



Santen Pharmaceutical Co., Ltd

Status of Clinical Development

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Forward-looking statements: The process of drug research and development from discovery to final approval and sales in long, complex and uncertain. Individual compounds are subject to a multitude of uncertainties, including the termination of clinical development at various stages and the non-approval of products after a regulatory filing has been submitted. Progress of new product development is greatly influenced by various factors, such as the delay of approval, ambiguous results of clinical data, an uncertainty of safety and effectiveness, unforeseen side-effects, and delay of launch or development.



Status of major clinical study (Ophthalmic) DE-085

● DE-085 (Glaucoma/Ocular hypertension)

Area	Development Stage	Note
JP	Applied for manufacturing and marketing approval	Applied : July, FY2006
EU	Applied for manufacturing and marketing approval	Applied : April, FY2007
U.S.	Will decide our future development plan based on the study results and marketability	



Status of major clinical study (Ophthalmic) DE-089

● DE-089

(Corneal and conjunctival epithelial disorder associated with dry eye, etc.)

Area	Development stage	Note
JP	Phase 3	To be filed : 2Q* FY2008

* It was originally scheduled to be filed 3Q FY2008



Status of major clinical study (ophthalmic)

- Corneal and conjunctival epithelial disorder associated with dry eye, etc.
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Code	Area	Indication	Development stage	Note
DE-099	JP	Corneal and conjunctival epithelial disorder associated with dry eye	P2	Generic name: Gefarnate
DE-101	U.S.	Corneal and conjunctival epithelial disorder associated with dry eye	P2	Generic name: Rivoglitazone
DE-103	JP	Allergic conjunctivitis	P1	PDE4 inhibitor



Status of major clinical study (Ophthalmic)

– Glaucoma/ Ocular hypertension –

Code	Area	Development stage	Note
DE-092	EU	Pilot study P2	Generic name: Olmesartan
DE-090	JP	P2	Generic name: Lomerizine HCl
DE-104	U.S.	P1	ROCK inhibitor



Status of major clinical study (Rheumatic/Retina)

Code	Area	Indication	Development stage	Note
DE-096	JP	Rheumatoid arthritis Diabetic Macular Edema	P2	TNF inhibitor
DE-098*	JP EU	Rheumatoid arthritis	P1/2a	Anti-APO-1 antibody
DE-102	JP	Diabetic Macular Edema	P1/2a	Steroid DDS

* Santen gave domestic development rights to Argense, Inc. Santen holds the marketing rights in Japan and the oversea marketing and development rights.