rd meeting:

Sr. no.	Drug Name	Name of the Firm	Indication	1. Recommendations of the Technical Committee 2. Recommendations of the SEC.
1.	Sodium Tetradecyl Sulphate injection 0.2% and 0.5% w/v **Date of Application:** 19.03.2015 **Regulatory status in India:** In India, 1.0% and 3 % was register for import on 1/9/2003 to M/s Medicon **Regulatory status in other countries:** in UK & Australia	M/s Pushpanjali medi India Pvt. Ltd	For the treatment of uncomplicated primary varicose veins, recurrent or residual varicose veins following surgery, reticular veins, venules and spider veins of the lower extremities that show simple dilation. Fibrovein is indicated in adults.	**1. Recommendation of the SEC (Oncology and Haematology) on 07.04.2016:** The committee recommended for permission to import Sodium Tetradecyl Sulphate injection 0.2% and 0.5% w/v for the indication "For the treatment of uncomplicated primary varicose veins, recurrent or residual varicose veins following surgery, reticular veins, venules and spider veins of the lower extremities that show simple dilation." The additional lower strengths will assist clinicians to treat a wider array of patients with CVI and would lessen complications. **SEC Expert List:** 1.Dr. Sameer Bakshi, Professor, Dept. of Medical Oncology, AIIMS, New Delhi. 2.Dr. Hemant Malhotra, Head, Division of Medical Oncology, SMS Medical College, Jaipur 3.Dr. C. K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata 4.Dr. (Brig.) Ajay Sharma, Professor, Dept of Hematology,

				Army Hospital (Research & Referral), DhaulaKuan, New Delhi, Delhi 110010 5. Dr. H.P Pati, Department of Oncology, AIIMS, New Delhi. 6. Dr. D S Arya, Prof., Dept. of Pharmacology, AIIMS ,New Delhi. 7. Dr. Raju Titus Chacko, Professor & Head, Department of Medical Oncology, Christian Medical, College, Vellore-632004 8. Dr. V Anand, HOD, Department of Vascular surgery, Army Hospital, New Delhi. 9. Dr. Anurag Srivastava , Prof & Head Department of surgical Disciplines, AIIMS, New Delhi. **2. Recommendations of the Technical Committee:** The committee noted that there is no clinical data available on the drug in Indian patients. Therefore after detailed deliberations, the Committee did not recommend for local clinical trial waiver.
2.	Eltrombopag olamine tablets 25mg/50mg (additional indication) **Date of Application:** M/s Novartis Healthcare Pvt. Ltd (Application date: 23.03.2016, initial application was made by M/s	M/s Novartis Healthcare Pvt. Ltd	Treatment of cytopenias in patients with severe aplastic anemia (SAA) who have had an insufficient response to immunosuppressive therapy	**1. Recommendation of the SEC Oncology & Haematology) held on 07.04.2016:** The firm presented the clinical trial data on use of Eltrombopag Olamine in the treatment of cytopenias in patients with severe aplastic anaemia (SAA) who have had an insufficient response to immunosuppressive therapy. The drug is already approved

	GSK dated: 01.05.2015). **Regulatory status in India:** Approved on 19.10.2010 **Regulatory status in other countries:** EU, USA & Australia			for the same in USA and EU, and also has Orphan drug status. After detailed deliberation the committee recommended for the proposed additional indication (the treatment of cytopenias in patients with severe aplastic anemia (SAA) who have had an insufficient response to immunosuppressive therapy). **SEC Expert List:** **1.** Dr. Sameer Bakshi, Professor, Dept. of Medical Oncology, AIIMS, New Delhi. **2.** Dr. Hemant Malhotra, Head, Division of Medical Oncology, SMS Medical College, Jaipur **3.** Dr. C. K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata **4.** Dr. (Brig.) Ajay Sharma, Professor, Dept of Hematology, Army Hospital (Research & Referral), DhaulaKuan, New Delhi, Delhi 110010 **5.** Dr. H.P Pati, Department of Oncology, AIIMS, New Delhi. **6.** Dr. D S Arya, Prof., Dept. of Pharmacology, AIIMS, New Delhi. **7.** Dr. Raju Titus Chacko, Professor & Head, Department of Medical Oncology, Christian Medical, College, Vellore- 632004 **8.** Dr. V Anand, HOD, Department of Vascular surgery, Army Hospital, New Delhi. **9.** Dr. Anurag Srivastava, Prof & Head, Department of surgical

