

(Managed by : K.G. Kothari Memorial Trust)

Regd. Office: Jawahar Lal Nehru Marg, JAIPUR-302 017 INDIA Tel.: 0141-2700107, 2702120, 2702899 Fax: 0141-2702021 E-mail: cancer@datainfosys.net, bmchrc@hotmail.com Web: www.bmchrc.org

Total Completed Clinical Trials In Research Department, BMCHRC Jaipur

S. No.	Completed clinical trials	Investigator
1.	Protocol #: PERT.21.001 Protocol Entitled: A Prospective, Randomized, Multicenter, Comparative, Double-blind, Parallel study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Immunogenicity of Test Pertuzumab (ZRC-3277, Cadila Healthcare Ltd.,) with Reference Pertuzumab (Perjeta®, Genentech Inc.,) in Previously Untreated Patients with HER2 Positive Metastatic Breast Cancer.	Dr. Tarachand Gupta
2.	Study Code: : CBYL719CIN02 Protocol Title: SPEAR(Study of PIK3CA mutations and Effectiveness and tolerability outcomes of Alpelisib in Real-world) A descriptive study of PIK3CA mutations and outcomes with Alpelisib in patients with HR-positive and HER2-negative advanced breast cancer (ABC)/ metastatic breast cancer (MBC) in India.	Dr. Deepak Gupta
3.	Protocol Title: "Treatment patterns and clinical outcomes among Indian patients receiving Palbociclib combinations for HR+/HER2- Advanced/Metastatic breast cancer in real world settings.	Dr. Ajay Bapna
4.	A prospective, multicenter, open label single arm Phase IV clinical trial to assess safety of ImbruvicaTM (Ibrutinib capsules 140 mg) in Indian patients with chronic lymphocytic leukemia or mantle cell lymphoma who have received at least one prior therapy or chronic lymphocytic leukemia with 17p deletion (Ibrutinib)	Dr. Upendra Sharma
5.	Ref No. "An open-label, multicenter, Phase IIIb study to assess the safety and efficacy of 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 CLEE011A2404.	Dr. Ajay Bapna
6.	Protocol LEE011A2207 Ref: A phase II, multicenter, randomized, open-label study to evaluate the safety and efficacy of 400 mg of ribociclib in combination with non-steroidal aromatase inhibitors for the treatment of pre- and postmenopausal women with hormone receptor-positive, HER2-negative advanced breast cancer who received no prior therapy for advanced disease	Dr. Ajay Bapna
7.	CLDK378AIN01 A real-world, open-label, multi-center, prospective, non-interventional (observational) study to evaluate the effectiveness and tolerability of ceritinib in Indian patients with ALK positive metastatic non-small cell lung cancer who have progressed or are intolerant to crizotinib.	Dr. Pawan Agarwal
8.	Ref:A randomized, double-blind, placebo-controlled, phase III study evaluating the efficacy and safety of pembrolizumab plus platinum-based doublet chemotherapy with or without canakinumab as first line therapy for locally advanced or metastatic non-squamous and squamous non-small cell lung cancer subjects (CANOPY-1).	Dr. Aseem K Samar
9.	Protocol CA209-887: Safety Study of Nivolumab for Selected Advanced Malignancies in India	Dr. Aseem K Samar
10.	Protocol ALN-AT3SC-003: ATLAS-INH: A Phase 3 Study to Evaluate the Efficacy and Safety of Fitusiran in Patients with Hemophilia A or B, with Inhibitory Antibodies to Factor VIII or IX	Dr. Upendra Sharma
11.	Ref: ALN-AT3SC-004 A Phase 3 Study to Evaluate the Efficacy and Safety of Fitusiran in Patients With Hemophilia A or B, Without Inhibitory Antibodies to Factor VIII or IX.	Dr. Upendra Sharma



(Managed by : K.G. Kothari Memorial Trust)

