Research & development

As of May 9, 2018

■Pipeline of prescription pharmaceuticals (clinical stage)

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
diquafosol sodium	DE-089	Dry eye	Merck Sharp & Dohme Corp. (U.S.)	China					Oct-17	
A dry eye treatment which stimulates secretion of mucin and aqueous components from the corneal and conjunctival epithelium. Its mechanism of action is different from existing treatments. Launched in December 2010 in Japan. Acquired import drug license in China in October 2017. Launched in October 2013 in Korea. Launched in Vietnam in February 2016. Launched in Thailand in April 2016. Currently seeking sequential approvals for marketing in Asia.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
sirolimus	DE-109	Uveitis	Original	U.S.						
				Japan						
				Europe						
				Asia					Apr-15	
An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. Planning an additional clinical trial in the U.S. NDA filed in Asia in April 2015.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
epinastine hydrochloride	DE-114A	Allergic conjunctivitis	Nippon Boehringer Ingelheim	Japan						
An H_1 receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis. High dose drug. Started Phase 3 in Japan in May 2017.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
omidenepag isopropyl	DE-117	Glaucoma/ Ocular hypertension	Co-development with Ube Industries	U.S.						
				Japan					Nov-17	
				Asia						
An EP2 receptor agonist with a new mechanism of action. Completed Phase 2b in the U.S. in February 2015. Filed for manufacturing and marketing approval in Japan in November 2017. Started Phase 3 in Asia in December 2016.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
carotuximab	DE-122	Wet Age-related macular degeneration	TRACON Pharmaceuticals	U.S.	(Phase 2a)					
An intravitreal injection of anti-endoglin antibody. Started Phase 2a in July 2017 for development in the U.S.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
sepetaprost	DE-126	Glaucoma/ Ocular hypertension	ONO PHARMACEUTICAL	U.S.	(Phase 2b)					
				Japan	(Phase 2b)					
A prostaglandin analogue eye drop drug product with a novel mode of action that is both FP and EP3 receptors dual agonist for the treatment of glaucoma and ocular hypertension. Started Phase 2b in the U.S. and Japan in July 2017.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
atropine sulfate	DE-127	Myopia	Singapore Health Services, Nanyang Technological University	Asia						
Muscarinic antagonist which reduces juvenile myopia progression. Started Phase 2 in Asia in November 2017.										

–	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
–	DE-128 *(InnFocus MicroShunt)*	Glaucoma	Original	U.S.			(Phase 2/3)			
				Europe						
In August 2016, acquired InnFocus, developer of InnFocus MicroShunt. MicroShunt is 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.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	DE-076B (Cyclokat)	Severe keratitis in patients with dry eye	Original	U.S.						
				Asia						Dec-17
An ophthalmic emulsion to treat severe keratitis in adult patients with dry eye through an immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption. Launched in Germany and England in July 2015 with successive launches following in European countries. Currently seeking sequential approvals for marketing in Asia and launched in Thailand in December 2017. Received a Notice of Non-compliance (NON) from Health Canada in April 2018.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
ciclosporin	DE-076C (Vekacia)	Vernal Keratoconjunctivitis	Original	Europe				Dec-16		
An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cationic emulsion technology has enhanced ocular tissue absorption. NDA filed and granted Priority Review status in Europe in December 2016. In July 2017, the Committee for Human Medicinal Products of the European Medicines Agency adopted a positive opinion, recommending the marketing authorization.										

Generic name	Dev. code	Indication	Original/Licensor	Region	P1	P2	P3	NDA Filed	Approved	Launched
latanoprost	DE-130A (Catioprost)	Glaucoma/ Ocular hypertension	Original	Europe						
An ophthalmic emulsion of a prostaglandin F2α derivative, for the treatment of glaucoma and ocular hypertension.										

■Changes from Q3 FY17 (February 6, 2018)

Dev. Code	Changes
DE-076B (Cyclokat)	Received a Notice of Non-compliance (NON) from Health Canada in April 2018.