# Permission given for clinical trial (r-DNA based Drug Product) (2014)

| S.NO. | FileNo. | Name of Firm | Name of Drug Product | Title of The Study | Date of Approval |
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| 1 | 4-211/Dr.Reddy/13-BD | Dr. Reddy Laboratories | Anti CD20 Monoclonal antibody | "a double blind, randomized, parallel group study comparing the pharmacokinetics, pharmacodynamics, safety, efficacy and immunogenicity of three anti-CD20 monoclonal antibodies in patients with moderate to severe active, serotopositive rheumatoid arthritis with an inadequate response to methotrexate based therapy" vide protocol no. RI-01-003 amendment 1 dated 18 Feb 213 (version 2.0) | 04-Jun-2014- |
| 2 | 39/PMS/ROCHE/13-BD | Roche Products (I) Pvt. Ltd | Rituximab | "an open label, prospective, post marketing study to evaluate the safety, tolerability and efficacy of Rituximab with glucocorticoids in adult patients with wegener's granulomatosis (Granulamotosis with polyangitis-GPA) or microscopic polyangitis" vide protocol no. ML28550, version no 3.0 dated 20/05/2013 | 10-Jan-2014 |
| 3 | 4-198/LUPIN/13-BD | Lupin Limited (Biotech Division) | Etanercept | "An open-label,balanced,randomized ,single dose,two treatment,two sequence two period crossover comparative pharmacokinetics-pharmacodynamics study of Etanercept 50mg solution for injection in prefilled syringes for subcutaenous | 30-Jan-14 |

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| | | | | injection,manufactured by M/s Lupin Ltd,India and Enbrel (Etanercept 50mg) solution for injection in prefilled syringes for subcutaneous Injection by M/s John Wyeth and Brother ltd.,UK in healthy,Adult,Human male subjects" Vide protocol no. LBC-P-020-13, version 01, dated 15-nmay-2013 | |
| 4 | 46/Phase-IV/GSK/13-BD | GlaskoSmithKline Pharmaceuticals Ltd. | Panitumumab | "An Open-label,Multicentre Non-Comparative,Phase IV study of Panitumumab to characterize its safety,Tolerability and Activity in India subjects with previously treated Wild-type RAS (KRAS and NRAS),Metastatic colorectal Cancer" vide study no. 200092; protocol no. 2013N159455_00 dated 14/06/2013 | 10-Feb-2014 |
| 5 | 4-178/CADILA/13-BD | Cadila Healthcare Ltd. | Trastuzumab | "<br><br>A prospective,randomized,Multi-centric clinical study to comapre Trastuzumab (Test product,Zydus) with Trastuzumab (Reference product,Roche/Genetech) in patients with metastatic Breast Cancer" vide protocol no. TRA.12.001.02.1, version no.2.1, dated 18/02/2014. | 10-march-2014 |
| 6 | 12/VCR-14/PINF/84-BD/VIRCHOW/11-SUPPL. | Virchow Biotech | PEG-Interferon (peg | "Efficacy and safety of PEG-innterferon (peg interferon alfa-2b) for | 09-May- |

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| | CHANGES-V | Pvt. Ltd. | interferon alfa-2b) | the treatment of chronic hepatitis C- an open label multicentre study in India" vide protocol No:. VB021/2012 version 1 dated 20-march- 2012 | 2014 |
| 7 | 33/phase IV/Novarts/12-BD | Novartis Healthcare Pvt. Ltd. | Ranibizumab | "Unveil DME : A multi-centre, open-label, observational study to evaluate the efficacy and safety of intravitreal injecton (IVI) of Lucentis (Ranibizumab) in patients with visual impairment due to Diabetic Macular Edema ( DME) " vide protocol no. CRFB002DIN03 final version 1.0 dated 08-may -2013 | 04-July-2014 |
| 8 | 48/PMS/NOVONORDISK/13-BD | Novo Nordisk India Pvt Ltd | Insulin Degludec | "post marketing study protocol-insulin Degludec for the treatment of the diabetes mellitus in adult" vide protocol no NN1250-4129, Version 1.0 dated 29/07/2013 | 14-Jul-2014 |
| 9 | 4-192/BIOCON/13-BD | Biocon Ltd. | BMab-100 (Avastin) | "A double blind,randomized,Active controlled, parallel design,comparative ,efficacy,safety and immunogenicity study of Bmab-100 and Avastin® both in combination with XELOX chemotherapy in patients with Metastatic colorectal cancer"vide protocol no. BM100-CC-03-I-01, Version 2.0, dated 5th Dec 2013. | 7-Aug-14 |
| 10 | 45/Phase IV/BharatSerum/13-BD | Bharat Serums & vaccines Ltd. | Foligraft(recombinant Human Follicle Stimulating | "Immunogenicity safety study of Foligraf (Recombinant human Follicle Stimulating Hormone) in subjects | 10-Aug-2014 |

