



Drugs in Development for the treatment of Lupus

Systemic Lupus Erythematosus

Drug	Tradename	Drug type	Originator	Partner	Mechanism	Disease	Phase ¹	Route	Other Indications ²	Notes
Belimumab; HGS-1006	LymphoStat-B	Monoclonal Antibody	Human Genome Sciences	GSK	BlyS antagonist	SLE	III	i.v.	Rheumatoid Arthritis (Phase II)	LymphoStat-B has received a Fast Track Product designation from the FDA for use in SLE and has been selected for inclusion in the FDA's Continuous Marketing Application Pilot 2 Program
Epratuzumab; anti-CD22 antibody; IMMU-103; AMG 412	LymphoCide	Monoclonal Antibody	Immunomedics	UCB	CD-22 antagonist	SLE	III	i.v.	Sjogren's (Phase II) Non-Hodgkin's Lymphoma (Discontinued) Acute Lymphoblastic Leukemia (Phase II) Diffuse Large B-Cell Lymphoma (Phase II)	Amgen licensed LymphoCide in 2000 but returned rights in 2004. NHL was dropped as an indication due to too much competition in this market. A clinical hold was introduced in 2006 due to concerns expressed by UCB about the sterility of Immunomedics manufacturing plant.
Prasterone; GL-701	Prestara	Small Molecule	Genelabs	Watson, Teva, Tanabe Genovate	Steroid	SLE	III	p.o.		In 2001 Genelabs received a non-approvable letter from the FDA, followed by an approvable letter in 2002. Approval was dependent on an additional clinical trial to ascertain efficacy. In 2006 the FDA requested that Genelabs carry out a further phase III clinical trial to support an indication for the treatment of the signs and symptoms of lupus. The FDA also stated that additional positive prospective phase III clinical trial data would be necessary before the FDA would consider reviewing an NDA for BMD in lupus. The company states that it "is in the process of designing a clinical trial protocol for an additional study, although the company does not believe that it will conduct the study on its own." Since no partners have been announced in the last year the future development of this drug seems uncertain.
Rituximab	Rituxan	Monoclonal Antibody	Genentech		CD-20 antagonist	SLE	III	i.v.	Multiple Sclerosis (Phase II/III) ANCA-associated vasculitis (Phase II/III) Arthritis (Launched) Lymphoma (Launched)	In December 2006 the FDA released an alert re incidence of progressive multifocal leukoencephalopathy when Rituxan was used in SLE patients
Ocrelizumab		Monoclonal Antibody	Genentech		CD-20 antagonist	SLE	II	i.v.	Rheumatoid Arthritis (Phase III) Multiple Sclerosis (Phase II)	Since this drug has the same mechanism as Rituxan, it may possibly exhibit the same adverse effects described above
Abatacept; CTLA4-Ig	Orencia	Fusion Protein	Bristol-Myers Squibb		CTLA-4 agonist	SLE	II	i.v.	Rheumatoid Arthritis (Launched) Ulcerative Colitis (Phase III) Crohn's Disease (Phase III)	
Edratide; TV-4710		Peptide	Teva		DNA antibody antagonist	SLE	II	s.c.		
IPP-201101		Peptide	Immupharma		Immunosuppressant	SLE	II	s.c.		
Abetimus; LJP 394	Riquent	Small Molecule	La Jolla Pharmaceuticals		dsDNA suppressant	SLE	II	i.v.		Prior rights agreements with Leo Pharmaceuticals (for Europe and the Middle East) and with Abbott (for the US) were returned to La Jolla Pharmaceuticals. Phase III clinical trials have been ongoing since 1997. In September 2000, the US FDA granted orphan drug status for abetimus in the treatment of lupus nephritis. As of 2006 Phase III trials are continuing. In October 2006 the company withdrew its European MAA application citing that it would not be able to complete clinical trials within the timelines required for approval.

¹ US phase of development unless otherwise stated

² International phase of development

³ Roche does not mention its collaboration with Roche for the SLE indication for MRA in its pipeline however Chugai does

Systemic Lupus Erythematosus (continued)