				Disciplines, AIIMS, New Delhi. **2. Recommendations of the Technical Committee:** After detailed deliberations, the Committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial.
3.	Bortezomib for injection 3.5mg/vial and 1mg/vial powder for injection (additional indication) **Date of Application:** 18.12.2015 **Regulatory status in India:** Approved on 19.05.2005 **Regulatory status in other countries:** EU, USA &Australia	M/s Johnson & Johnson Pvt. Ltd	For the treatment of patients with mantle cell lymphoma	**1. Recommendation of the SEC (Oncology) held on 15.03.2016:** The committee noted that the drug is being marketed in India since 2005 and for indication "for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy" drug is used since 2007. Based on the data from pivotal study conducted globally since 2008, the committee recommended approval of additional indication i.e. treatment of patients with mantle cell lymphoma. **SEC Expert List:** 1. Dr. Sameer Bakshi, Professor, Dept. of Medical Oncology, AIIMS, New Delhi 2. Dr. Sanjay Kumar Singh, , Dept. of Medical Oncology, Gajara Raja Medical College, Veer Savarkar Marg,

				Gwalior 3. Dr. S.D. Banavali, Head, Dept. of Medical Oncology, Tata Memorial Hospital, Parel, Mumbai-400 012 4. Dr. Geeta Narayanan, Professor, Dept. of Medical Oncology, Regional Cancer Centre, Trivandrum- 695011 5. Dr.Urmila Thatte, Prof.and Head, Dept. of Clinical Pharmacology, SGS Medical College, KEM Hospital, Mumbai.-400012 **2. Recommendations of the Technical Committee:** After detailed deliberations, the Committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial.
4.	Anagrelide 0.5 mg Capsules **Date of Application:** 15-10-2015 **Regulatory status in India:** Not approved in India **Regulatory status in other countries:** USA & UK	M/s. Cipla Ltd.	Indicated for the treatment of patients with thrombocythemia, secondary to myeloproliferative neoplasms, to reduce the elevated platelet count and the risk of thrombosis and to ameliorate associated symptoms, including thrombo-haemorrhagic events	**1. Recommendation of the SEC (Oncology & Hematology) held on 07.04.2016** The Committee deliberated the proposal in detail and recommended for local clinical trial waiver with the conditions i) that the drug should be used as a second line therapy "for the reduction of elevated platelet counts in at risk essential thrombocythemia patients who are intolerant to their current therapy or whose platelet counts are not reduced to an acceptable level by their

				current therapy" as approved in EU. ii) The BE study should be conducted in statistically significant number of subjects as per the protocol presented before the Committee. **SEC Expert List:** **1.** Dr. Sameer Bakshi, Assistant Professor, AIIMS, New Delhi **2.** Dr. Hemant Malhotra, Head, Division of Medical Oncology, SMS Medical College, Jaipur **3.** Dr. C. K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata **4.** Dr. (Brig.) Ajay Sharma, Professor & Senior Advisor, Army Hospital (Research & Referral), New Delhi **5.** Dr. Raju Titus Chacko, Professor & Head, Department of Medical Oncology, Christian Medical, College, Vellore **6.** Dr. H.P. Pati, AIIMS, Ansari Nagar Delhi **7.** Dr. D S Arya Professor, Department of Pharmacology AIIMS, New Delhi. **8.** Dr. V Anand, HOD, Dept of Vascular Surgery, Army Hospital, New Delhi. **9.** Dr. Anurag Srivastava, Prof & Head, Department of surgical discipline, AIIMS,

				New Delhi. **2. Recommendations of the Technical Committee:** After detailed deliberations, the Committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial.

****