

Experience of MTZ Clinical Research

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
4	Monoclonal antibodies	Adalimumab	Healthy subjects
5	Monoclonal antibodies	Rituximab	Non-Hodgkin Lymphoma
6	Monoclonal antibodies	Rituximab	Rheumatoid arthritis
7	Monoclonal antibodies	Tocilizumab	Healthy subjects
8	Monoclonal antibodies	Denosumab	Healthy subjects

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
9	FIH	Protein kinase inhibitors	Healthy subjects
10	SAD	Antipsoriatics	Healthy subjects
11	SAD	Antipsoriatics	Healthy subjects
12	SAD	Selective α 1 receptor antagonist	Healthy subjects
13	SAD	Anesthetics	Healthy subjects
14	SAD	Anti-parkinson drugs	Healthy subjects
15	SAD	Antiepileptics	Healthy subjects
16	SAD	Antiepileptics	Healthy subjects
17	SAD	Anterior pituitary lobe hormones and analogues	Healthy subjects
18	SAD	Endocrine therapy	Post-menopausal women
19	SAD	Drugs used in diabetes	Impaired Hepatic Function
20	SAD	Anesthetics	Impaired Hepatic Function
21	SAD	Tyrosine kinase inhibitor (TKI)	Impaired Hepatic Function
22	SAD	Monoclonal antibodies	Conventional Dendritic Cell (cDC)- and Plasmacytoid Dendritic Cell (pDC)- Mediated Rheumatic
23	SAD / MAD	Analgesics	Cancer pain

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24	SAD	18F-labeled SYN2 tag	Imaging of the perfusion of the heart muscle
25	MAD	Recombinant Factor IX	Hemophilia B
26	MAD	Tyrosine kinase inhibitor (TKI)	Impaired Hepatic Function
27	MAD	Protein kinase inhibitors	Impaired Hepatic Function
28	MAD	Interleukin inhibitors	Primary Immune Thrombocytopenia (ITP)
29	MAD	Selective progesterone receptor modulator	Uterine fibroids
30	DDI	Cladribine	Multiple sclerosis
31	DDI	Simeprevir / escitalopram	Healthy subjects
32	DDI	Etravirine; Darunavir; artemether/lumefantrine	Healthy subjects
33	DDI	Tested drug/ tested drug/ Tofacitinib	Rheumatoid arthritis
34	Dose escalation	Tyrosine kinase inhibitor (TKI)	(AML) Acute Myelogenous Leukemia
35	Dose escalation	Monoclonal antibodies	Asthma
36	Dose escalation	Monoclonal antibodies	Atopic Dermatitis
37	Dose escalation	Dual TYK2 / JAK1	Atopic Dermatitis
38	Dose escalation	Bruton's tyrosine kinase inhibitor	Mantle Cell Lymphoma
39	Dose escalation	Monoclonal antibodies	Non-Hodgkin Lymphoma
40	Dose escalation	Antiparasitic products, insecticides and repellents	Peritoneal cancer
41	Dose escalation	Dual TYK2 / JAK1	Plaque Psoriasis
42	Dose escalation	Protein kinase inhibitors	Rheumatoid arthritis
43	Dose escalation	Monoclonal antibodies	Rheumatoid arthritis
44	Dose escalation	Antiinflammatory and antirheumatic products	Rheumatoid arthritis
45	PoC	Selective Inhibitor of Nuclear Export (SINE)	(ALL) Acute Lymphoblastic Leukemia
46	PoC	Prostaglandin D2 receptor	Asthma
47	PoC	Galectin receptors	Biliary Cancer
48	PoC	Selective Inhibitor of Nuclear Export (SINE)	(DLBCL) Diffuse Large B-Cell Lymphoma
49	PoC	Monoclonal antibodies	(DLBCL) Diffuse Large B-Cell Lymphoma
50	PoC	Monoclonal antibodies	(DLBCL) Diffuse Large B-Cell Lymphoma
51	PoC	Monoclonal antibodies	(DLBCL) Diffuse Large B-Cell Lymphoma
52	PoC	Selective progesterone receptor modulator	Endometriosis
53	PoC	Monoclonal antibodies	Primary Immune Thrombocytopenia (ITP)
54	PoC	Bruton's tyrosine kinase inhibitor	Mantle Cell Lymphoma
55	PoC	Tyrosine kinase inhibitor (TKI)	Metastatic Solid Tumors
56	PoC	Proteasome inhibitor	Multiple Myeloma
57	PoC	Bruton's tyrosine kinase inhibitor	Multiple Myeloma
58	PoC	Other antineoplastic agents	Multiple Myeloma