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| | | | Hormone) | undergoing assisted Reproductive Techniques"vide protocol no. BSV/r-FSH-IMG-2012 Version 01 dated 22/04/2013 | |
| 11 | 34/phase IV/Novarts/12-BD | Novartis Healthcare Pvt. Ltd. | Ranibizumab | "An observational ,multi centre open label study assessing the efficacy and safety of Lucentis (Ranibizumab intravitreal injection) in patients with visual impairment due to Macular Edema secondary to retinal vein occlusion (RVO)" vide protocol no. CRFB002EIN01 version 1.0 dated 14-Jun -2012 | 11-Aug-2014 |
| 12 | 4-112/RELIANCE/11-BD | Reliance Life Science Pvt. Ltd. | Pegfilgrastim | "Prospective,multicentric,open label,two arm, parallel,group,active control,randomized, comparative clinical study to evaluate efficacy and safety of R-TPR-029/Neulasta® when given subcutaneously in patients with chemotherapy induced Netropenia" vide protocol no.: RLS/TP/2011/01; version 5.0, dated 24th march 2014. | 21-Aug-2014 |
| 13 | 4/223/RELIANCE/13-BD | Reliance life sciences pvt ltd | Cetuximab | "permission to carryout a phase III clinical trial entitled prospective multi centric randomized open-label two arm parallel group active control comparative clinical study to evaluate efficacy safety and pharmacokinetics of r-033/erbitux in patients with recurrent locoregional or metastatic sqamous cell carcinoma of the head | 21-Aug-14 |

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| | | | | and neck vide protocol rls/onc/2013/04 versio 2.0 dated 24-mar-2014". | |
| 14 | 4-193/ADOCIA/13-BD | Virchow Biotech Pvt Ltd. | Biochaperon PDGF-BB | "A phase III, Multicentre, randomized,parallel group, double blinded, and control group clinical trial to assess the effectiveness of Biochaperon PDGF-BB in the treatment of chronic diabetic foot ulcer". Vide protocol no. BC1-CT4, version- V1, dated 23rd july 2013. | 22-Aug-2014 |
| 15 | 38/PMS/ROCHE/13-BD | Roche Products (I) Pvt. Ltd | Bevacizumab | "an Indian multicentre open label prospective post marketing surveillance study of bevacizumab in the front line management of advance/metastatic epithelial ovarian cancer, fallopian tube cancer o primary peritoneal cancer in real life clinical practice" vide protocol no. ML28446, version on 1.0 dated 26/11/2012 | 22-Aug-2014 |
| 16 | 4-224/lupin/13-BD | M/s Lupin Ltd., | Rituximab | "Permission to carryout out Phase I PK/PD clinical trial tilted "A Randomized, Open Label, Parallel Group, Active Controlled Pharmacokinetic,pharmacodynamic Study with Single Dose of Lupin's Rituximab and Roche's Rituximab in Patients with Rheumatoid Arthritis" vide Protocol No. LRP/RTX/2013/002, Version No. 1.0 | 26-Aug-14 |

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| | | | | dated 18th Dec 2013" | |
| 17 | 4-221/INTAS/13-BD | Intas Pharmaceuticals Ltd. | Bevacizumab | "A prospective, Comparative Open label,randomized,Multicentric, Phase III study to compare the safety and efficacy of Bevacizumab of intas Pharmaceuticals ltd against Avastin® in patients with unresectable or metastatic Non-Squamous Non-Small cell lung Cancer"Vide Protocol No.476-13, Version No.02, Dated 10.03.2014 | 27-Aug-14 |
| 18 | 4-113/RELIANCE/11-BD | Reliance life science pvt. Ltd | Recombinant human growth hormone inj. (R-TPR-029 | "prospective, multicenter, randomized, open label, two arm, parallel group, active control, comparative clinical study to evaluate efficacy, safety, pharmacodynamics and pharmacokinetics of R-TPR-007/Norditropin (Nordilet) in growth hormone- deficient children" vide protocol no. RLS/TP/2012/02, version 3.0 dated 10-Jul-2014 | 03-Sept-2014 |