As of April 2024

Pipeline Development Status (Clinical Stage)

<Glaucoma and ocular hypertension area>

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
tafluprost / timolol maleate	STN1011101 / DE-111A	Glaucoma / Ocular hypertension	Co-development with AGC	China				Dec-2022		

A fixed dose combination drug of a prostaglandin $F_{2\alpha}$ derivative and a beta-adrenergic receptor blocker. Launched in Japan in November 2014. Launched successively in European countries since January 2015. Launched successively in Asian countries since April 2016. Filed marketing approval in December 2022 in China.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sepetaprost	STN1012600 / DE-126	Glaucoma / Ocular hypertension	ONO PHARMACEUTICAL	U.S.						
				Japan						
				Europe	(Exploratory study)					

A prostaglandin analogue eye drop drug product with a novel mode of action that is a dual agonist for both FP and EP3 receptors for the treatment of glaucoma and ocular hypertension. Completed an additional Phase 2 in December 2021 in the U.S.. Completed Phase 3 in June 2023 in Japan. Completed Phase 2 (exploratory study) in Europe.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
latanoprost	STN1013001 / DE-130A (Catioprost)	Glaucoma / Ocular hypertension	Original	Europe				Nov-2023		
				Asia						

An ophthalmic emulsion of a prostaglandin $F_{2\alpha}$ derivative, for the treatment of glaucoma and ocular hypertension. Completed Phase 3 in March 2022 in Asia. Received marketing approval in November 2023 in Europe.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesilate	STN1013900 / AR-13324	Glaucoma / Ocular hypertension	Alcon Inc.	Japan						
				Europe						Feb-2023
				Asia					Jan-2023	

A ROCK (Rho-associated kinase) inhibitor. Developed and sold by Alcon Inc. in the U.S.. Conducting Phase 3 from November 2020 in Japan. Received marketing approval in Europe and has been launched in Sweden and other countries from February 2023. Filed successively for marketing approval in Asian countries and received marketing approval in Thailand and other countries from January 2023 onward.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesilate / latanoprost	STN1014000 / PG-324	Glaucoma / Ocular hypertension	Alcon Inc.	Europe						Jan-2023
				Asia					Jan-2023	

A fixed dose combination drug of a ROCK (Rho-associated kinase) inhibitor and a prostaglandin $F_{2\alpha}$ derivative. Developed and sold by Alcon Inc. in the U.S.. Received marketing approval in Europe and has been launched in Germany and other countries from January 2023. Filed successively for marketing approval in Asian countries and received marketing approval in Thailand and other countries from January 2023 onward.

<Keratoconjunctival disease area including dry eye >

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
ciclosporin	STN1007603 / DE-076C	Vernal keratoconjunctivitis	Original	China				Apr-2022		

An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue penetration. Launched successively in European countries since October 2018. Launched successively in Asian countries after receiving approval for an indication expansion for *Ikervis* in August 2019. Launched in November 2019 in Canada. Launched in May 2022 in the U.S. and received marketing approval in April 2022 in China. In July 2023, the Company granted Harrow Health, Inc. (U.S.) exclusive rights in the U.S. and Canada for product manufacturing and commercialization.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
diquafosol sodium	STN1008903 / DE-089C	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	Japan						Nov-2022
				Asia					Mar-2024	

A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Long-acting drug. Launched in November 2022 in Japan. In Asia, received marketing approval in March 2024 in South Korea.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
olodaterol hydrochloride	STN1014100	Dry eye	Boehringer Ingelheim	Japan	(Phase 1/2a)					

β2 receptor agonist. Completed Phase 1/2a in March 2024 in Japan.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	STN1010904	Fuchs endothelial corneal dystrophy	Joint development with ActualEyes	U.S. France India	(Phase 2a)					

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
An ophthalmic suspension which treats Fuchs endothelial corneal dystrophy via mTOR inhibition. Conducting Phase 2a in U.S., France and India from May 2022. (*The development code (STN1010904) is due to be assigned to the product when Santen obtains an exclusive license upon completion of Phase 2 clinical trial)										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	STN1010905	Meibomian gland dysfunction	Original	Japan	(Phase 2a)					
An ophthalmic suspension which improves meibomian gland function via mTOR inhibition. Completed Phase 2a in August 2022 in Japan. Planning an additional Phase 2a.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
epinastine hydrochloride	STN1011402	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan				Mar-2024		
A histamine H_1 receptor antagonist with mediator release inhibitor function, as treatment for allergic conjunctivitis. Ophthalmic eyelid cream. Received manufacturing and marketing approval in March 2024 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
epinastine hydrochloride	STN1011403	Allergic conjunctivitis	Nippon Boehringer Ingelheim	China						
A histamine H_1 receptor antagonist with mediator release inhibitor function, as treatment for allergic conjunctivitis. High dose formulation to instill twice a day. Started Phase 3 in March 2024 in China.										

<Refractive error>

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
atropine sulfate	STN1012700 / DE-127	Myopia	Singapore Health Services, Nanyang Technological University	Japan				Feb-2024		
				China			(Phase 2/3)			
				Asia						
Non-selective muscarinic antagonist which reduces progression of juvenile myopia. Filed for manufacturing and marketing approval in February 2024 in Japan. Conducting Phase 2/3 from June 2022 in China. Completed Phase 2 in April 2020 in Asia.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
atropine sulfate	STN1012701 / SYD-101	Myopia	Sydnexis Inc.	Europe						
Non-selective muscarinic antagonist which reduces progression of juvenile myopia. Sydnexis Inc., the licensor, is conducting Phase 3 trial in Europe and the U.S.. Santen has obtained the exclusive license for Europe, Middle East and Africa.										

Compound name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
AFDX0250BS	STN1013400	Myopia	Boehringer Ingelheim	Japan		(Phase 2a)				
				China						
Selective muscarinic M2 antagonist which reduces progression of juvenile myopia. Reduces mydriasis by selectively inhibiting a subtype of receptors. Conducting Phase 2a from May 2023 in Japan. Completed Phase1 in March 2024 in China.										

<Others>

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
oxymetazoline hydrochloride	STN1013800	Ptosis	RVL Pharmaceuticals	Japan						
A direct-acting alpha adrenergic receptor agonist. Developed and sold by RVL Pharmaceuticals in the U.S.. Completed Phase 3 in March 2024 in Japan.										

Changes from Q3 FY2023 (February 8, 2024)

Dev. Code	Changes
STN1008903 / DE-089C	Received marketing approval in March 2024 in South Korea.
STN1011402	Received manufacturing and marketing approval in March 2024 in Japan.
STN1011403	Started Phase 3 in March 2024 in China.
STN1012700 / DE-127	Filed for manufacturing and marketing approval in February 2024 in Japan.

※ STN1011700 (DE-117, generic name: omidenepag isopropyl) is sold as *Eybelis* in Japan and Asia. In the U.S., Santen has received approval as *OMLONTI* and granted exclusive rights for product manufacturing and commercialization to Visiox Pharmaceuticals, Inc. (U.S.) in July 2023.
※ The development of STN1013600 (generic name: ursodeoxycholic acid) was discontinued following the review of Phase 2a data.