

LIST OF CLINICAL TRIAL STUDIES CONDUCTED IN MTR



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Pivotal Studies

S.NO	MOLECULES	NO. OF SUBJECTS	INDICATIONS	SUBMISSION
1	Doxorubicin Injection	24 Patients	MULTIPLE MYELOMA	EU Submission
2	Doxorubicin Injection	24 Patients	OVARIAN CANCER	US FDA Submission
3	Capecitabine 500mg	44 Patients	CANCER PATIENTS 1. Ca.Breast 2. Ca.Rectum 3. Ca. Colon	EU Submission
4	Capecitabine 500mg	54 Patients	CANCER PATIENTS 1. Ca.Breast 2. Ca.Rectum 3. Ca. Colon	US FDA Submission
5	Temozolomide 250 Mg	24 Patients	HIGH GRADE GLIOMA	US FDA Submission
6	Omega-3 Acid Ethyl Esters	36 Patients	HYPERTRIGLYCERIDEMIA	DCGI Submission
Phase III Trial				
7	Moist Exposed Burn Ointment (MEBO)	120 Patients	MILD THERMAL BURN INJURIES	DCGI Submission

S.NO	MOLECULES	NO. OF SUBJECTS	INDICATIONS
8	Temozolomide 250 mg	12 Patients	GLIOBLASTOMAMULTIFORME or REFRACTORY ANAPLASTIC ASTROCYTOMA
9	Capecitabine 500mg (Fast condition)	18 Patients	CANCER PATIENTS Ca. Breast Ca. Rectum Ca. Colon
10	Capecitabine 500mg (Fed condition)	18 Patients	CANCER PATIENTS Ca. Breast Ca. Rectum Ca. Colon
11	GOODLYFE in control blood sugar	10 Adult Patients	TYPE 2 DIABETES
12	GOODLYFE in controlling blood pressure	10 Adult Patients	MILDLY ELEVATED BLOOD PRESSURE
13	Leuprolide Acetate 7.5 mg	60 Patients	PROSTATIC CARCINOMA
Bio Marker studies			
14	Collection of specimen (serum)	200 subjects	TYPE I DIABETES MELLITUS UNDER FASTING/FED CONDITIONS
15		200 Patients	METASTATIC BREASTCANCER STAGE IV
16		100 Patients	METASTATIC BREAST CANCER STAGE IV

Proof of Concept Study

S.No	MOLECULES	NO. OF SUBJECTS	INDICATIONS
17	Vida-Defense 500mg Capsule	100 Patients	Cancer patients receiving standard chemo/radiotherapy

Ongoing Studies

S.No	MOLECULES	NO. OF SUBJECTS	INDICATIONS
18	Bortezomib Powder for Solution For Injection 3.5 mg/vial	40 Patients	Multiple Myeloma
19	Leuprolide Acetate 7.5 mg	12 Patients	Prostatic Carcinoma
20	Doxorubicin Hydrochloride Liposome Injection 2mg/ml (50mg/m ² dose)	54 Patients	Metastatic Breast Cancer/Advanced Ovarian Cancer