Latanoprostene bunod for open-angle glaucoma or ocular hypertension – first line

LAY SUMMARY

Glaucoma is a common condition that can lead to a loss of vision and eventually blindness. It is usually caused by increased pressure of fluid in the eye (ocular hypertension) when the fluid cannot drain away as well as usual. Glaucoma is usually treated with eye drops, however current treatments are not always effective, and patients may require laser treatment or eye surgery.

Latanoprostene bunod is a new drug for the treatment of open-angle glaucoma and ocular hypertension. It is given as an eye drop taken once daily. Some studies have suggested latanoprostene bunod may be useful as a first line treatment and more studies are now aiming to show how well it works and that it is safe to use.

If latanoprostene bunod is licensed for use in the UK, it could be a new treatment option for patients with glaucoma which may reduce pressure in the eye and reduce vision loss. If it is more effective than the current first line treatment, it could mean fewer eye drops and fewer visits to clinics would be needed.

NIHR HSRIC ID: 2576
TARGET GROUP

- Open-angle glaucoma or ocular hypertension – first line.

TECHNOLOGY

DESCRIPTION

Latanoprostene bunod (Vesneo; BOL-303259X; NCX-116; PF-03187207) is a nitric oxide-donating prostaglandin F2-alpha analogue. Nitric oxide is believed to play a role in controlling intraocular pressure through relaxation of ciliary muscles and other structures which allow fluid drainage of the eye. In the phase III clinical trial, latanoprostene bunod is administered as a 0.024% ophthalmic solution once daily for a treatment period lasting up to a year.

Latanoprostene bunod does not currently have Marketing Authorisation in the EU for any indication and there are no other indications in development.

INNOVATION and/or ADVANTAGES

If licensed, latanoprostene bunod has the potential to provide an alternative treatment option for patients with open-angle glaucoma and ocular hypertension.

DEVELOPER

Bausch & Lomb.

AVAILABILITY, LAUNCH OR MARKETING

In phase III clinical trials.

PATIENT GROUP

BACKGROUND

Glaucoma is the name given to a group of eye conditions which cause optic nerve damage. This can be caused by raised intraocular pressure (ocular hypertension) or a weakness in the optic nerve. Open-angle glaucoma causes severe vision loss without any warning. The peripheral vision is affected initially, with vision loss in the centre of the visual field occurring later in the disease progress. This has a major impact on the quality of life of the patient.

Ocular hypertension is a term used to describe increased pressure inside the eye. It increases a person’s risk of developing glaucoma; approximately 10% of people with untreated ocular hypertension go on to develop glaucoma. Ocular hypertension differs from glaucoma as it is not directly associated with a detectable change in vision, evidence of visual field loss or damage to the optic nerve. Ocular hypertension is caused by inadequate draining of the aqueous humour, causing an excess of fluid in the eye and therefore increased pressure.
This topic is relevant to:

**CLINICAL NEED and BURDEN OF DISEASE**

In England and Wales, it is estimated that more than 500,000 people have glaucoma. Approximately 10% of UK blindness registrations are attributed to glaucoma. Open-angle glaucoma is the most common type of glaucoma; it has an overall prevalence of approximately 2% of people over the age of 40 years, and 5% of people over the age of 80 years.

In 2012, 7.96 million prescriptions were dispensed for topical glaucoma therapies costing approximately £103.7 million. In 2014, there were 2,463 admissions for ocular hypertension (H40.0) and 7,829 admissions for open-angle glaucoma (H40.1) in England, resulting in 387 bed days for ocular hypertension and 1,128 for open-angle glaucoma.

**PATIENT PATHWAY**

**RELEVANT GUIDANCE**

**NICE Guidance**

**Other Guidance**

**CURRENT TREATMENT OPTIONS**

Treatments for glaucoma aim to reduce pressure in the affected eye. Initial therapy is usually topical drug therapy (normally eye drops), followed by laser then surgical treatment if topical therapy alone is inadequate.

