

Experience of MTZ Clinical Research in Late Clinical Development

Biosimilarity – Phase III

Lp.	Therapeutic /Chemical subgroup	Chemical substance	Indication / Population
138	Monoclonal antibodies	Adalimumab	Plaque Psoriasis
139	Monoclonal antibodies	Adalimumab	Plaque Psoriasis
140	Monoclonal antibodies	Adalimumab	Plaque Psoriasis
141	Monoclonal antibodies	Adalimumab	Plaque Psoriasis
142	Monoclonal antibodies	Adalimumab	Rheumatoid arthritis
143	Monoclonal antibodies	Bevacizumab	Non-small cell Lung Cancer
144	TNF- α inhibitors	Etanercept	Plaque Psoriasis
145	TNF- α inhibitors	Etanercept	Rheumatoid arthritis
146	Monoclonal antibodies	Infliximab	Rheumatoid arthritis
147	Peptide hormone	Insulin glargine	Type 2 diabetes mellitus
148	Granulocyte colony-stimulating factor	Pegfilgrastim	Neutropenia
149	Granulocyte colony-stimulating factor	Pegfilgrastin	Neutropenia
150	Monoclonal antibodies	Rituximab	Rheumatoid arthritis

Phase III Studies

Lp.	Therapeutic/Chemical subgroup	Indication / Population
Alimentary tract and metabolism		
151	Drugs used in diabetes	Type 2 diabetes mellitus
Antineoplastic and immunomodulating agents		
152	Immunoglobulin	(AL) Amyloidosis
153	Monoclonal antibodies	(ALL) Acute Lymphoblastic Leukemia
154	Selective immunosuppressants	(ALL) Acute Lymphoblastic Leukemia
155	FLT3 Inhibitor	(ALL) Acute Lymphoblastic Leukemia
156	FLT3 Inhibitor	(ALL) Acute Lymphoblastic Leukemia
157	Tyrosine kinase inhibitor (TKI)	(CML) Chronic Myelogenous Leukemia
158	Tyrosine kinase inhibitor (TKI)	(CML) Chronic Myelogenous Leukemia
159	Tyrosine kinase inhibitor (TKI)	(CML) Chronic Myelogenous Leukemia
160	Bruton's tyrosine kinase inhibitor	(CLL) Chronic Lymphocytic Leukemia
161	Bruton's tyrosine kinase inhibitor	(CLL) Chronic Lymphocytic Leukemia
162	Inhibitor of kinase (PI3K)	(CLL) Chronic Lymphocytic Leukemia
163	Inhibitor of kinase (PI3K)	(CLL) Chronic Lymphocytic Leukemia
164	Monoclonal antibodies	(DLBCL) Diffuse Large B-Cell Lymphoma
165	Histone deacetylase inhibitor	(DLBCL) Diffuse Large B-Cell Lymphoma

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INITIAL CAPITAL: 208 500 PLN



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Lp.	Therapeutic/Chemical subgroup	Indication / Population
166	Protein kinase inhibitors	(DLBCL) Diffuse Large B-Cell Lymphoma
167	Monoclonal antibodies	Gastric cancer
168	Janus kinase (JAK) inhibitor	Graft Versus Host Disease
169	Monoclonal antibodies	Hepatocellular carcinoma
170	Monoclonal antibodies	Hepatocellular carcinoma
171	Protein kinase inhibitors	Hepatocellular carcinoma
172	Monoclonal antibodies	Hodgkin Lymphoma
173	Bruton's tyrosine kinase inhibitor	Mantle Cell Lymphoma
174	Monoclonal antibodies	Multiple Myeloma
175	Proteasome inhibitor	Multiple Myeloma
176	Proteasome inhibitor	Multiple Myeloma
177	Proteasome inhibitor	Multiple Myeloma
178	Monoclonal antibodies	Multiple Myeloma
179	Monoclonal antibodies	Multiple Myeloma
180	Inhibitor of kinase (PI3K)	(MDS) Myelodysplastic syndrome
181	Antimetabolites	(MDS) Myelodysplastic syndrome
182	Antianemic preparations	(MDS) Myelodysplastic syndrome
183	Protein kinase inhibitors	Myelofibrosis
184	Monoclonal antibodies	(PNH) Paroxysmal nocturnal hemoglobinuria
185	Mistletoe Extract	Pancreatic Cancer
	Antiinfectives for systemic use	
186	Immune sera and immunoglobulins	(ITP) Idiopathic thrombocytopenic purpura
187	Antivirals for systemic use	CMV positive patients
	Blood and blood forming organs	
188	Antianemic preparations	Chemotherapy Induced Anemia
	Cardiovascular system	
189	Cardiac therapy	Orthostatic Hypotension
190	Vasoprotectives	Telangiectasia and lipodystrophy
	Dermatologicals	
191	Corticosteroids	Acne vulgaris
192	Corticosteroids	Acne vulgaris
193	Monoclonal antibodies	Atopic Dermatitis
194	Janus kinase (JAK) inhibitor	Atopic Dermatitis
195	Janus kinase (JAK) inhibitor	Atopic Dermatitis
196	Janus kinase (JAK) inhibitor	Atopic Dermatitis
197	Janus kinase (JAK) inhibitor	Atopic Dermatitis
198	Phosphodiesterase type 4 inhibitor (PDE4)	Atopic Dermatitis
199	Interleukin inhibitors	Plaque Psoriasis
200	Interleukin inhibitors	Plaque Psoriasis
201	Janus kinase (JAK) inhibitor	Plaque Psoriasis
202	Janus kinase (JAK) inhibitor	Plaque Psoriasis
203	Interleukin inhibitors	Plaque Psoriasis
204	TNF- α inhibitors	Psoriatic arthritis

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Lp.	Therapeutic/Chemical subgroup	Indication / Population
	Genito-urinary system and sex hormones	
205	Gonadatropin releasing hormone	Endometriosis-associated pain
206	Gonadatropin releasing hormone	Endometriosis-associated pain
	Musculo-skeletal system	
207	Monoclonal antibodies	Osteoarthritis of the hip or knee
208	Monoclonal antibodies	After a Total Knee, Hip, or Shoulder Replacement
209	Janus kinase (JAK) inhibitor	Rheumatoid arthritis
210	Janus kinase (JAK) inhibitor	Rheumatoid arthritis
	Nervous system	
211	Inhibitor of Tau protein aggregation	Alzheimer's Disease
212	Inhibitor of Tau protein aggregation	Alzheimer's Disease
	Respiratory system	
213	Drugs for obstructive airway diseases	Asthma
214	Drugs for obstructive airway diseases	(COPD) Chronic obstructive pulmonary disease
215	Growth hormone (GH) stimulation test	Growth hormone deficiency

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