



Santen Pharmaceutical Co., Ltd.

Status of Clinical Development

November 2, 2006

Toshiaki Nishihata, Ph.D.

Senior Corporate Officer

Head of Research and Development Division

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 Nov. 2, 2006 | As of May 9, 2006 (Previous announcement) | |
| Japan | Applied July 2006 | Preparing for application | To be Launched in FY 2008 |
| Europe | Preparing for application | Preparing for application | To be filed in FY 2006 |

| | | | |
|-----|---------------------------------------------------------------------------------|--|--|
| USA | Deciding the possibility of NDA filing after careful study of its marketability | | |
|-----|---------------------------------------------------------------------------------|--|--|



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

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

| Region | Development Stage | | Remarks |
|--------|--------------------|----------------------------------------------|--------------------------|
| | As of Nov. 2, 2006 | As of May 9, 2006 (Previous announcement) | |
| Japan | Start P3 | Preparing P3 | To be launched in FY2010 |

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

| Region | Development Stage | | Remarks |
|--------|--------------------|----------------------------------------------|--------------------------------------------------------------|
| | As of Nov. 2, 2006 | As of May 9, 2006 (Previous announcement) | |
| Japan | Preparing P2 | P1 | Generic name: Gefarnate; preservative-free ointment |



Status of major clinical studies (ophthalmics and IOL):

DE-101 MD-14

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

| Region | Development Stage | | Remarks |
|--------|-------------------|----------------------------------------------|--------------------------------|
| | As of Nov 2, 2006 | As of May 9, 2006 (Previous announcement) | |
| USA | P1 | Preparing for P1 | Generic name: Rivoglitazone |

- MD-14 (IOL)

| Region | Development Stage | | Remarks |
|--------|-------------------|----------------------------------------------|-------------------------------|
| | As of Nov 2, 2006 | As of May 9, 2006 (Previous announcement) | |
| Japan | Approved | Preparing for application | US: preparing for application |



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

- DE-092 (Glaucoma, Ocular hypertension)

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

➔ Clinical studies have been suspended

Future plan : Considering development options such as conducting with another dosage and/or different formulation, future plan to be decided within FY 2006



Status of major clinical studies: DE-096

- DE-096 (RA, DME)

| Region | Indication | Stage | Status |
|--------|------------|-------|-----------------------|
| Japan | RA | P2a | Conducting as planned |
| | DMA | P2a | |

 **New pipelines**

- Clinical studies planned to start by June, 2007

| Field | Dev. Code | Remarks | Origin |
|-----------------|------------------|-----------------------|-----------------------------------------|
| Retina | DE-102 | Steroid DDS | Co-development with Oakwood, USA |
| Allergy | DE-103 | PDE4 inhibitor | In-licensed from Ono, Japan |
| Glaucoma | DE-104 | ROCK inhibitor | Co-development with Ube, Japan |