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 extension for Ikervis in August 2019. Launched in November 2019 in Canada. Launched in May 2022 in the U.S. and obtained 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				Aug-2021		
A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Long-lasting drug. Filed for manufacturing and marketing approval in August 2021 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
sirolimus	STN1010904	Fuch's endothelial corneal dystrophy	Joint development with ActualEyes	TBD						
An ophthalmic suspension which treats Fuch's endothelial corneal dystrophy via mTOR inhibition. Phase 1 has completed, and the IND for Phase 2a in US and other countries has been submitted to US FDA (*The development code (STN1010904) is due to be assigned to the product when Santen obtains 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. Started P2a in October 2021 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 $F_2\alpha$ 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. Conducting Phase 3 from 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						
An H_1 receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis. Ophthalmic cream. Started Phase 3 in February 2022 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
omidenepag isopropyl	STN1011700 / DE-117	Glaucoma/ Ocular hypertension	Co-development with UBE Corporation	U.S.				Nov-2020		
				Japan						Nov-2018
				Asia						Feb-2021
An EP2 receptor agonist with a new mechanism of action. Received a complete response letter from FDA in November 2021 and preparing for resubmission in May 2022 in the U.S. Launched in November 2018 in Japan. Filed successively for marketing approval in Asian countries and launched 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		(Phase 2b)				
				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 2b in Japan. Started Phase 2 (exploratory study) in 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						
				Asia						
Non-selective muscarinic antagonist which reduces juvenile myopia progression. Conducting Phase 2/3 from August 2019 in Japan.Completed Phase 1 in April 2022 in China. Completed P2 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 juvenile myopia progression. 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.										

—	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
glaucoma implant device	STN2000100* / DE-128	Glaucoma	Original	Japan					Feb-2022	
				Europe						Apr-2019
				Asia					Sep-2021	
A drainage implant device designed to lower and sustain intraocular pressure (IOP) for the treatment of primary open-angle glaucoma through the drainage of aqueous humor. Received marketing approval in February 2022 in Japan. Launched in Europe in April 2019. Filed successively for marketing approval in Asian countries since March 2020 and received approval in Singapore and other countries since September 2021. Received rejection letter in April 2021 but considering re-filing in Korea.										

*License-out to Glaukos in Americas, Australia and New Zealand in May 2021. Received a not approvable letter of PMA from FDA in April 2022 in U.S. Received marketing approval in March 2021 in Canada and in May 2021 in Australia.

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

Compound name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
AFDX0250BS	STN1013400	Myopia	Boehringer Ingelheim	Japan						
Selective muscarinic M2 antagonist which reduces juvenile myopia progression. Reduce mydriasis to selectively inhibit a subtype of receptors. Completed Phase1 in September 2021 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
Ursodeoxycholic acid	STN1013600	Presbyopia	Original	Japan						
Improvement of presbyopia by improving the lens elasticity. Completed Phase 1 in April 2022 in Japan.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesylate	STN1013900 / AR-13324	Glaucoma / Ocular hypertension	Aerie	Japan						
				Asia					Mar-2022	
A ROCK (Rho-associated kinase) inhibitor. Developed and sold by Aerie in the U.S. Conducting Phase 3 from November 2020 in Japan. Filed for marketing approval in March 2022 in Asia.										

Changes from Q3 FY2021 (February 10, 2022)

Dev. Code	Changes
STN1007603 / DE-076C	Launched in May 2022 in the U.S. Obtained marketing approval in April 2022 in China.
STN1010900 / DE-109	The company has discontinued development upon reassessment of business feasibility.
STN1011402	Started Phase 3 in February 2022 in Japan.
STN2000100 / DE-128	Received marketing approval in February 2022 in Japan.
STN1013600	Completed Phase 1 in April 2022 in Japan.
STN1013900 / AR-13324	Filed for marketing approval in March 2022 in Asia.