12.	A Prospective, Randomized, Multicenter, Comparative, Open label, Parallel study to evaluate the Efficacy, Safety and Pharmacokinetics of Test-Trastuzumab Emtansine (ZRC3256;Cadila Reference-Trastuzumab Emtansine (Kadcyla®, Roche Products (India) Pvt. Ltd.) in HER2- Positive Metastatic Breast Cancer Patients. (Breast Cancer)	Dr. Ajay Bapna
13.	Protocol No.: -"A randomised, double-blind, parallel group, equivalence, multicenter phase III trial to compare the efficacy, safety,pharmacokinetics and immunogenicity of HD204 to Avastin® in patients with metastatic or recurrent non-squamous non-small cell lung cancer" SAMSON-II (Lung Cancer)	Dr. L.M. Sharma
14.	CLDK378A2301 - A phase III multicenter, randomized study of oral LDK378 versus standard chemotherapy in previously untreated adult patients with ALK rearranged (ALK-positive), stage IIIB or IV, non-squamous non-small cell lung cancer (Phase-III) (Alk Lung Cancer)	Dr. L.M. Sharma
15.	Study Title: Clinical Outcomes of CLL and MCL patients treated with Ibrutinib: An observational retrospective medical chart review from India	Dr. Naresh Somani
16.	Ref: Protocol: 0063-17_ A global, multicenter, three arms, open-label randomized study to evaluate the efficacy and safety of Nanosomal Docetaxel Lipid Suspension compared to Taxotere® (Docetaxel Injection Concentrate) in triple-negative breast cancer patients with locally advanced or metastatic breast cancer after failure to prior chemotherapy.	Dr. Naresh Somani
17.	Reference: A Two-Part, Open-Label, Randomized, Phase II/III Study of Dinutuximab and Irinotecan versus Irinotecan for Second Line Treatment of Subjects with Relapsed or Refractory Small Cell Lung Cancer Protocol Number: DIV-SCLC-301	Dr. Naresh Somani
18.	Reference: Project # MYL-1402O-3001 :Multicentre, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First -line treatment of Patient with Stage IV Non-Squamous Non-Small Cell Lung Cancer. (Phase –III)	Dr. Naresh Somani
19.	Protocol Title:CPZP034AIC04 Parachute: Pazopanib Real-world Assessment of Clinical effectiveness and safety in patients who have Undergone treatment in different settings in advanced renal cell carcinoma; a prospective, non-interventional, observation study (Phase-IV)	Dr. Naresh Somani
20.	"Post-Mastectomy Radiation Therapy in High Risk, Node Negative women with Early Breast Cancer (PMRT-NNBC) " (Investigator Initiative)	Dr. Nidhi Patni
21.	CT-P6 3.2- A Phase 3, Double-Blind, Randomized, Parallel-Group, Active-Controlled Study to Compare the Efficacy and Safety of CT-P6 and Herceptin as Neoadjuvant and Adjuvant Treatment in Patients with HER2-Positive Early Breast Cancer (Phase – III)	Dr. Lalit Mohan Sharma
22.	<u>Protocol No CT-P10 3.3-</u> A Phase 1/3, Randomised, Parallel-Group, Active-Controlled, Double-Blind Study to Demonstrate Equivalence of Pharmacokinetics and Noninferiority of Efficacy for CT-P10 in Comparison With Rituxan, Each Administered in Combination With Cyclophosphamide, Vincristine, and Prednisone (CVP) in Patients With Advanced Follicular Lymphoma.(Phase –III)	Dr. Lalit Mohan Sharma
23.	A Phase II, Multicenter, Randomized, open Label, and Parallel Group Study to Evaluate Safety and Efficacy of endoxifen as First- Line Therapy in Women with Metastatic Estrogen Receptor Positive Breast Cancer (Phase-II)	Dr. Pawan Agarwal
24.		Dr. Naresh Somani



(Managed by : K.G. Kothari Memorial Trust)

