



Santen Pharmaceutical Co., Ltd.

Status of Clinical Development

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Forecasts in this report are based on the currently available information. Actual results may differ materially depending on a number of factors including adverse economic conditions, delays in new products launch, currency exchange rate, legislative and regulatory development.



Status of major clinical studies: DE-085

DE-085 (Glaucoma, Ocular hypertension)

	Comparative study		Application (Schedule)
	vs. Latanoprost	vs. Timolol	
Japan	Confirmed non-inferiority		September, 2006
Europe	Main analysis: Not confirmed non-inferiority Sub analysis: Confirmed non-inferiority	Confirmed non-inferiority	During FY 2006
USA	Deciding the possibility of NDA filing after careful study of its marketability		



Status of major clinical studies: DE-092

DE-092 (Glaucoma, Ocular hypertension)

Region	Dev.Stage	Results of clinical study
Japan	P2b	• Clear dose-response relationship was not seen • Efficacy of IOP reduction was insufficient
USA	P2a	

➔ Clinical studies have been suspended

Future plan: Considering development options such as conducting with another dosage and/or different formulation



Status of major clinical studies: DE-089• DE-096

DE-089 (Corneal and conjunctival epithelial disorder associated with dry eye, etc.)

Region	Dev.stage	Results of clinical study	Starting P3
Japan	P2b	As expected	1 st half of FY2006

DE-096 (RA, DME)

Region	Indication	Dev.stage	Current status
Japan	RA	P2a	Conducting as planned
	DME	P2a	



FY2005 Topics

PAPILOCK Mini

Approved	October, 2005
Launched	January, 2006
Generic name	Ciclosporin
Indication	Vernal keratoconjunctivitis (In patients whose symptom cannot be adequately controlled by anti-allergy drugs)
Characteristics	Orphan drug

New pipelines

Clinical study is planned to start by FY2006

Field	Dev.Code	Memo	Origin
Cornea	DE-101	Rivoglitazone	In-licensed
Retina	DE-102	Steroid DDS	Co-development
Glaucoma	DE-104	ROCK inhibitor	Co-development
*Allergy	DE-103	PDE4 inhibitor	In-licensed

* Clinical study is planned to start by June, 2007