



Santen Pharmaceutical Co., Ltd.

Status of Clinical Development

May 9, 2008

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Forward-looking statements

The process of drug research and development from discovery to final approval and sales is 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.



Status of major clinical studies (ophthalmics): DE-085

- DE-085 (Glaucoma, Ocular hypertension)

Region	Development Stage		Remarks
	As of May 9, 2008	As of Jan. 30, 2008 (Previous announcement)	
Japan	Applied for manufacturing and marketing approval	Applied for manufacturing and marketing approval	Applied in July 2006
Europe	Approved*	Applied for manufacturing and marketing approval	Applied in April 2007

* The first national approval was granted in Denmark on April 30, 2008. On May 7, 2008, Germany received the national approval; the 9 remaining countries are in the process.

U.S.	Deciding the possibility of NDA filing after careful study of its marketability
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Status of major clinical studies (ophthalmics): DE-089

- DE-089 (Corneal and conjunctival epithelial disorders associated with dry eye)

Region	Development Stage		Remarks
	As of May 9, 2008	As of Jan. 30, 2008 (Previous announcement)	
Japan	Preparing for application	P3	To be filed in 1Q*/FY2008

* To be filed in 2Q/FY2008 in the previous announcement



Status of major clinical studies

-Keratoconjunctival epithelial disorders including dry eye-

- DE-099 (Corneal and conjunctival epithelial disorders associated with dry eye)

Region	Development Stage		Remarks
	As of May 9, 2008	As of Jan. 30, 2008 (Previous announcement)	
Japan	Discontinued study	P2	Generic name: Gefarnate

- DE-101(Corneal and conjunctival epithelial disorders associated with dry eye)

Region	Development Stage		Remarks
	As of May 9, 2008	As of Jan. 30, 2008 (Previous announcement)	
U.S.	P2	P2	Generic name: Rivoglitazone
Japan	Preparing P2	—	

- DE-103 (Allergic conjunctivitis)

Region	Development Stage		Remarks
	As of May 9, 2007	As of Jan. 30, 2008 (Previous announcement)	
Japan	P2	P2	PDE4 inhibitor



Status of major clinical studies -Glaucoma, Ocular hypertension-

- DE-092

Region	Development Stage		Remarks
	As of May 9, 2008	As of Jan. 30, 2008 (Previous announcement)	
Europe	P2 pilot study	P2 pilot study	Generic name: Olmesartan

- DE-090

Region	Development Stage		Remarks
	As of May 9, 2008	As of Jan. 30, 2008 (Previous announcement)	
Japan	P2	P2	Generic name: Lomerizine HCl

- DE-104

Region	Development Stage		Remarks
	As of May 9, 2008	As of Jan. 30, 2008 (Previous announcement)	
U.S.	P2	P1 (Preparing P2)	ROCK inhibitor
Japan	P2	(Preparing P2)	



Status of major clinical studies -Retina/Rheumatic -

- DE-102 (Diabetes Macular Edema)

Region	Development Stage		Remarks
	As of May 9, 2008	As of Jan. 30, 2008 (Previous announcement)	
Japan	P1 / 2a	P1 / 2a	Steroid DDS

- DE-098* (Rheumatoid arthritis)

Region	Development Stage		Remarks
	As of May 9, 2007	As of Jan. 30, 2008 (Previous announcement)	
Japan	P1 / 2a	P1 / 2a	Anti-APO-1 antibody
Europe	P1 / 2a	P1 / 2a	

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Santen holds the marketing rights in Japan and development rights in overseas.