25.	"A pilot study (Phase II Trial) of Nivolumab With Pemetrexed as Palliative	Dr. Naresh
	Chemotherapy in Patients With Advanced Non-Small-Cell Lung Cancer With Activating	Somani
	Epidermal Growth Factor Receptor Mutations positive patients	
26.	"A pilot study (Phase II Trial) of Gefitinib/Afatinib With Pemetrexed as First-Line	Dr. Naresh
	Therapy in Patients With Advanced Non-squamous Non-Small-Cell Lung Cancer With	Somani
	Activating Epidermal Growth Factor Receptor Mutations positive patients.	
27.	CBKM120H2201- Phase II multicenter randomized, double blind, placebo	Dr. Naresh
	controlledstudy assessing the efficacy of buparlisib (BKM120) plus paclitaxel vs.	Somani
	placebo plus paclitaxel in patients with platinum pre-treated recurrent or metastatic head	
	and neck squamous cell carcinoma.	
28.	1200.131 LUX- Head & Neck 2: A randomized, double blind, placebo- controlled, phase	Dr Naresh
	III study to evaluate the efficacy and safety of afatinib (BIBW 2992) as adjuvant therapy	Somani
	after chemo-radiotherapy in primary unresected patients with stage III, IVa or IVb loco-	
	regionally advanced head and neck squamous cell carcinoma.	
29.	IPI – 145- 21: A Phase 2, Randomized Study of Duvelisib Administered in Combination	Dr Naresh
	with Rituximab vs R-CHOP in Subjects with Relapsed/Refractory Follicular Lymphoma.	Somani
30.	A randomized, controlled, double-blind Phase III trial to compare the efficacy, safety and	Dr. Naresh
	pharmacokinetics of GP2013 plus cyclophosphamide, vincristine, prednisone vs.	Somani
	MabThera® plus cyclophosphamide, vincristine, prednisone, followed by GP2013 or	
	MabThera® maintenance therapy in patients with previously untreated, advanced stage	
	follicular lymphoma	
31.	An open label, Randomized, Parallel Group , Multi-centre Study to Compare	Dr. Naresh
	ZOLADEX TM 10.8 mg Given Every 12 Weeks with ZOLADEX 3.6 mg Given Every 4	Somani
	Weeks in Pre-menopausal Women with Oestrogen Receptor positive Advanced Breast	
	Cancer	
32.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy,	Dr. Naresh
32.		Dr. Naresh Somani
	Study Title : A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer.	Somani
32.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or	Somani Dr. Naresh
	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene	Somani
	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or	Somani Dr. Naresh
	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label,	Somani Dr. Naresh Somani Dr. Naresh
33.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus	Somani Dr. Naresh Somani
33.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving	Somani Dr. Naresh Somani Dr. Naresh
33.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010	Dr. Naresh Somani Dr. Naresh Somani
33.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebo-	Somani Dr. Naresh Somani Dr. Naresh
33.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebocontrolled clinical trial investigating the efficacy and safety of Somatuline Depot	Dr. Naresh Somani Dr. Naresh Somani
33.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebocontrolled clinical trial investigating the efficacy and safety of Somatuline Depot (lanreotide) Injection in the treatment of carcinoid syndrome	Dr. Naresh Somani Dr. Naresh Somani Dr. Naresh Somani Dr. Naresh Somani
33.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebocontrolled clinical trial investigating the efficacy and safety of Somatuline Depot (lanreotide) Injection in the treatment of carcinoid syndrome "A Multi centre, open label, single arm, Phase IV, interventional study to evaluate the	Dr. Naresh Somani Dr. Naresh Somani Dr. Naresh Somani Dr. Naresh Somani Dr. Naresh
33.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebocontrolled clinical trial investigating the efficacy and safety of Somatuline Depot (lanreotide) Injection in the treatment of carcinoid syndrome "A Multi centre, open label, single arm, Phase IV, interventional study to evaluate the efficacty of Erlotinib (Tarceva®) following 4 cycles of platinum based chemotherapy in	Dr. Naresh Somani Dr. Naresh Somani Dr. Naresh Somani Dr. Naresh Somani
33.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebocontrolled clinical trial investigating the efficacy and safety of Somatuline Depot (lanreotide) Injection in the treatment of carcinoid syndrome "A Multi centre, open label, single arm, Phase IV, interventional study to evaluate the efficacty of Erlotinib (Tarceva®) following 4 cycles of platinum based chemotherapy in patients with locally advanced or metastatic non small cell lung cancer (NSCLC) who	Dr. Naresh Somani Dr. Naresh Somani Dr. Naresh Somani Dr. Naresh Somani Dr. Naresh
