

Pipeline Development Status (Clinical Stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
cyclosporin	STN1007603 / DE-076C	Vernal keratoconjunctivitis	Original	U.S.	May-2022					
				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.										
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					
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.										
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)					
An ophthalmic suspension which treats Fuchs endothelial corneal dystrophy via mTOR inhibition. Started Phase 2a in U.S., France and India in 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.										
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						
A fixed dose combination drug of a prostaglandin F _{2α} 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. Started Phase 3 in January 2019 in China.										
Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
epinastine hydrochloride	STN1011402	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan						
A histamine H ₁ receptor antagonist with mediator release inhibitor function, as treatment for allergic conjunctivitis. Ophthalmic cream. Completed Phase 3 in October 2022 in Japan.										
Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
omidenepeg isopropyl	STN1011700 /DE-117	Glaucoma/ Ocular hypertension	Co-development with UBE Corporation	U.S.	Sep-2022					
				Japan	Nov-2018					
				Asia	Feb-2021					
An EP2 receptor agonist with a new mechanism of action. Received marketing approval in September 2022 in the U.S.. Launched in November 2018 in Japan. Launched successively in Asian countries since launch in February 2021 in Korea.										
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.. Started Phase 3 in August 2022 in Japan. Conducting Phase 2 (exploratory study) since September 2021 in Europe.										
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	(Phase 2/3)					
				China	(Phase 2/3)					
				Asia						
Non-selective muscarinic antagonist which reduces progression of juvenile myopia. Conducting Phase 2/3 from August 2019 in Japan. Started Phase 2/3 in 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.										

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glaucoma implant device	STN2000100 / DE-128	Glaucoma	Original	Japan						Jul-2022
				Europe						Apr-2019
				Asia						Oct-2022

A drainage implant device designed to lower intraocular pressure (IOP) for the treatment of primary open-angle glaucoma through the drainage of aqueous humor. Launched (soft launch) in July 2022 in Japan. Launched in Europe in April 2019. In Asia received approval in Singapore and other countries since September 2021, and launched in October 2022 in Malaysia.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
latanoprost	STN1013001 / DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe					Sep-2022	
				Asia						

An ophthalmic emulsion of a prostaglandin F_{2α} derivative, for the treatment of glaucoma and ocular hypertension. Completed Phase 3 in March 2022 in Europe and Asia. Filed for marketing approval in September 2022 in Europe.

Compound name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
AFDX0250BS	STN1013400	Myopia	Boehringer Ingelheim	Japan						

Selective muscarinic M2 antagonist which reduces progression of juvenile myopia. Reduce mydriasis by selectively inhibiting a subtype of receptors. Completed Phase 1 in September 2021 in Japan.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
ursodeoxycholic acid	STN1013600	Presbyopia	Original	U.S.		(Phase 2a)				
				Japan						

Improvement of presbyopia by improving lens elasticity. Started P2a in December 2022 in U.S.. Completed Phase 1 in April 2022 in Japan.

Generic name	Dev. code	Indication	Original/Licensors	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.. Started Phase 3 in October 2022 in Japan.

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

A ROCK (Rho-associated kinase) inhibitor. Developed and sold by Alcon in the U.S.. Conducting Phase 3 from November 2020 in Japan. Received marketing approval in Europe. Received marketing approval in January 2023 in Thailand with successive filings made in Asian countries.

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

A fixed dose combination drug of a ROCK (Rho-associated kinase) inhibitor and a prostaglandin F_{2α} derivative. Developed and sold by Alcon in the U.S. Received marketing approval in Europe and launched in January 2023 in Germany. Received marketing approval in January 2023 in Thailand with successive filings planned for Asian countries.

*changed to Alcon due to the completion of its acquisition of Aerie Pharmaceuticals, Inc. in Nov 2022

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

β₂ receptor agonist. Started Phase 1/2a in January 2023 in Japan.

Changes from Q2 FY2022 (November 8, 2022)

Dev. Code	Changes
STN1008903 / DE-089C	Launched in November 2022 in Japan.
STN2000100 / DE-128	Launched in October 2022 in Malaysia.
STN1013600	Started P2a in December 2022 in U.S.
STN1013900 / AR-13324	Received marketing approval in January 2023 in Thailand.
STN1014000 / PG-324	Launched in January 2023 in Germany. Received marketing approval in January 2023 in Thailand.
STN1014100	Started Phase 1/2a in January 2023 in Japan.