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59	PoC	Flavonoid	Plaque Psoriasis
60	PoC	Tyrosine kinase 2 inhibitor (TKI2)	Plaque Psoriasis
61	PoC	Drugs used in diabetes	Type 2 diabetes mellitus
62	PoC	Antimetabolites	Myelodysplastic syndrome (MDS)
63	PoC	Antiepileptics	Neuropathic pain
64	PoC	Antihistamines	Plaque Psoriasis
65	PoC	Flavonoid	Plaque Psoriasis
66	PoC	Immunosuppressants	Plaque Psoriasis
67	PoC	Janus kinase (JAK) inhibitor	Plaque Psoriasis
68	PoC	Janus kinase (JAK) inhibitor	Alopecia Areata
69	PoC	Bcl-2 antiapoptotic protein inhibitor	Acute myeloid leukemia
70	PoC	Selective pan-FGFR inhibitor	Solid Tumors
71	PoC	Sex hormones and modulators of the genital system	Vasomotor symptoms in Post-Menopausal Women
72	PoC	Antihistamines	Local skin inflammatory
73	PoC	Anti-inflammatories	Osteoarthritis
74	PoC	P2X3 antagonist	Symptomatic endometriosis

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Bioequivalence studies

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Alimentary tract and metabolism			
75	Drugs used in diabetes	Glimepiride	Healthy subjects
76	Lipid modifying agents	Lovastatin	Healthy subjects
77	Lipid modifying agents	Rosuvastatin	Healthy subjects
78	Lipid modifying agents	Rosuvastatin	Healthy subjects
79	Lipid modifying agents	Simvastatin	Healthy subjects
Antiinfectives for systemic use			
80	Antibacterials for systemic use	Azithromycin	Healthy subjects
81	Antibacterials for systemic use	Azithromycin	Healthy subjects
82	Antibacterials for systemic use	Azithromycin	Healthy subjects
83	Antivirals for systemic use	Oseltamivir	Healthy subjects
84	Antivirals for systemic use	Aciclovir	Healthy subjects
Antineoplastic and immunomodulating agents			
85	Antineoplastic agents	Capecitabine	Healthy subjects
86	Antineoplastic agents	Capecitabine	Metastatic Solid Tumors
87	Antineoplastic agents	Capecitabine	Metastatic Solid Tumors
88	Antineoplastic agents	Capecitabine	Healthy subjects
89	Antineoplastic agents	Capecitabine	Healthy subjects
90	Antineoplastic agents	Doxorubicin Hydrochloride Liposome	Advanced Carcinoma of the Ovary
91	Taxane	Paclitaxel	Metastatic breast cancer
Blood and blood forming organs			
92	Antithrombotic agents	Acetylsalicylic Acid	Healthy subjects
Cardiovascular system			
93	Agents acting on the renin-angiotensin system	Lisinopril	Healthy subjects
94	Agents acting on the renin-angiotensin system	Lisinopril	Healthy subjects
95	Agents acting on the renin-angiotensin system	Lisinopril	Healthy subjects
96	Calcium channel blockers	Nitrendypine	Healthy subjects
97	Calcium channel blockers	Nicardipine hydrochloride	Healthy subjects
98	Cardiac therapy	Isosorbide-5-mononitrate	Healthy subjects
99	Cardiac therapy	Isosorbide-5-mononitrate	Healthy subjects
100	Cardiac therapy	Isosorbide-5-mononitrate	Healthy subjects
101	Diuretics	Indapamide	Healthy subjects
102	Diuretics	Indapamide	Healthy subjects
103	Hypertension	Perindopril/Amlodipine	Healthy subjects
104	Lipid modifying agents	Simvastatin	Healthy subjects
105	Vasoprotectives	Calcium dobesilate	Healthy subjects

