

## Reference information

# Research & development

### Pipeline of prescription pharmaceuticals (Clinical studies)

Generic name	Brand name/dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Levofloxacin (0.5%)	Cravit	Bacterial conjunctivitis	Daiichi Pharmaceutical	Japan						Apr-00
	Quixin			USA						Nov-00
	Ofraqix			Europe						May-02
Levofloxacin + prednisolone A	DE-094	Infectious keratitis	Daiichi Pharmaceutical	USA						

Characteristics: Fluoroquinolone antibacterial agent. Levofloxacin + prednisolone A is a combination treatment with steroids.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Tafluprost	DE-085	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	Japan				Jul-06		
				Europe			In preparation			
				USA						

Characteristics: Prostaglandin glaucoma treatment for ocular hypertension. In Japan, a comparison study demonstrated its non-inferiority to latanoprost and we filed for manufacturing and marketing approval for glaucoma and ocular hypertension. In Europe, also preparing for NDA filing based on the results of 1) the sub-analysis of the comparison study demonstrated its non-inferiority to latanoprost although it did not demonstrate its non-inferiority to latanoprost for the primary analysis, and 2) another comparison study demonstrated non-inferiority to timolol maleate ophthalmic solution. In the USA, we will decide our future development plan based on the study results and marketability.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Diquafosol tetrasodium	DE-089	Corneal and conjunctival epithelial disorder associated with dry eye,	Inspire Pharm.	Japan						

Characteristics: A treatment for corneal and conjunctival epithelial disorder associated with dry eye, etc. that stimulates the ocular surface to secrete tear fluid and moisture. Expected to be used in combination with existing dry eye treatments.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Olmesartan	DE-092	Glaucoma/ Ocular hypertension	Sankyo	Japan						
				USA/Europe			In preparation for pilot study			

Characteristics: The angiotensin II receptor antagonist. In preparation for pilot study with different formulation.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Lomerizine HCL	DE-090	Glaucoma	Nippon Organon	Japan						

Characteristics: A new type of oral glaucoma treatment studied for inhibiting the progression of visual field defects. The only calcium antagonist in full-fledged development as a glaucoma treatment. Compared with NMDA receptor antagonists, fewer generalized side effects are expected, thus having excellent safety. Marketed by Nippon Organon as a migraine drug.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-096	Rheumatoid arthritis	Original	Japan						
		Diabetes Macular Edema		Japan						

Characteristics: An oral TNF inhibitor. Anti-rheumatic effect comparable to injectable biological agents. In addition to RA, the effect on DME was also observed in basic research, and the phase II studies are being conducted with both diseases.

Generic name	Dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Gefarnate	DE-099	Corneal and conjunctival epithelial disorder associated with dry eye,	Original	Japan						

Characteristics: Treats corneal and conjunctival epithelial disorder mostly associated with dry eye, by stimulating the secretion of mucin and promoting the corneal epithelial migration. Preservative-free eye ointment that can be used in combination with existing drugs.

Generic name (USA)	Dev. code	Indication	Original/in-licenso	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Rivoglitazone	DE-101	Corneal and conjunctival epithelial disorder associated with dry eye,	Sankyo	USA						

Characteristics: It is expected to show a potent effect on corneal and conjunctival epithelial disorders by directly acting on the corneal and conjunctival epithelial cells. It has an action mechanism which differs from any other existing treatment or drug candidate in development. The compound is currently under development by Sankyo as an oral anti-diabetic in the USA.

\*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, etc..

## Pipeline of prescription pharmaceuticals (In preparation for clinical trials)

Generic name	Brand name	Indication	Original/in-licensor
Bucillamine	Rimatil	Osteoarthritis (additional indication)	Original

Characteristics: Shown to be effective on joint inflammation caused by osteoarthritis.

Generic name	Dev. code	Indication	Original/in-licensor
(Undetermined)	DE-102	Diabetes Macular Edema	Co-development with Oakwood (USA)

Characteristics: A steroid microsphere product for a sustained release injectable drug delivery. Demonstrated sustained efficacy when injected around the affected area. In order to produce sterile microsphere in commercial scale, we collaborate with Oakwood Laboratories (USA).

Generic name	Dev. code	Indication	Original/in-licensor
(Undetermined)	DE-103	Allergic conjunctivitis	Ono

Characteristics: A PDE4 (Phosphodiesterase type 4) inhibitor for allergic conjunctivitis which has a different action mechanism from the existing drugs. Expected to be effective for allergic conjunctivitis through its inhibitory effect against PDE4.

Generic name	Dev. code	Indication	Original/in-licensor
(Undetermined)	DE-104	Glaucoma/ Ocular hypertension	Co-development with Ube Industries

Characteristics: A ROCK inhibitor co-development with Ube Industries for treatment of glaucoma and ocular hypertension which has a different action mechanism from other existing drugs. It is expected to show a strong IOP-reduction by promoting aqueous humor outflow by acting directly on trabecular cells.

## Medical Device

Product under development	Product name	Region
Intraocular lens	MD-14	Japan and USA

Characteristics: Foldable intraocular lens using acrylic material with high refractive index. Developed by U.S. subsidiary Advanced Vision Science, Inc. Approved in October, 2006 in Japan. Preparing for NDA filing in USA.

## License out

Dev. code	Indication	Region	Licensee	Status	in-licensor
DE-098 (Anti-APO-1 antibody)	Rheumatoid arthritis	Japan	Argenes	preparing for clinical trials	Centocor

Characteristics: Joint injection that induces apoptosis in diseased joints of rheumatoid arthritis patients. Bulk pharmaceutical manufacturing process for actual production scale has been established, and drug development is being studied. Santen granted the domestic development rights to Argenes, Inc. The compound had been in-licensed from Centocor. Santen continues to hold the marketing rights in Japan and the overseas marketing and development rights.

## Changes from November 1, 2006

[Progress]

Dev. code	Indication	Status change	Clinical trial, NDA filing, Launch Region
DE-099	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	In preparation for Phase II to Phase II	Japan

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