33.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebocontrolled clinical trial investigating the efficacy and safety of Somatuline Depot (lanreotide) Injection in the treatment of carcinoid syndrome "A Multi centre, open label, single arm, Phase IV, interventional study to evaluate the efficacty of Erlotinib (Tarceva®) following 4 cycles of platinum based chemotherapy in	Dr. Naresh Somani
33.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebocontrolled clinical trial investigating the efficacy and safety of Somatuline Depot (lanreotide) Injection in the treatment of carcinoid syndrome "A Multi centre, open label, single arm, Phase IV, interventional study to evaluate the efficacty of Erlotinib (Tarceva®) following 4 cycles of platinum based chemotherapy in patients with locally advanced or metastatic non small cell lung cancer (NSCLC) who have not experienced disease progression or unacceptable toxicity during Chemotherapy" Protocol I4T-MC-JVBA(c) (also known as IMCL CP12-1027[c]) A Randomized,	Dr. Naresh Somani Dr. Naresh
33. 34. 35.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebocontrolled clinical trial investigating the efficacy and safety of Somatuline Depot (lanreotide) Injection in the treatment of carcinoid syndrome "A Multi centre, open label, single arm, Phase IV, interventional study to evaluate the efficacty of Erlotinib (Tarceva®) following 4 cycles of platinum based chemotherapy in patients with locally advanced or metastatic non small cell lung cancer (NSCLC) who have not experienced disease progression or unacceptable toxicity during Chemotherapy" Protocol I4T-MC-JVBA(c) (also known as IMCL CP12-1027[c]) A Randomized, Double-Blind, Phase 3 Study of Docetaxel and Ramucirumab versus Docetaxel and	Dr. Naresh Somani
33. 34. 35.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebocontrolled clinical trial investigating the efficacy and safety of Somatuline Depot (lanreotide) Injection in the treatment of carcinoid syndrome "A Multi centre, open label, single arm, Phase IV, interventional study to evaluate the efficacty of Erlotinib (Tarceva®) following 4 cycles of platinum based chemotherapy in patients with locally advanced or metastatic non small cell lung cancer (NSCLC) who have not experienced disease progression or unacceptable toxicity during Chemotherapy" Protocol I4T-MC-JVBA(c) (also known as IMCL CP12-1027[c]) A Randomized,	Dr. Naresh Somani Dr. Naresh
33. 34. 35.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebocontrolled clinical trial investigating the efficacy and safety of Somatuline Depot (lanreotide) Injection in the treatment of carcinoid syndrome "A Multi centre, open label, single arm, Phase IV, interventional study to evaluate the efficacty of Erlotinib (Tarceva®) following 4 cycles of platinum based chemotherapy in patients with locally advanced or metastatic non small cell lung cancer (NSCLC) who have not experienced disease progression or unacceptable toxicity during Chemotherapy" Protocol I4T-MC-JVBA(c) (also known as IMCL CP12-1027[c]) A Randomized, Double-Blind, Phase 3 Study of Docetaxel and Ramucirumab versus Docetaxel and	Dr. Naresh Somani Dr. Naresh
33. 34. 35.	Study Title: A randomized, double-blind, parallel group, Phase III trial to compare the efficacy, safety, and immunogenicity of TX05 with Herceptin® in subjects with HER2 positive early breast cancer. Protocol: A Phase 3 Study of Erdafitinib Compared with Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations Protocol entitled "EPO-ANE-3010/Amendment INT-8: A Randomized Open-Label, Multicentre, Phase 3 study of Epoetin Alfa plus Standard Supportive Care versus Standard Supportive Care in Anemic Patients With Metastatic Breast Cancer Receiving First-Line Standard Chemotherapy". Protocol No. EPO-ANE-3010 Protocol No. 2-55-52030-730/TR321: Title" A double-blind, randomized placebo-controlled clinical trial investigating the efficacy and safety of Somatuline Depot (lanreotide) Injection in the treatment of carcinoid syndrome "A Multi centre, open label, single arm, Phase IV, interventional study to evaluate the efficacty of Erlotinib (Tarceva®) following 4 cycles of platinum based chemotherapy in patients with locally advanced or metastatic non small cell lung cancer (NSCLC) who have not experienced disease progression or unacceptable toxicity during Chemotherapy" Protocol I4T-MC-JVBA(c) (also known as IMCL CP12-1027[c]) A Randomized, Double-Blind, Phase 3 Study of Docetaxel and Ramucirumab versus Docetaxel and Placebo in the Treatment of Stage IV Non-Small Cell Lung Cancer Following Disease	Dr. Naresh Somani Dr. Naresh



