

Experience of MTZ Clinical Research in Early Clinical Development

Biosimilarity – Phase I

Lp.	Therapeutic /Chemical subgroup	Chemical substance	Indication / Population
1	Antithrombotic agents	Enoxaparin sodium	Healthy subjects
2	Monoclonal antibodies	Adalimumab	Healthy subjects
3	Monoclonal antibodies	Rituximab	Non-Hodgkin Lymphoma
4	Monoclonal antibodies	Rituximab	Rheumatoid arthritis

Early Phases - Phase I and II

FIH – first in human study
SAD – single drug administration
MAD – multiple-dose drug administration

DDI – drug-drug interaction
Dose escalation
PoC – Proof of Concept

Lp.	Study Type	Therapeutic/Chemical subgroup	Indication / Population
5	FIH	Protein kinase inhibitors	Healthy subjects
6	SAD	Antipsoriatics	Healthy subjects
7	SAD	Antipsoriatics	Healthy subjects
8	SAD	Selective $\alpha 1$ receptor antagonist	Healthy subjects
9	SAD	Anesthetics	Healthy subjects
10	SAD	Anti-parkinson drugs	Healthy subjects
11	SAD	Antiepileptics	Healthy subjects
12	SAD	Antiepileptics	Healthy subjects
13	SAD	Anterior pituitary lobe hormones and analogues	Healthy subjects
14	SAD	Endocrine therapy	Post-menopausal women
15	SAD	Drugs used in diabetes	Impaired Hepatic Function
16	SAD	Anesthetics	Impaired Hepatic Function
17	SAD	Tyrosine kinase inhibitor (TKI)	Impaired Hepatic Function
18	SAD / MAD	Analgesics	Cancer pain
19	MAD	Recombinant Factor IX	Hemophilia B
20	MAD	Tyrosine kinase inhibitor (TKI)	Impaired Hepatic Function
21	MAD	Protein kinase inhibitors	Impaired Hepatic Function
22	MAD	Interleukin inhibitors	Primary Immune Thrombocytopenia (ITP)
23	MAD	Selective progesterone receptor modulator	Uterine fibroids
24	DDI	Cladribine	Multiple sclerosis
25	DDI	Simeprevir / escitalopram	Healthy subjects
26	DDI	Etravirine; Darunavir; artemether/lumefantrine	Healthy subjects

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Lp.	Study Type	Therapeutic/Chemical subgroup	Indication / Population
27	Dose escalation	Tyrosine kinase inhibitor (TKI)	(AML) Acute Myelogenous Leukemia
28	Dose escalation	Monoclonal antibodies	Asthma
29	Dose escalation	Monoclonal antibodies	Atopic Dermatitis
30	Dose escalation	Dual TYK2 / JAK1	Atopic Dermatitis
31	Dose escalation	Bruton's tyrosine kinase inhibitor	Mantle Cell Lymphoma
32	Dose escalation	Monoclonal antibodies	Non-Hodgkin Lymphoma
33	Dose escalation	Antiparasitic products, insecticides and repellents	Peritoneal cancer
34	Dose escalation	Dual TYK2 / JAK1	Plaque Psoriasis
35	Dose escalation	Protein kinase inhibitors	Rheumatoid arthritis
36	Dose escalation	Monoclonal antibodies	Rheumatoid arthritis
37	PoC	Selective Inhibitor of Nuclear Export (SINE)	(ALL) Acute Lymphoblastic Leukemia
38	PoC	Prostaglandin D2 receptor	Asthma
39	PoC	Galectin receptors	Biliary Cancer
40	PoC	Selective Inhibitor of Nuclear Export (SINE)	(DLBCL) Diffuse Large B-Cell Lymphoma
41	PoC	Monoclonal antibodies	(DLBCL) Diffuse Large B-Cell Lymphoma
42	PoC	Monoclonal antibodies	(DLBCL) Diffuse Large B-Cell Lymphoma
43	PoC	Monoclonal antibodies	(DLBCL) Diffuse Large B-Cell Lymphoma
44	PoC	Selective progesterone receptor modulator	Endometriosis
45	PoC	Monoclonal antibodies	Primary Immune Thrombocytopenia (ITP)
46	PoC	Bruton's tyrosine kinase inhibitor	Mantle Cell Lymphoma
47	PoC	Tyrosine kinase inhibitor (TKI)	Metastatic Solid Tumors
48	PoC	Proteasome inhibitor	Multiple Myeloma
49	PoC	Bruton's tyrosine kinase inhibitor	Multiple Myeloma
50	PoC	Other antineoplastic agents	Multiple Myeloma
51	PoC	Flavonoid	Plaque Psoriasis
52	PoC	Tyrosine kinase 2 inhibitor (TKI2)	Plaque Psoriasis
53	PoC	Drugs used in diabetes	Type 2 diabetes mellitus
54	PoC	Antimetabolites	Myelodysplastic syndrome (MDS)
55	PoC	Antiepileptics	Neuropathic pain
56	PoC	Antihistamines	Plaque Psoriasis
57	PoC	Flavonoid	Plaque Psoriasis
58	PoC	Immunosuppressants	Plaque Psoriasis
59	PoC	Janus kinase (JAK) inhibitor	Plaque Psoriasis
60	PoC	Selective pan-FGFR inhibitor	Solid Tumors
61	PoC	Sex hormones and modulators of the genital system	Vasomotor symptoms in Post-Menopausal Women
62	PoC	Antihistamines	Local skin inflammatory

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