Current treatment options include:
- Topical drug therapies (eye drops):
  - Prostaglandin analogues – latanoprost; bimatoprost; tafluprost; travoprost.
  - Beta-adrenergic receptor blockers – betaxolol hydrochloride; levobunolol hydrochloride; timolol.
  - Alpha-agonists.
- Sympathomimetics – brimonidine tartrate.
- Carbonic anhydrase inhibitors – brinzolamide; dorzolamide.
- Cholinergic agonists.
- Oral therapy – carbonic anhydrase inhibitors.
- Laser treatment – laser trabeculoplasty is used to open up blocked drainage tubes.
- Surgical treatment – trabeculectomy, which removes part of the drainage tubes.

### EFFICACY and SAFETY

<table>
<thead>
<tr>
<th>Trial</th>
<th>Sponsor</th>
<th>Status</th>
<th>Location</th>
<th>Design</th>
<th>Participants</th>
<th>Schedule</th>
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</thead>
<tbody>
<tr>
<td>APOLLO, NCT01749904,</td>
<td>Bausch &amp; Lomb Incorporated.</td>
<td>Complete but unpublished.</td>
<td>Bulgaria and United States.</td>
<td>Randomised, active-controlled.</td>
<td>n=421; aged 18 years and older; open-angle glaucoma or ocular hypertension; first line treatment.</td>
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<tr>
<td>EudraCT2013-000552-18;</td>
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<td>Randomised to latanoprostene bunod ophthalmic solution once daily in the evening and its vehicle administered once daily in the morning; or timolol maleate eye drops (0.5%) once in the morning and once in the evening.</td>
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<td>BOL-303259-X vs timolol;</td>
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<td>Latanoprostene bunod 0.024% instilled into the eye once daily.</td>
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<tr>
<td>phase III.</td>
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<td>LUNAR, NCT01749930,</td>
<td>Bausch &amp; Lomb Incorporated.</td>
<td>Complete but unpublished.</td>
<td>Germany, Italy and United States.</td>
<td>Randomised, active-controlled.</td>
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<td>phase III.</td>
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<td>Follow-up</td>
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<td>Primary outcomes</td>
<td>Intraocular pressure.</td>
<td>Intraocular pressure.</td>
<td>Intraocular pressure and ocular AEs.</td>
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<tr>
<td>Secondary outcomes</td>
<td>Intraocular pressure ≤18mmHg; Intraocular pressure reduction ≥25%; and adverse events (AEs). No quality of life measurement included in trial outcomes.</td>
<td>Intraocular pressure ≤18mmHg; Intraocular pressure reduction ≥25%; and AEs. No quality of life measurement included in trial outcomes.</td>
<td>Not reported. No quality of life measurement included in trial outcomes.</td>
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<td>Adverse effects (AEs)</td>
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<td>Expected reporting date</td>
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<td>Previously reported as May 2015.</td>
<td>Study completion date reported as May 2015.</td>
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## ESTIMATED COST and IMPACT

### COST

The cost of latanoprostene bunod is not yet known. The current treatment latanoprost (50mg/ml) costs approximately £2.00 for a 2.5ml dropper bottle (approximately 50 drops)\(^{15}\).

### IMPACT - SPECULATIVE

#### Impact on Patients and Carers

- ✗ Reduced mortality/increased length of survival
- ✗ Reduced symptoms or disability; *If effective, visual field loss may be reduced*\(^{a}\).
- ✔ Other: *If effective, fewer clinic visits may be required*\(^{b}\).
- ✗ No impact identified

#### Impact on Health and Social Care Services

- ✗ Increased use of existing services
- ✗ Decreased use of existing services; *If effective, fewer clinic visits may be required*\(^{b}\).
- ✗ Re-organisation of existing services
- ✗ Need for new services
- ✔ Other: *If effective, there may be a reduced need for invasive surgery*\(^{b}\).
- ✗ None identified

#### Impact on Costs and Other Resource Use

- ✔ Increased drug treatment costs
- ✗ Reduced drug treatment costs
- ✗ Other reduction in costs; *There is potential for a reduction in cost due to a smaller number of therapies required.*
- ✔ None identified

#### Other Issues

- ✗ Clinical uncertainty or other research question identified:
- ✗ None identified

### REFERENCES


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\(^a\) Expert personal communication  
\(^b\) Expert personal communication