(Managed by : K.G. Kothari Memorial Trust)

	Safety and Efficacy of BAL8557 versus a Caspofungin followed by Voriconazole	Somani
	Regimen in the Treatment of Candidemia and other Invasive Candida Infection"	
39.	Protocol No. BI-1200.98, titled "An open label, phase II trial of BIBW 2992 (Afatinib) in	Dr. Naresh
	patients with Metastatic HER2-overexpressing breast cancer failing HER2-targeted	Somani
	treatment in the neoadjuvant or adjuvant treatment setting"	
40.	Multicentre, randomised, double-blind, Phase III trial to investigate the efficacy and	Dr. Naresh
	safety of oral BIBF 1120 plus standard docetaxel therapy compared to placebo plus	Somani
	standard docetaxel therapy in patients with stage IIIB/IV or recurrent non small cell lung	
	cancer after failure of first line chemotherapy	
41.	An Open-Label, Multi-centre, Randomized, Active Controlled, Comparative, Phase III	Dr. Naresh
	Clinical Study to Assess Efficacy and Safety of Lupin's Filgrastim Versus Neupogen®	Somani
	as an Adjunct to Chemotherapy for Prevention of Neutropenia in Patients with Non-	
	My7eloid Malignancies.	
42.	An International, Multi- Center, Randomized, Double Blind Placebo Controlled Phase II	Dr. Naresh
	Study to Evaluate the safety and Efficacy of Lucanthone Administered as an Adjunct to	Somani
	Radiation and Temozolomide for Primary Therapy of Glioblastoma Multiforme	
43.	A Phase III Randomized Placebo Controlled, Clinical Trial to Study the safety and	Dr. Naresh
	Efficacy of V212 in Adult Patient with Solid Tumor or Hematologic Malignancy	Somani
44.	Protocol P1446-05/19/08: An Open Lable, Multicenter Phase 1 Study Of Selective	Dr. Naresh
	Cyclin Dependent Kinase Inhibitor P1446A-05 In Subjects With Advanced Refractory	Somani
	Malignacies (Hence Reffered To As 'SERENITY'	
45.	Protocol 276-00/31/08: An Open Label, Multicenter Phase/II Study Of Selective Cyclin	Dr. Naresh
	Dependent Kinase Inhibitor P276-00 In Combination With Radiation In Subjects With	Somani
	Recurrent And/ Or Locally Advanced Squamous Cell Carcinoma Of Head And Neck.	
46.	Axitinib (AG-013736) As Second Line Therapy For Metastatic Renal Cell Cancer: Axis	Dr. Naresh
	Trial Protocol No.: A4061032	Somani
47.	Safety and Efficacy of Recombinant Human Granulocyte-colony Stimulating Factor-	Dr. Naresh
	rhGCSF (ReliGrast TM or Neupogen®) in Patients with Chemotherapy Induced	Somani
	Neutropenia (Protocol No. : GMX-GCSF-CT001	
48.	A Phase III, Randomized, Double –Blind Study of Galiximab in combination with	Dr. Naresh
	Rituximab Compared with Rituximab in Combination with placebo for the Treatment of	
	Subjects with Relapsed or Refractory, Follicular Non- Hodgkin's Lymphoma. Study	
	Number: 114-NH-301.	
49.	A Multinational, Randomized, Double Blind Study, Comparing the Efficacy of	Dr. Naresh
	Aflibercept Once Every 2 weeks versus Placebo in Patients Treated with Gemcitabine for	Somani
	Metastatic Pancreatic Cancer. Protocol No. EFC – 10547	
50.	A Multicentre Randomized, Double Blind, Placebo-Controlled, Parallel Arm Study of	Dr. Naresh
	the Effect of Intravenous AVE0005 (VEGF Trap) Administered Every 2 Weeks in	Somani
	Advanced Ovarian Cancer Patients With Recurrent Symptomatic Malignant Ascites,	
	Protocol No. – EFC6125 (AVE0005A/3001)	
51.	A Pivotal Phase 3 Observer-Blind Randomized Clinical Trial of the Efficacy and Safety	Dr. Naresh
	of APF 530 Compared to Aloxi for the Prevention of Acute-Onset and Delayed-Onset	Somani
	Chemotherapy-Induced Nausea and Vomiting Following Administration of Moderately	
	or Highly Emetogenic Chemotherapy Regimens". Protocol No:C2006-01	
52.	A Phase 3b, Randomized, Open-Label Study of Bevacizumab (Avastin®) +	Dr. Naresh
	Temsirolimus (Torisel®) vs. Bevacizumab (Avastin®) + Interferon-Alfa (Roferon®) as	Somani
	First-Line Treatment in Subjects with Advanced Renal Cell Carcinoma (Wyeth Study)	
	<u> </u>	1