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Dermatologicals			
106	Antipsoriatics	Tacalcitol	Plaque Psoriasis
107	Antipsoriatics	Tacalcitol	Plaque Psoriasis
108	Corticosteroids	Mometasone furoate	Healthy subjects
109	Corticosteroids	Mometasone furoate	Healthy subjects
110	Corticosteroids	Mometasone furoate	Healthy subjects
111	Corticosteroids	Mometasone furoate	Healthy subjects
112	Corticosteroids	Betamethasone dipropionate	Healthy subjects
113	Corticosteroids	Betamethasone dipropionate and salicylic acid	Healthy subjects
114	Corticosteroids	Betamethasone dipropionate and salicylic acid	Healthy subjects
115	Corticosteroids	Betamethasone dipropionate and gentamicin sulfate	Healthy subjects
116	Corticosteroids	Betamethasone dipropionate and gentamicin sulfate	Healthy subjects
117	Corticosteroids	Clobetasol propionate	Healthy subjects
118	Flavonoid	Genistein	Healthy subjects
Genito-urinary system and sex hormones			
119	Sex hormones and modulators of the genital system	Megestrol	Healthy subjects
120	Sex hormones and modulators of the genital system	Megestrol	Healthy subjects
Musculo-skeletal system			
121	Antiinflammatory and antirheumatic products	Ibuprofen	Healthy subjects
122	Antiinflammatory and antirheumatic products	Ibuprofen	Healthy subjects
123	Antiinflammatory and antirheumatic products	Ibuprofen	Healthy subjects
124	Anti-inflammatory and antirheumatic products	Ibuprofen	Healthy subjects
125	Antiinflammatory and antirheumatic products	Naproxen	Healthy subjects
126	Drugs for treatment of bone diseases	Alendronic acid	Healthy subjects
127	Drugs for treatment of bone diseases	Risedronic acid	Healthy subjects
128	Muscle relaxants	Thiocolchicoside	Healthy subjects
Nervous system			
129	Antiepileptics	Lamotrigine	Healthy subjects
130	Antiepileptics	Pregabalin	Healthy subjects
131	Antiepileptics	Topiramate	Healthy subjects
132	Antiepileptics	Topiramate	Healthy subjects
133	Antivertigo preparations	Cinnarazinum & Dimenhydrinatum	Healthy subjects
134	Other nervous system drugs	Betahistine	Healthy subjects
135	Psychoanaleptics	Amitriptyline	Healthy subjects
136	Psychoanaleptics	Amitriptyline	Healthy subjects
137	Psychoanaleptics	Aniracetam	Healthy subjects
138	Psychoanaleptics	Memantine	Healthy subjects
139	Psychoanaleptics	Mirtazapine	Healthy subjects
140	Psychoanaleptics	Rasagiline	Healthy subjects

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141	Psychoanaleptics	Trazodone	Healthy subjects
142	Psycholeptics	Olanzapine	Healthy subjects
143	Anesthetics	Bupivacaine	Healthy subjects
	Respiratory system		
144	Antihistamines	Clemastine	Healthy subjects
145	Antihistamines	Levocetirizine	Healthy subjects
146	Antihistamines	Loratadine	Healthy subjects
147	Drugs for obstructive airway diseases	Fluticasone propionate / salmeterol	Healthy subjects
148	Drugs for obstructive airway diseases	Mometasone furoate	Healthy subjects
149	Drugs for obstructive airway diseases	Mometasone furoate	Healthy subjects
150	Nasal preparations	Fluticasone furoate	Healthy subjects
	Various		
151	Antiinflammatory / Sympathomimetics	Ibuprofen / Pseudoephedrine	Healthy subjects
152	Antiinflammatory / Sympathomimetics	Ibuprofen / Pseudoephedrine	Healthy subjects

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Experience of MTZ Clinical Research

Late Experience of MTZ Clinical Research

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Late Clinical Development

Biosimilarity – Phase III

Lp.	Therapeutic /Chemical subgroup	Chemical substance
153	Monoclonal antibodies	Adalimumab
154	Monoclonal antibodies	Adalimumab
155	Monoclonal antibodies	Adalimumab
156	Monoclonal antibodies	Adalimumab
157	Monoclonal antibodies	Adalimumab
158	Monoclonal antibodies	Bevacizumab
159	TNF- α inhibitors	Etanercept
160	TNF- α inhibitors	Etanercept
161	Monoclonal antibodies	Infliximab
162	Peptide hormone	Insulin glargine
163	Granulocyte colony-stimulating factor	Pegfilgrastim
164	Granulocyte colony-stimulating factor	Pegfilgrastin
165	Monoclonal antibodies	Rituximab

