



Santen Pharmaceutical Co., Ltd.

Status of Clinical Development

May 9, 2007

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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, 2007	As of Nov. 1, 2007 (Previous announcement)	
Japan	Applied for manufacturing and marketing approval	Applied for manufacturing and marketing approval	Applied in July 2006
Europe	Applied for manufacturing and marketing approval	Preparing for application	Applied in April 2007
USA	Deciding the possibility of NDA filing after careful study of its marketability		



Status of major clinical studies (ophthalmics): DE-089• DE-099• DE-101

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

Region	Development Stage		Remarks
	As of May 9, 2007	As of Nov. 1, 2006 (Previous announcement)	
Japan	P3	Start P3	To be filed in 3Q/FY2008

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

Region	Development Stage		Remarks
	As of May 9, 2007	As of Nov. 1, 2006 (Previous announcement)	
Japan	Start P2a	Preparing P2a	Generic name: Gefarnate; preservative-free ointment

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

Region	Development Stage		Remarks
	As of May 9, 2007	As of Nov. 1, 2006 (Previous announcement)	
USA	Start P2a	Start P1	Generic name: Rivoglitazone



Status of major clinical studies: DE-096 (ophthalmics and other)

- DE-096 (RA, DME)

Region	Indication	Stage	Remarks
Japan	Rheumatoid Arthritis	P2a	Conducting as planned
	Diabetic Macular Edema	P2a	



Status of major clinical studies (ophthalmics): DE-092

- DE-092 (Glaucoma, Ocular hypertension)

	Region	Stage	Remarks
As of May 8, 2007	Europe	Preparing P2a pilot study	Generic name: Olmesartan
As of Nov. 1, 2006 (Previous announcement)	Japan• USA	Clinical studies have been suspended	

1. The P2b studies in Japan and P2a studies in Europe did not demonstrate clear dose-response relationship nor sufficient IOP-lowering effect.

➡ Clinical studies have been suspended

2. Now we are preparing for the P2a pilot study with a different formulation.



Status of major clinical studies (ophthalmics): DE-102• DE-104

- DE-102 (Diabetes Macular Edema)

Region	Development Stage		Remarks
	As of May 9, 2007	As of Nov. 1, 2006 (Previous announcement)	
Japan	Start P1 / 2a	Preparing for clinical studies	Steroid DDS

- DE-104 (Glaucoma/ Ocular hypertension)

Region	Development Stage		Remarks
	As of May 9, 2007	As of Nov. 1, 2006 (Previous announcement)	
USA	Start P1	Preparing for clinical studies	ROCK inhibitor



New pipelines

- Clinical studies planned to start by June, 2007

Field	Dev. Code	Remarks	Origin
Allergy	DE-103	PDE4 inhibitor	In-licensed from Ono Pharmaceutical