(Managed by : K.G. Kothari Memorial Trust)

53.	A Multicenter, Randomized, Double-Blind, Phase 3 Study Of Sunitinib In Metastatic	Dr. Naresh
	Colorectal Cancer Patients Receiving Irinotecan, 5-Fluorouracil And Leucovorin (Folfiri)	Soamni
	As Firstline Treatment. Protocol No A6181122	
54.	Phase III Randomized, Multi Center Study of Sunitinib Malate (SU 011248) or	Dr. Naresh
	Capecitabine in Subjects with Advanced Breast Cancer who failed both a taxane and an	Somani
	anthracycline chemotherapy regimen or failed with a taxane and for whom further	
	anthracycline therapy is not indicated. Study A6181107	
55.	An Open-Label Sunitinib Malate (Su011248) Continuation Protocol For Patients Who	Dr. Naresh
	Have Completed A Prior Sunitinib Study And Are Judged By The Investigator To Have	Somani
	The Potential To Benefit From Sunitinib Treatment. Study A6181114	
56.	A Two-Way Crossover Experimental Evaluation Of Relative Bioavailability Of Two	Dr. Naresh
	Formulations Of Temozolomide 250 Mg Capsules In Adult Human Male And/Or Female	Somani
	Patients Under Fasting Conditions Protocol No. – 141-06	
57.	International, Randomized, Open-label, phase 3 Trial of Paclitaxel / Carboplatin Plus Pf-	Dr. Naresh
	3512676 Versus Paclitaxel / Carboplatin Alone As First-Line Treatment Of Patients	Somani
	With Advanced Non-Small Cell Lung Cancer Protocol No A8501001	
58.	A Phase 3, Double-Blind, Placebo-Controlled Study of Maintenance Pemetrexed plus	Dr. Naresh
	Best Supportive Care versus Best Supportive Care Immediately Following Induction	Somani
	Treatment for Advanced Non-Small Cell Lung Cancer Protocol No H3E-MC-JMEN	~ 011.W111
59.	A Phase 2, Randomized, Double-masked, Placebo-controlled Study to Evaluate the	Dr. Naresh
55.	Efficacy of SNX-1012 in Reducing the Duration and Severity of Ulcerative Oral	Somani
	Mucositis in Patients Receiving Cytotoxic Chemotherapy for Breast or Lung Cancer	Somerin
	Protocol No. –SNX -1012- CLN2-006	
60.	A Multinational, Randomized, Double Blind Study, Comparing the Efficacy of	Dr. Naresh
00.	Aflibercept Once Every 2 weeks versus Placebo in Patients Treated with Gemcitabine for	Somani
	Metastatic Pancreatic Cancer. Protocol No. EFC – 10547	Somerin
61.	A Multicentre Randomized, Double Blind, Placebo-Controlled, Parallel Arm Study of	Dr. Naresh
01.	the Effect of Intravenous AVE0005 (VEGF Trap) Administered Every 2 Weeks in	Somani
	Advanced Ovarian Cancer Patients With Recurrent Symptomatic Malignant Ascites,	Somani
	Protocol No. – EFC6125 (AVE0005A/3001)	
62.	A Pivotal Phase 3 Observer-Blind Randomized Clinical Trial of the Efficacy and Safety	Dr Naresh
02.	of APF 530 Compared to Aloxi for the Prevention of Acute-Onset and Delayed-Onset	Somani
	Chemotherapy-Induced Nausea and Vomiting Following Administration of Moderately	Somani
	or Highly Emetogenic Chemotherapy Regimens". Protocol No:C2006-01	
63.	A Phase 3b, Randomized, Open-Label Study of Bevacizumab (Avastin®) +	Dr. Naresh
05.	Temsirolimus (Torisel®) vs. Bevacizumab (Avastin®) + Interferon-Alfa (Roferon®) as	Somani
	First-Line Treatment in Subjects with Advanced Renal Cell Carcinoma (Wyeth Study)	Somani
64.	A Multicenter, Randomized, Double-Blind, Phase 3 Study Of Sunitinib In Metastatic	Dr. Naresh
04.	Colorectal Cancer Patients Receiving Irinotecan, 5-Fluorouracil And Leucovorin (Folfiri)	Soamni
	As Firstline Treatment. Protocol No A6181122	Southin
65.	LUX-Lung 6: A randomized, open-label, phase III study of BIBW 2992 versus	Dr. Naresh
05.	chemotherapy as first-line treatment for patients with Stage IIIB or IV adenocarcinoma	Somani
	of the lung harbouring an EGFR activating mutation.	Somani
66	Protocol No: B7391003"A Phase 3 Randomized, Double-Blind Study of Pf-06439535	Dr. Lalit
66.	·	Mohan
	Plus Paclitaxel-Carboplatin and Bevacizumab Plus Paclitaxel-Carboplatin for the First-Line Treatment of Patients with Advanced Non Squamous Non Small Cell Lung Cancer	
67	Line Treatment of Patients with Advanced Non-Squamous Non-Small Cell Lung Cancer. Protocol No. J. 00070 IN 205 RO - Study Title - A Phosp III Study Of Vinflyning Physics	Sharma Dr. Lalit
67.	Protocol No. L00070 IN 305 B0 : Study Title : A Phase III Study Of Vinflunine Pluse	Dr. Lalit



