

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 Sankyo	Japan						Apr-00
	Quixin			USA						Nov-00
	Oftaquix			Europe						May-02
Levofloxacin + prednisolone A	DE-094	Infectious keratitis	Daiichi Sankyo	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						Apr-07
				USA						

Characteristics: Prostaglandin derivative treatment for glaucoma and 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, applied for approval in April, 2007 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, etc.	Inspire Pharm.	Japan						

Characteristics: A treatment for corneal and conjunctival epithelial disorder mostly associated with dry eye, etc. that stimulates the ocular surface to secrete tear fluid and components. Expected to be used in combination with existing 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	Daiichi Sankyo	Japan						
				USA/Europe		pilot study				

Characteristics: The angiotensin II receptor antagonist. In Japan, Europe and the USA, the Phase II studies did not demonstrate clear dose-response, and therefore we decided to suspend clinical studies. We are now conducting the phase II pilot study in Europe 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 development as a glaucoma treatment. Compared with NMDA receptor antagonists, fewer systemic side effects are expected, thus having excellent safety. Marketed by Nippon Organon as a migraine treatment.

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, etc.	Original	Japan						

Characteristics: Treats corneal and conjunctival epithelial disorder mostly associated with dry eye, by stimulating the secretion of mucin and accelerating 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-licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Rivoglitazone	DE-101	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Daiichi Sankyo	USA						

Characteristics: It is expected to show a potent effect on corneal and conjunctival epithelial disorder mostly associated with dry eye, etc. 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 Daiichi Sankyo as an oral anti-diabetic drug in the USA.

Generic name (USA)	Dev. code	Indication	Original/in-licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-102	Diabetic Macular Edema	Co-development with Oakwood (USA)	Japan		(Phase I / IIa)				

Characteristics: A steroid microsphere product for a sustained release injection. Animal studies demonstrated sustained efficacy when injected around the injected area. In order to produce sterile microsphere in commercial scale, we collaborate with Oakwood Laboratories (USA).

Generic name (USA)	Dev. code	Indication	Original/in-licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-104	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	USA						

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 meshwork cells.

Generic name (USA)	Dev. code	Indication	Original/in-licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
(Undetermined)	DE-103	Allergic conjunctivitis	Ono Pharmaceutical	Japan						

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.

Reference information

Research & development

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.

License out

Dev. code	Indication	Licensee	Status	in-licensor
DE-098 (Anti-APO-1 antibody)	Rheumatoid arthritis	Argenes	Phase I / IIa	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. Santen granted the domestic development rights to Argenes, Inc. The compound had been in-licensed from Centocor. In Japan and Europe, the clinical study has been started. Santen continues to hold the marketing rights in Japan and the overseas marketing and development rights.

Changes from November 2, 2007

[Progress]

Dev. code	Indication	Status change	Clinical trial, NDA filing, Launch Region
DE-103	Allergic conjunctivitis	Phase I to Phase II	Japan