As of January 2025

# 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 |
|---|---|---|---|---|---|---|---|---|---|---|
| omidenepag 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/Licensor | 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/Licensor | Region | P1 | P2 | P3 | Filed | Approved | Launched |
|---|---|---|---|---|---|---|---|---|---|---|
| Netarsudil mesylate / 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. 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 |
| | | | | 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) | | | | |

$\beta_2$ 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.<br>France<br>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 | | | | | | |
| A histamine $H_1$ receptor antagonist with mediator release inhibitor function, as treatment for allergic conjunctivitis. High dose formulation to instill twice a day. Completed Phase 3 in November 2024 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 | | | | | Dec-2024 | |
| | | | | China | | (Phase 2/3) | | | | |
| | | | | Asia | | | | | | |
| Non-selective muscarinic antagonist which reduces progression of juvenile myopia. Received manufacturing and marketing approval in December 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 | | | | 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 in Europe | | | | | | | | | | |

| 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 | | | | 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 Q2 FY2024 (November 7, 2024)

| Dev. Code | Changes |
|---|---|
| STN1011702 | Started Phase 3 in November 2024 in China. |
| STN1013001 / DE-130A | Filed for marketing approval in November 2024 in Asia. |
| STN1013900 / AR-13324 | Completed Phase 3 in January 2025 in Japan. |
| STN1011403 | Completed Phase 3 in November 2024 in China. |
| STN1012700 / DE-127 | Received manufacturing and marketing approval in December 2024 in Japan. |
| STN1012701 / SYD-101 | Filed for marketing authorization approval in March 2024 in Europe. |
| STN1013800 | Filed for manufacturing and marketing approval in December 2024 in Japan.<br>Started Phase 3 in December 2024 in Europe. |