

Reference information

Research & development

■ Pipeline of prescription pharmaceuticals (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Tafluprost	DE-085	Glaucoma/ Ocular hypertension	Co-development with Asahi Glass	Japan						Dec-08
				Europe						Jun-08
				U.S.	(Licensed Out)					
				Latin America	(Licensed Out)					Aug-10
				Asia						Mar-10

Prostaglandin F2 α derivative for the treatment of glaucoma and ocular hypertension. Launched in Japan in December, 2008. In Europe, it is marketed in Germany, Denmark, etc. In U.S., development rights were granted to Merck &Co., Inc. (U.S.) in April, 2009. In Asia, it is marketed in Hong Kong, Korea, Indonesia, Singapore. NDA filed in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Diquafosol sodium	DE-089	Dry eye	Inspire	Japan						Dec-10
				Asia						Mar-11

A dry eye treatment drug which stimulates secretion of mucin and aqueous components from the corneal epithelium. Its mechanism of action is different from other existing treatments. Launched in Japan in December, 2010. NDA has been filed in Korea, and NDA is under preparation in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Lomerizine HCl	DE-090	Glaucoma	MSD	Japan						

A new type of glaucoma treatment which inhibits the progression of visual field defects. It is the only calcium antagonist being development as an oral glaucoma treatment. Compared to NMDA receptor antagonists, systemic adverse drug reactions are mild and has excellent safety profile.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Rivoglitazone	DE-101	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Daiichi Sankyo	U.S.						

Based on its anti-inflammatory properties, quantitative and qualitative tear film improvement effect is expected. P2 study has been started in U.S.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Betamethasone	DE-102	Diabetic macular edema	Co-development with Oakwood	Japan		(Phase 2/3)				

A steroid microsphere product for sustained release injection. Animal studies demonstrated sustained efficacy when injected around the affected area. Collaborating with Oakwood Laboratories (U.S.) for manufacturing technology development on commercial scale.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
(Undetermined)	DE-105	Persistent corneal epithelial defects	Original	U.S.						
				Japan						

Expected to accelerate corneal epithelial migration and demonstrate high safety profile in treatment-resistant, persistent corneal epithelial defects.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Levofloxacin (1.5%)	DE-108	Bacterial conjunctivitis	Daiichi Sankyo	Japan						Jun-11

A high-concentration fluoroquinolone antibacterial agent. Launched in Japan in June 2011.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Sirolimus	DE-109	Uveitis	Original	U.S.						

Intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. Santen acquired global development, manufacturing and marketing rights in June 2010.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
(Undetermined)	DE-110	Corneal and conjunctival epithelial disorder associated with dry eye, etc.	Original	U.S.						

A selective glucocorticoid receptor agonist (SEGRA). Phase 2 clinical trials are being conducted in the U.S. for the treatment of corneal and conjunctival epithelial disorders associated with dry eye, etc.

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Tafluprost/ timolol maleate	DE-111	Glaucoma/ Ocular hypertension	Original	Japan						
			Co-development	Europe						
A combination drug of a prostaglandin F2 α derivative and a beta-adrenergic receptor blocker.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
(Undetermined)	DE-112	Glaucoma/ Ocular hypertension	Forest Laboratories	U.S.	(Phase 1/2a)					
A highly selective adenosine A _{2A} receptor agonist for the treatment of glaucoma and ocular hypertension. A new mechanism of action different from prostaglandin derivative, and is expected to promote aqueous humor outflow from trabecular meshwork.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
Epinastine HCl	DE-114	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan						
An H1 receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
(Undetermined)	DE-098 (Anti-APO-1 antibody)	Rheumatoid arthritis	Centocor	Japan						
Joint injection inducing apoptosis in diseased joints of rheumatoid arthritis patients. Santen acquired domestic and international development and marketing rights of Anti-APO-1 antibody from Centocor, Inc.										

■ Changes from August 2, 2011

[Progress]

Dev. code	Changes
DE-089	NDA under preparation in China
DE-101	Phase 2 Started