(Managed by : K.G. Kothari Memorial Trust)

	E-mail: <u>cancer@datainfosys.net, bmchrc@hotmail.com</u> Web: <u>www.bmchrc</u>	
	Capecitabine Versus Capecitabine Alone In Apatients With Advance Breast Cancer	Mohan
	Previously Treated With Or Resistant To An Anthracycline And Who Are Taxane	Sharma
	Resistant	
68.	AYUSH QOL-2C as an adjuvant therapy for patients of Cancer under	Dr. Lalit
00.		Mohan
	chemotherapy/radiotherapy	
		Sharma
69.	FORTIS-M, LF-0207: A Phase 3, randomized, double-blind, placebo-controlled study of	Dr. Lalit
	oral talactoferrin in addition to best supportive care in patients with non-small cell lung	Mohan
	cancer who have failed two of more prior treatment regimens	Sharma
70.	Protocol number: 1200.42 "Phase III randomized trial of Study drug plus weekly	Dr. Lalit
,	paclitaxel versus Investigator's choice of chemotherapy following study drug	Mohan
	monotherapy in non-small cell lung cancer patients failing previous erlotinib or gefitinib	Sharma
	treatment	
71.	Protocol MORAb-003-004: A Randomized, Double-blind, Placebo-Controlled, Phase 3	Dr. Lalit
	Study to Assess the Efficacy and Safety of Weekly Farletuzumab (MORAb-003) in	Mohan
	Combination with Carboplatin and Taxane in Subjects with Platinum-sensitive Ovarian	Sharma
	Cancer in First Relapse.	
72		Dr. Lalit
72.	Phase II Clinical And Pharmacokinetic Trial of PM00104(Zalypsis ®)in Patients with	
	Advanced and/ or Metastatic Endometrial or Cervical Cancer Previously Treated with	Mohan
	One Line of Systemic Chemotherapy.	Sharma
73.	"A Phase IIb RCT of Neoadjuvant chemotherapy comparing Paclitaxel, ifosfamide and	Dr. Lalit
	Cisplatin with Paclitaxel, cisplatin and 5-FU in Patients with Locally Advanced Head	Mohan
	and Neck Cancer."	Sharma
74.	A Prospective, Open Label Study of ANASTRZOLE In Post-Menopausal Women With	Dr. Ajay
/	Hormone Sensitive Advanced Breast Cancer Protocol No	3 5
		Bapna
75.	A Randomized, Double-Blind, Parallel-group, Multicentre, Phase III Study Comparing	Dr. Ajay
	the Efficacy and Tolerability of Fulvestrant (FASLODEXTM) 500 mg with Fulvestrant	Bapna
	(FASLODEXTM) 250 mg in Postmenopausal Women with Oestrogen Receptor Positive	
	Advanced Breast Cancer Progressing or Relapsing	
76.	A randomized, double blind, placebo controlled, Phase 2 study of oral recombinant	Dr. Ajay
	human lactoferrin (rhLF) monotherapy in patients with locally advanced or metastatic	Bapna
	non-small cell lung cancer (NSCLC) who have failed 1 st or 2 nd line chemotherapy PNo.	Вирпи
	LF-0201	- · ·
