## Pipeline of prescription pharmaceuticals (Clinical Stage)

### diquafosol sodium

**Generic name**: Diquafosol sodium

**Dev. code**: DE-089

**Indication**: Dry eye

**Original/Licensor**: Merck Sharp & Dohme Corp. (U.S.)

**Region**

- **P1**: NDA Filed (Jan-2012)
- **P2**: Approved
- **P3**: Launched


### sirolimus

**Generic name**: Sirolimus

**Dev. code**: DE-109

**Indication**: Uveitis

**Original/Licensor**: Original

**Region**

- **P1**: NDA Filed (Feb-2017)
- **P2**: Approved
- **P3**: Launched

An intravitreal injection with immunosuppressive effect, anti-angiogenic effect, etc. NDA filed in the U.S. in February 2017. Preparing NDA file in Europe. NDA filed in Asia in April 2015.

### epinastine hydrochloride

**Generic name**: Epinastine hydrochloride

**Dev. code**: DE-114A

**Indication**: Allergic conjunctivitis

**Original/Licensor**: Nippon Boehringer Ingelheim

**Region**

- **P1**: NDA Filed (Japan)

An H1 receptor antagonist with membrane-stabilizing function, as treatment for allergic conjunctivitis. High dose drug. Started Phase 3 in Japan in May 2017.

### omidenepag isopropyl

**Generic name**: Omidenepag isopropyl

**Dev. code**: DE-117

**Indication**: Glaucoma/ Ocular hypertension

**Original/Licensor**: Co-development with Ube Industries

**Region**

- **P1**: NDA Filed (U.S.)
- **P2**: Approved
- **P3**: Launched


### carotuximab

**Generic name**: Carotuximab

**Dev. code**: DE-122

**Indication**: Wet Age-related macular degeneration

**Original/Licensor**: TRACON Pharmaceuticals

**Region**

- **P1**: NDA Filed (U.S.) (Phase 2a)


### sepetaprost

**Generic name**: Sepetaprost

**Dev. code**: DE-126

**Indication**: Glaucoma/ Ocular hypertension

**Original/Licensor**: ONO PHARMACEUTICALS

**Region**

- **P1**: NDA Filed (Japan) (Phase 2b)

A prostaglandin analogue eye drop 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.

### ciclosporin

**Generic name**: Ciclosporin

**Dev. code**: DE-128 (InnFocus MicroShunt)

**Indication**: Glaucoma

**Original/Licensor**: InnFocus MicroShunt

**Region**

- **P1**: NDA Filed (U.S.) (Phase 2/3)

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.

### ciclosporin

**Generic name**: Ciclosporin

**Dev. code**: DE-129

**Indication**: Severe keratitis in patients with dry eye

**Original/Licensor**: Original

**Region**

- **P1**: NDA Filed (U.S.)
- **P2**: Approved
- **P3**: Launched

An ophthalmic emulsion to treat severe keratitis in adult patients with dry eye through an immunosuppressive effect. Cicatricial emulsion technology has enhanced ocular tissue absorption. Launched in Germany and England in July 2015 and planning successive launches in European countries. NDA filed in Asian countries successively and approved in some countries including Thailand (November 2016) and Korea (March 2017). NDA filed in Canada in April 2016.

### ciclosporin

**Generic name**: Ciclosporin

**Dev. code**: DE-130

**Indication**: Vernal Keratoconjunctivitis

**Original/Licensor**: Original

**Region**

- **P1**: NDA Filed (Europe)

An ophthalmic emulsion which improves vernal keratoconjunctivitis by immunosuppressive effect. Cicatricial 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.
<table>
<thead>
<tr>
<th>Generic name</th>
<th>Dev. name</th>
<th>Indication</th>
<th>Original/Licensor</th>
<th>Region</th>
<th>P1</th>
<th>P2</th>
<th>P3</th>
<th>NDA Filed</th>
<th>Approved</th>
<th>Launched</th>
</tr>
</thead>
<tbody>
<tr>
<td>latanoprost</td>
<td>Catiprost</td>
<td>Glaucoma/ Ocular hypertension</td>
<td>Original</td>
<td>Europe</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

An ophthalmic emulsion of a prostaglandin F2α derivative, for the treatment of glaucoma and ocular hypertension.

### Changes from Q4 FY16 (May 10, 2017)

<table>
<thead>
<tr>
<th>Dev. code / name</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>DE-114A</td>
<td>Started Phase 3 in Japan in May 2017.</td>
</tr>
</tbody>
</table>