Glaucoma Pharmacology

Dr. James Thimons
Founding Partner/ Medical Director
Dr. Robert Noecker

Disclosures

• Speaker
  • Alcon
  • Allergan
  • PRN
  • Tear Lab
  • Shire
  • Zeiss
  • B&L
  • Diopsys
  • Reichart
  • Glaukos
  • InFocus
  • Aerie
Financial Disclosure

• I have the following financial interests or relationships to disclose:
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Medical Management of Glaucoma

The “Pearls” of Topical Therapy
Pathways to lower Intraocular Pressure

• Inflow
  • Alpha 2–agonists
  • B1 blockers
  • CAI

• Outflow
  • Alpha 2–agonists
  • Cholinergics
  • Prostaglandins/Prostamindes

Timolol

• Equally effective in blacks and whites
• IOP decrease 30-60 min
• Long term drift
  • 47% decrease at 1 wk
  • 25% at 1 yr
Systemic

- Bradycardia
- Congestive heart failure
- Exacerbation of heart block
- Bronchospasm
- Mood change
- Impotence
- Lipid profile

Contraindications

- Asthma
- Severs COPD
- Emphysema
- CHF
- Heart block
- Myasthenia gravis
- Diabetes
Brimonidine 0.1% alphagan alpha-2

- Decrease aqueous production
- Also increase uveoscleral outflow (small amount)
- Not as effective as timolol but close
- May be neuroprotective
- More effective than betaxalol or dorzolamine
- Can cause mild mydriasis

Side effects

- 10-30% dry mouth
- 10% allergy rate
- Avoid with MAO inhibitors
- Alphagan P 0.15%
  - Better tolerated
Alpha Agonists-side effects

- Ocular-
  - dermatitis,
  - lid retraction,
  - conjunctival blanching,
  - allergic reactions

- Systemic
  - dry mouth,
  - dry eye
  - lethargy,
  - apnea in children,
  - hypotension

Carbonic Anhydrase Inhibitors

- Aqueous humor formation depends on secretion of bicarbonate from the ciliary processes when bicarbonate is formed, it tied with sodium and water follows
- Similar process in CSF production and in kidney
CAI

- Dorzolamide 2%
- Brinzolamide 1%
- Acetazolamide 125, 250, 500mg sequels
- Methazolamide 25, 50 mg

Contraindications

- Sulfa allergies
- Sickle cell
- Marked kidney/liver
- Low potassium
- Low sodium level
- Pregnancy Category C
- Metabolic acidosis
Prostaglandins /Prostamides

• Uveal seleral outflow
• Affects many properties with the
• 1955-Ambache described irin which medicated ocular response to inflammation
• Naturally synthesized by trabecularendothelial cells/ciliary muscle cells
• May have only minor inflammatory
• Regulatory effects

• Latanoprost 0.005% Xalatan
  • Prostaglandin F 2a analogue
  • Prodrug
• Travoprost 0.004% Travatan
  • Prostaglandin F 2a analogue
  • Prodrug
• Brimatoprost 0.03% Lumigan
  • Synthetic prostamide analog
  • Not a prodrug
Latanoprost
(Xalatan 0.005%)

- More effective than timolol
- Can be used as a 1st line drug
- Lowers IOP 33% (about 7-8 mmHg)
- Prodrug activated by esterase in the cornea
- Does not cause or reactivate HSV

Xalatan side effects

- 2% CME pseudophakic pt but reversible
- 6% uveitis
- 7-16% hazel iris turn brown, hypertrichosis
Bimatoprost  
(Lumigan 0.03%)

- Lowers IOP 30-33%
- Favorable lowering of IOP with lumigan vs xalatan
- Side effects
  - 15-45% hyperemia
  - 15% ocular pruritis
  - 45% Eyelash growth
  - CME rare

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Glaucoma Therapy for the 21\textsuperscript{st} Century
INTRODUCING RHOPRESSA® (NETARSUDIL OPHTHALMIC SOLUTION) 0.02%

- RHOPRESSA® is a new class of drug and has a white cap
- RHOPRESSA® is available in 1-month supply (2.5 mL)
- After opening, the product may be kept at room temperature for up to 6 weeks

RHOPRESSA® (NETARSUDIL OPHTHALMIC SOLUTION) 0.02% IS A ONCE-DAILY THERAPY DESIGNED TO INHIBIT ROCK

**RHOPRESSA® PRODRUG**

- RHOPRESSA® was specifically designed to target the TM at the cellular level
- RHOPRESSA® prodrug is converted by corneal esterases into an active metabolite that has 5 x higher potency for ROCK inhibition
- RHOPRESSA® inhibits the creation of stress fibers in the TM tissues to relax the meshwork and improve trabecular outflow

**ACTIVE METABOLITE**

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Rhopressa
Inhibitor of Rho Kinase (ROCK) and Norepinephrine Transporter (NET)

Potentially lower IOP by three mechanisms
1. Increasing TM outflow
2. Reducing episcleral venous pressure
3. Reducing aqueous production (via NET inhibition)
IN A ROBUST CLINICAL TRIAL PROGRAM, OVER 800 PATIENTS WERE TREATED WITH RHOPRESSA® (NETARSUDIL OPHTHALMIC SOLUTION) 0.02%

