

Pipeline Development Status (Clinical Stage)

<Glaucoma and ocular hypertension area>

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
tafluprost / timolol maleate	STN1011101 / DE-111A	Glaucoma / Ocular hypertension	Co-development with AGC	China	Mar-2025					

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. Received marketing approval in March 2025 in China.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
omidenepeg isopropyl	STN1011702	Glaucoma / Ocular hypertension	Co-development with UBE Corporation	China						

A unit dose, preservative free eye drop, EP2 receptor agonist with a new mechanism of action, sold in Japan and Asia. Started Phase 3 in November 2024 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	Sep-2024						
				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.. Filed for manufacturing and marketing approval in September 2024 in Japan. Completed Phase 2 (exploratory study) in Europe.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
latanoprost	STN1013001 / DE-130A (Catioprost)	Glaucoma / Ocular hypertension	Original	Europe	Aug-2024					
				Asia	Nov-2024					

An ophthalmic emulsion of a prostaglandin $F_{2\alpha}$ derivative, for the treatment of glaucoma and ocular hypertension. Filed for marketing approval in November 2024 in Asia. Launched in August 2024 in European countries including Spain.

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
netarsudil mesylate	STN1013900 / AR-13324	Glaucoma / Ocular hypertension	Alcon Inc.	Japan						
				Europe	Feb-2023					
				Asia	Nov-2024					

A ROCK (Rho-associated kinase) inhibitor. Developed and sold by Alcon Inc. in the U.S.. Completed Phase 3 in January 2025 in Japan. Received marketing approval in Europe and has been launched in Sweden and other countries from February 2023. Successively received marketing approval in Asian countries and launched in South Korea in November 2024.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
Netarsudil mesylate / latanoprost	STN1014000 / PG-324	Glaucoma / Ocular hypertension	Alcon Inc.	Europe	Jan-2023					
				Asia	Mar-2025					

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. Received marketing approval successively in Asian countries and launched in March 2025 in Singapore.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
Netarsudil mesylate / latanoprost	STN1014003	Glaucoma / Ocular hypertension	Alcon Inc.	Japan						

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.. Uses a different container from that of STN1014000. Started Phase 3 in February 2025 in Japan.

<Keratoconjunctival disease area including dry eye >

Generic name	Dev. code	Indication	Original/Licensors	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. Received marketing approval in April 2022 in China.

Generic name	Dev. code	Indication	Original/Licensors	Region	P1	P2	P3	Filed	Approved	Launched
diquafosol sodium	STN1008903 / DE-089C	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	Japan	Nov-2022					
				Asia	Received marketing approval but deregistered product license					

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 South Korea in March 2024 but deregistered product license in August 2024.

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)					
β ₂ 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)					
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. Started an additional Phase 2a in June 2024 in Japan.										
Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
epinastine hydrochloride	STN1011402	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan	May-2024					
A histamine H ₁ receptor antagonist with mediator release inhibitor function, as treatment for allergic conjunctivitis. Ophthalmic eyelid cream. Launched in May 2024 in Japan.										
Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
epinastine hydrochloride	STN1011403	Allergic conjunctivitis	Boehringer Ingelheim	China	Mar-2025					
A histamine H ₁ receptor antagonist with mediator release inhibitor function, as treatment for allergic conjunctivitis. High dose formulation to instill twice a day. Filed for marketing approval in March 2025 in China.										
< Refractive disorder>										
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	Apr-2025					
				China	(Phase 2/3)					
				Asia						
Non-selective muscarinic antagonist which reduces progression of juvenile myopia. Launched in April 2025 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	Mar-2024					
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 and filed for marketing authorization approval in March 2024 and received a positive CHMP opinion in March 2025 in Europe										
<Others>										
Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	Filed	Approved	Launched
oxymetazoline hydrochloride	STN1013800	Ptosis	RVL Pharmaceuticals	Japan	Dec-2024					
				Europe						
				China						
A direct-acting alpha adrenergic receptor agonist. Developed and sold by RVL Pharmaceuticals in the U.S.. Filed for manufacturing and marketing approval in December 2024 in Japan. Started Phase 3 in December 2024 in Europe. Started Phase 3 in October 2024 in China.										

Changes from Q3 FY2024 (February 6, 2025)

Dev. Code	Changes
STN1011101 / DE-111A	Received marketing approval in March 2025 in China.
STN1014000 / PG-324	In Asian countries, launched in March 2025 in Singapore.
STN1014003	Started Phase 3 in February 2025 in Japan.
STN1011403	Filed for marketing approval in March 2025 in China.
STN1012700 / DE-127	Launched in April 2025 in Japan.
STN1012701 / SYD-101	Received positive CHMP opinion in March 2025 in Europe

※ The development of STN1013400 (compound name: AFDX0250BS) was discontinued following the review of Phase 2a data.