77.	An Open label phase 2 study of oral recombinant human lactoferrin (rhLF) monotherapy	Dr. Ajay
	in patients with advanced or metastatic renal cell carcinoma (RCC). Protocol No. LF-	Bapna
	0202	
78.	A randomized, double blind, placebo controlled Phase 2 study of oral recombinant	Dr. Ajay
	human lactoferrin (rhLF) in combination with Carboplatin and Paclitaxel (C/P)	Bapna
	chemotherapy in patients with locally advanced or metastatic non-small cell lung cancer	
	(NSCLC) Protocol No. LF-0206	D D • • •
79.	CPO44/06/FCNS: A Multicentre, Double blind, Double dummy Two phase crossover	Dr. Pushplata
	study of Nasalfent (Fentanyl Citrate Nasal Spray) compared to Immediate Release	Gupta
	Morphine Sulphate Tablets in the treatment of Breakthrough Cancer Pain (BTCP) in	
	subjects taking Regular Opioid Therapy.	
80.	CP045/06/FCNS: An Open-Label Study Investigating Long-Term Safety and	Dr. Pushplata
00.	Tolerability of Nasalfent (Fentanyl Citrate Nasal Spray) in the Treatment of	Gupta
		Jupia
	Breakthrough Cancer Pain (BTCP) in Subjects Taking Regular Opioid Therapy	



(Managed by : K.G. Kothari Memorial Trust)

Regd. Office : Jawahar Lal Nehru Marg, JAIPUR-302 017 INDIA Tel. : 0141-2700107, 2702120, 2702899 Fax : 0141-2702021

E-mail: cancer@datainfosys.net, bmchrc@hotmail.com Web: www.bmchrc.org

81	GWCA01103: A two-part, placebo- controlled, study of the safety and efficacy of	Dr. Pushplata
	Sativex oromucosal spray (Sativex®; Nabiximols) as adjunctive therapy in relieving	Gupta
	uncontrolled persistent chronic pain in patients with advanced cancer, who have	
	inadequate analgesia even with optimized chronic opioid therapy.	
82.	GWCA0999: A multicenter, non-comparative, open-label extension study to assess the	Dr. Pushplata
	long term safety of Sativex oromucosal spray (Sativex®; Nabiximols) as adjunctive	Gupta
	therapy in patients with uncontrolled persistent chronic cancer related pain	
83.	Prospective, multi-centric, open label, two arm, parallel group, active control,	Dr. Pawan
	randomized, comparative clinical study to evaluate efficacy and safety of R-TPR-029	Agarwal
	/Neulasta® (Neulastim®) when given subcutaneously in patients with Chemotherapy	
	Induced Neutropenia (Protocol No.: RLS/TP/2011/01; Version 5.0, Dated: 24 Mar 2014)	
84.	BM100-CC-03-I-01 A Double Blind, Randomized, Active Controlled, Parallel Design,	Dr. Pawan
	Comparative PK, Efficacy, Safety and Immunogenicity Study of Bmab-100 and Avastin®,	Agarwal
	both in Combination with XELOX Chemotherapy in Patients with Metastatic Colorectal	
	Cancer	