Drug	Tradename	Drug type	Originator	Partner	Mechanism	Disease	Phase ¹	Route	Other Indications ²	Notes
AM-623		Fusion Protein	Amgen		B cell maturation inhibitor	SLE	I			
MEDI-545		Monoclonal Antibody	MedImmune	Medarex	IFN-alpha antagonist	SLE	I	i.v.		
paquinimod; 57-57; ABR-215757		Small Molecule	Active Biotech		Immunosuppressant	SLE	I	p.o.	Rheumatoid Arthritis (Phase I)	
TACI-Ig	Atacept	Fusion Protein	ZymoGenetics	Serono	BLyS antagonist	SLE	I	s.c. i.v.	Rheumatoid Arthritis (Phase II) Non-Hodgkin's Lymphoma (Phase I) Chronic Lymphocytic Leukemia (Phase I) Multiple Myeloma (Phase I)	
MRA; tocilizumab	Actemra	Monoclonal antibody	Chugai	Roche3	IL-6 antagonist	SLE	I	i.v.	Multiple myeloma (Phase II) Castleman's disease (Phase I) Rheumatoid Arthritis (Pre-Registration) Crohn's disease (Phase II)	
p53 protein antagonist		Peptide; Monoclonal Antibody	Yeda		P53 antagonist	SLE	P			
TRX1		Monoclonal Antibody	TolerRx	Genentech	CD4 antagonist	SLE	P	i.v.	Multiple Sclerosis (Preclinical)	

Lupus Nephritis

Drug	Tradename	Drug type	Originator	Partner	Mechanism	Disease	Phase ¹	Route	Other Indications ²	Notes
FK-506; Tacrolimus	Prograf	Small Molecule	Astellas		Immunosuppressant	Lupus Nephritis	PR (Japan)	topical	Transplantation (Launched)	
Rituximab	Rituxan	Monoclonal Antibody	Genentech		CD-20 antagonist	Lupus Nephritis	III	i.v.	Multiple Sclerosis (Phase II/III) ANCA-associated vasculitis (Phase II/III) Arthritis (Launched) Lymphoma (Launched)	In December 2006 the FDA released an alert re incidence of progressive multifocal leukoencephalopathy when Rituxan was used in SLE patients
Mycophenolate mofetil	Cellcept	Small Molecule	Roche	Aspreva	IMPDH inhibitor	Lupus Nephritis	III	i.v.	Pemphigus vulgaris (Phase III)	
abetimus; LJP 394	Riquent	Small Molecule	La Jolla		dsDNA suppressant	Lupus Nephritis	III	i.v.		Prior rights agreements with Leo Pharmaceuticals (for Europe and the Middle East) and with Abbott (for the US) were returned to La Jolla Pharmaceuticals. Abbott returned rights in 1999 based on the results of a phase II/III trial lupus patients with a history of renal disease. Further clinical trials have been carried out to better screen patients and help increase the cost-effectiveness of clinical development. In September 2000, the US FDA granted orphan drug status for abetimus in the treatment of lupus nephritis. As of 2006 Phase III trials are ongoing. In October 2006 the company withdrew its European MAA application citing that it would not be able to complete clinical trials within the timelines required for approval
Ocrelizumab		Monoclonal Antibody	Genentech		CD-20 antagonist	Lupus Nephritis	II	i.v.	Rheumatoid Arthritis (Phase III) Multiple Sclerosis (Phase II)	Since this drug has the same mechanism as Rituxan, it may possibly exhibit the same adverse effects described above

Cutaneous Lupus

Drug	Tradename	Drug type	Originator	Partner	Mechanism	Disease	Phase ¹	Route	Other Indications ²	Notes
Lupus drug		Small Molecule	Mediquest		Unknown	Cutaneous lupus	P			
TRX1		Monoclonal Antibody	TolerRx	Genentech	CD4 antagonist	Cutaneous lupus	I	i.v.	Multiple Sclerosis (Preclinical)	

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Existing drugs under clinical investigation for lupus by academic institutions

Drug	Tradename	Drug Type	Originator	Investigator	Mechanism	Disease	Phase
infliximab	Remicade	Monoclonal antibody	Centocor	University of Vienna	TNF antagonist	SLE	II
infliximab	Remicade	Monoclonal antibody	Centocor	University of Vienna	TNF antagonist	Lupus nephritis	III
Sirolimus	Rapamycin	Small molecule	Wyeth	NIDDK	Immunosuppressant	Lupus nephritis	II
rosuvastatin	Crestor	Small molecule	AstraZeneca	Tuen Mun Hospital	HMG-CoA reductase inhibitor	Atherosclerosis in SLE patients	IV
Atorvastatin	Lipitor	Small molecule	Pfizer	NIAMS	HMG-CoA reductase inhibitor	Atherosclerosis in SLE patients	III
Atorvastatin	Lipitor	Small molecule	Pfizer	New York University	HMG-CoA reductase inhibitor	SLE	II
efalizumab	Raptiva	Monoclonal antibody	Genentech	The Cleveland Clinic	CD11a antagonist	Cutaneous lupus	II
pimecrolimus	Elidel	Small molecule	Novartis	University of Leipzig	Immunosuppressant	Cutaneous lupus	

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