Phase III Studies

Lp.	Therapeutic/Chemical subgroup	Indication / Population
	Alimentary tract and metabolism	
166	Drugs used in diabetes	Type 2 diabetes mellitus
	Antineoplastic and immunomodulating agents	
167	Immunoglobulin	(AL) Amyloidosis
168	Immunoglobulin	Biliary Cancer
169	Monoclonal antibodies	(ALL) Acute Lymphoblastic Leukemia
170	Selective immunosuppressants	(ALL) Acute Lymphoblastic Leukemia
171	FLT3 Inhibitor	(ALL) Acute Lymphoblastic Leukemia
172	FLT3 Inhibitor	(ALL) Acute Lymphoblastic Leukemia
173	Tyrosine kinase inhibitor (TKI)	(CML) Chronic Myelogenous Leukemia
174	Tyrosine kinase inhibitor (TKI)	(CML) Chronic Myelogenous Leukemia
175	Tyrosine kinase inhibitor (TKI)	(CML) Chronic Myelogenous Leukemia
176	Bruton's tyrosine kinase inhibitor	(CLL) Chronic Lymphocytic Leukemia
177	Bruton's tyrosine kinase inhibitor	(CLL) Chronic Lymphocytic Leukemia
178	Inhibitor of kinase (PI3K)	(CLL) Chronic Lymphocytic Leukemia
179	Inhibitor of kinase (PI3K)	(CLL) Chronic Lymphocytic Leukemia
180	Monoclonal antibodies	(DLBCL) Diffuse Large B-Cell Lymphoma
181	Histone deacetylase inhibitor	(DLBCL) Diffuse Large B-Cell Lymphoma

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182	Protein kinase inhibitors	(DLBCL) Diffuse Large B-Cell Lymphoma
183	Monoclonal antibodies	Gastric cancer
184	Janus kinase (JAK) inhibitor	Graft Versus Host Disease
185	Monoclonal antibodies	Hepatocellular carcinoma
186	Monoclonal antibodies	Hepatocellular carcinoma
187	Protein kinase inhibitors	Hepatocellular carcinoma
188	Monoclonal antibodies	Hodgkin Lymphoma
189	Bruton's tyrosine kinase inhibitor	Mantle Cell Lymphoma
190	Monoclonal antibodies	Multiple Myeloma
191	Proteasome inhibitor	Multiple Myeloma
192	Proteasome inhibitor	Multiple Myeloma
193	Proteasome inhibitor	Multiple Myeloma
194	Monoclonal antibodies	Multiple Myeloma
195	Monoclonal antibodies	Multiple Myeloma
196	Monoclonal antibodies	Multiple Myeloma
197	Monoclonal antibodies	Multiple Myeloma
198	Inhibitor of kinase (PI3K)	(MDS) Myelodysplastic syndrome
199	Antimetabolites	(MDS) Myelodysplastic syndrome
200	Antianemic preparations	(MDS) Myelodysplastic syndrome
201	Bcl-2 antiapoptotic protein inhibitor	(MDS) Myelodysplastic syndrome
202	Bcl-2 antiapoptotic protein inhibitor	Myelofibrosis
203	Protein kinase inhibitors	Myelofibrosis
204	Bcl-2 antiapoptotic protein inhibitor	Myelofibrosis
205	Monoclonal antibodies	(PNH) Paroxysmal nocturnal hemoglobinuria
206	Monoclonal antibodies	(PNH) Paroxysmal nocturnal hemoglobinuria
207	Monoclonal antibodies	(PNH) Paroxysmal nocturnal hemoglobinuria
208	Mistletoe Extract	Pancreatic Cancer
Antiinfectives for systemic use		
209	Immune sera and immunoglobulins	(ITP) Idiopathic thrombocytopenic purpura
210	Monoclonal antibodies	(ITP) Idiopathic thrombocytopenic purpura
211	Antivirals for systemic use	CMV positive patients
Blood and blood forming organs		
212	Antianemic preparations	Chemotherapy Induced Anemia
213	Monoclonal antibodies	Warm Autoimmune Hemolytic Anemia
Cardiovascular system		
214	Cardiac therapy	Orthostatic Hypotension
215	Vasoprotectives	Telangiectasia and lipodystrophy
Dermatologicals		
216	Corticosteroids	Acne vulgaris
217	Corticosteroids	Acne vulgaris
218	Monoclonal antibodies	Atopic Dermatitis
219	Janus kinase (JAK) inhibitor	Atopic Dermatitis
220	Janus kinase (JAK) inhibitor	Atopic Dermatitis
221	Janus kinase (JAK) inhibitor	Atopic Dermatitis

