

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
	Oftaquix			Europe						May-02
Levofloxacin + prednisolone A	DE-094	Infectious keratitis	Daiichi Pharmaceutical	USA						

Characteristics: Fluoroquinolone antibacterial agent. In Europe, Ofaquix has obtained marketing authorization in 22 countries and was launched in 11 countries including Germany. Levofloxacin + prednisolone A is a combination treatment with steroids.

Generic name	Brand name/dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Pemirolast potassium	Alegysal	Allergic conjunctivitis	Mitsubishi Pharma	Japan						Apr-95
	Alamast			USA						Jul-00
	Alamast			Europe					Dec-99	

Characteristics: A mast cell stabilizer with superior efficacy on allergic conjunctivitis and vernal keratoconjunctivitis.

Generic name	Brand name/dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Ciclosporin	PAPILOCK Mini	Vernal keratoconjunctivitis	Novartis Pharma	Japan						Jan-06

Characteristics: An orphan drug. Ophthalmic application of immuno-suppressant ciclosporin. Expected to treat advanced vernal keratoconjunctivitis for which existing anti-allergic agents are not effective.

Generic name	Brand name/dev. code	Indication	Original/licensor	Region	Ph I	Ph II	Ph III	NDA Filed	Approved	Launched
Tafloprost	DE-085	Glaucoma/ ocular hypertension	Co-development with Asahi Glass	Japan						
				USA/Europe						

Characteristics: Prostaglandin glaucoma treatment that reduces intraocular pressure. Clinical trials are being conducted in parallel in Japan, the U.S. and Europe. Expected to have greater efficacy in reducing intraocular pressure than other prostaglandin products. Can be stored at room temperature.

Generic name	Brand 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						

Characteristics: The only angiotensin II receptor antagonist in full-fledged development as a glaucoma treatment. Comparable to prostaglandin products in reducing intraocular pressure. Very few side effects, including conjunctival hyperemia, are expected. Great potential for the U.S. and European markets where patients with ocular hypertension account for the majority of the glaucoma population.

Generic name	Brand 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	Brand 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 dry eye that stimulates the ocular surface to secrete tear fluid and moisture. Expected to be used in combination with existing dry eye treatments, and be effective for patients for whom existing treatments are insufficient.

Generic name	Brand 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 has been observed in basic research. In addition to RA the effect on DME was also observed in basic research, clinical studies are being conducted with both.

Generic name	Brand 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 promoting the corneal epithelial migration. Preservative-free eye ointment that can be used in combination with existing drugs.

Pipeline of prescription pharmaceuticals (In preparation for clinical trials)

Generic name	Brand name/dev. code	Indication	Original/in-licensor
Bucillamine	Rimatil	Osteoarthritis (additional indication)	Original
Characteristics: Shown to be effective on joint inflammation caused by osteoarthritis.			

Generic name (USA)	Code name	Indication	Original/in-licensor
Rivoglitazone	DE-101	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Sankyo
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.			

Product under development	Product name	Region
Intraocular lens	MD-14	Japan and USA
Characteristics: Foldable intraocular lens using new material with high refractive index. Developed by U.S. subsidiary Advanced Vision Science, Inc.. NDA filed in Japan. Preparing for NDA file in the USA.		

License out

Brand name/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, 2005

[Progress]

Brand name/dev. code	Indication	Region	Status change
Ciclosporin / PAPILOCK Mini	Vernal keratoconjunctivitis	Japan	Approved to launched