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222	Janus kinase (JAK) inhibitor	Atopic Dermatitis
223	Janus kinase (JAK) inhibitor	Atopic Dermatitis
224	Phosphodiesterase type 4 inhibitor (PDE4)	Atopic Dermatitis
225	Interleukin inhibitors	Plaque Psoriasis
226	Interleukin inhibitors	Plaque Psoriasis
227	Janus kinase (JAK) inhibitor	Plaque Psoriasis
228	Janus kinase (JAK) inhibitor	Plaque Psoriasis
229	Interleukin inhibitors	Plaque Psoriasis
230	TNF- α inhibitors	Psoriatic arthritis
Genito-urinary system and sex hormones		
231	Gonadatropin releasing hormone	Endometriosis-associated pain
232	Gonadatropin releasing hormone	Endometriosis-associated pain
Musculo-skeletal system		
233	Monoclonal antibodies	Osteoarthritis of the hip or knee
234	Monoclonal antibodies	After a Total Knee, Hip, or Shoulder Replacement
235	Janus kinase (JAK) inhibitor	Rheumatoid arthritis
236	Janus kinase (JAK) inhibitor	Rheumatoid arthritis
Nervous system		
237	Inhibitor of Tau protein aggregation	Alzheimer's Disease
238	Inhibitor of Tau protein aggregation	Alzheimer's Disease
Respiratory system		
239	Drugs for obstructive airway diseases	Asthma
240	Drugs for obstructive airway diseases	(COPD) Chronic obstructive pulmonary disease
Systemic hormonal preparations, excluding sex hormones and insulins		
241	Growth hormone (GH) stimulation test	Growth hormone deficiency

Other projects

Lp.	Type of project	Description
242	Medical Consulting and Writing	Study design -Antipsoriatics
243	Medical Consulting and Writing	Study design - Inhibitor of Tau protein aggregation
244	Medical Consulting and Writing	Study design - Antihemorrhagics
245	Medical Consulting and Writing	Study design - Antihemorrhagics
246	Medical Consulting and Writing	Study design - Antihemorrhagics
247	Medical Consulting and Writing	Study design -Antineoplastic agents
248	Medical Consulting and Writing	Study design - Antipsoriatics
249	Medical Consulting and Writing	Study design - Cosmetics
250	Biowaiver Expert Report	Oseltamivir
251	Biowaiver Expert Report	Levocetirizine oral solution
252	Biowaiver Expert Report	Doxylamine
253	Expert opinion	Thiocolchicoside
254	Expert opinion	3-substance product plan development

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255	Expert opinion	OTC medicinal products registration strategy (ointment and suppositories)
256	Drug Development Plan	Solid Tumors Expressing Death Receptor 5 Treatment
257	Drug Development Plan	Helicobacter Pylori Infections Treatment
258	Cosmetics	skin appearance in cases of reddening and rashes
259	Cosmetics	Rosacea
260	Cosmetics	Aphthous Ulcers
261	Cosmetics	Rosacea
262	Cosmetics	Skin flora
263	Dietary supplement	Glycemic Index
264	Dietary supplement	Glycemic Index
265	Dietary supplement	Functional Cognitive Deficiencies
266	Dietary supplement	Water retention problems
267	Medical device	Reference range determination in general population
268	Medical device	Atrial fibrillation
269	Medical device	Atrial fibrillation
270	Reference range determination	Percentage of lymphocytes expressing CD16/CD56/CD69 in General population
271	Reference range determination	Diffuse Large B-Cell Lymphoma (DLBCL)
272	Medical device	Hand cracks
273	Medical device	Contact thermography
274	Medical device	Finger cracks
275	Medical device	Protective masks with iodine
276	Medicinal experiment	Leukoferase
277	Herbal preparation	Aphthous Ulcers
278	Herbal preparation	Alopecia areata
279	Survey to evaluate the readability and usefulness of package leaflet	Calcium channel blockers
280	Survey to evaluate the readability and usefulness of package leaflet	ACE inhibitor
281	Survey to evaluate the readability and usefulness of package leaflet	Selective $\alpha 1$ receptor antagonist

Study in Smokers

Lp.	Type of project	Description
282	Exploatory study	Evaluating the exposure to selected smoke constituents in smokers
283	Exploatory study	Comparing the levels of biomarkers of exposure in smokers
284	Exploatory study	Evaluating the changes in biomarkers of cardio-vascular risk in adult smokers
285	Phase IV	Evaluating pharmacodynamic effects of tested product
286	PK study	Abuse liability and puffing topography assessments
287	PK study	Study to characterize nicotine PK parameters

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