- RHOPRESSA® 0.02% QD (PM) was compared with timolol 0.5% BID in ROCKET 1, ROCKET 2, and ROCKET 4.1,2
- Primary efficacy endpoint for all trials was mean IOP at week 2, week 6, and month 3.1,2

<table>
<thead>
<tr>
<th></th>
<th>PRIMARY EFICICITY ANALYSIS</th>
<th>SAFETY ANALYSIS</th>
<th>PRIMARY EFICICITY POPULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROCKET 11</td>
<td>n=202 (RHOPRESSA®)</td>
<td>3 months</td>
<td>3 months (post hoc analysis, &lt;27 mmHg)</td>
</tr>
<tr>
<td>(NCT02207491)</td>
<td>n=209 (timolol)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ROCKET 22</td>
<td>n=251 (RHOPRESSA®)</td>
<td>3 months</td>
<td>12 months &lt;25 mmHg</td>
</tr>
<tr>
<td>(NCT02207921)</td>
<td>n=251 (timolol)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ROCKET 42</td>
<td>n=351 (RHOPRESSA®)</td>
<td>3 months</td>
<td>6 months &lt;25 mmHg</td>
</tr>
<tr>
<td>(NCT02553374)</td>
<td>n=357 (timolol)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BID, twice daily; IOP, intraocular pressure; QD, once daily.

RHOPRESSA® (NETARSUDIL OPHTHALMIC SOLUTION) 0.02% MAINTAINED EFICICITY THROUGH 1 YEAR IN THE ROCKET 2 TRIAL

Mean IOP in Patients with Baseline IOP <25 mmHg Treated With RHOPRESSA® 0.02% QD (n=129)1-3

- IOP was collected at 8 AM only at months 6, 9, and 12 as a safety measure

For important safety information refer to the RHOPRESSA® Prescribing Information at the end of this presentation or at www.RHOPRESSA.com.
IOP, intraocular pressure; QD, once daily; SEM, standard error of the mean.
### RHOPRESSA® (NETARSUDIL OPHTHALMIC SOLUTION) 0.02% OCULAR ADVERSE EVENT PROFILE

<table>
<thead>
<tr>
<th>PREFERRED TERM (with incidence ≥25% [pooled safety population*])</th>
<th>RHOPRESSA® 0.02% OD (N=805) n (%)</th>
<th>TIMOLEL 0.5% BID (N=816) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conjunctival hyperemia</td>
<td>428 (53.2)</td>
<td>85 (10.4)</td>
</tr>
<tr>
<td>Corneal verticillata (corneal deposits)</td>
<td>162 (20.1)</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td>Conjunctival hemorrhage</td>
<td>137 (17.0)</td>
<td>15 (1.8)</td>
</tr>
<tr>
<td>Vision blurred</td>
<td>60 (7.5)</td>
<td>12 (1.5)</td>
</tr>
<tr>
<td>Lacrimation increased</td>
<td>53 (6.6)</td>
<td>5 (0.6)</td>
</tr>
<tr>
<td>Erythema of eyelid</td>
<td>52 (6.5)</td>
<td>4 (0.5)</td>
</tr>
<tr>
<td>Visual acuity reduced</td>
<td>44 (5.5)</td>
<td>13 (1.6)</td>
</tr>
<tr>
<td>General Disorders and Administration Site Conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instillation site pain</td>
<td>158 (19.6)</td>
<td>175 (21.4)</td>
</tr>
<tr>
<td>Instillation site erythema</td>
<td>74 (9.2)</td>
<td>13 (1.6)</td>
</tr>
<tr>
<td>Investigations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vital dye staining cornea present</td>
<td>65 (8.1)</td>
<td>57 (7.0)</td>
</tr>
</tbody>
</table>

*Includes ROCKET 1, ROCKET 2, and ROCKET 4.
1. Data on file, Aerie Pharmaceuticals, Inc.

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**Corneal Verticillata**

- Corneal Verticillata
  - Corneal verticillata occurred in approximately 20% of the patients in controlled clinical studies.
  - The corneal verticillata seen in RHOPRESSA-treated patients were first noted at 4 weeks of daily dosing.
  - This reaction did not result in any apparent visual functional changes in patients. Most corneal verticillata resolved upon discontinuation of treatment.
IN THE POOLED ROCKET STUDIES, CORNEA VERTICILLATA WAS MILD AND DID NOT AFFECT VISION

- Whorl-like pattern of phospholipid deposits caused by several cationic amphiphilic drugs
- The corneal verticillata were first noted at 4 weeks of daily dosing in RHOPRESSA® (netarsudil ophthalmic solution) 0.02% -treated patients
- Were asymptomatic and did not result in an apparent change in visual function
- Resolved in majority upon discontinuation of RHOPRESSA®

QD, once daily.
1. Ritzman et al. Surv Ophthalmol. 2017;62:286. 2. RHOPRESSA® (netarsudil ophthalmic solution) 0.02% Prescribing Information. 3. Courtesy of ROCKET Investigator.

IN THE POOLED ROCKET STUDIES, MILD CONJUNCTIVAL HEMORRHAGE WAS SELF-RESOLVING AND RARELY RESULTED IN DISCONTINUATION

- Typically small microhemorrhages localized to the limbal area which may be related to vasodilatory effect of the molecule
- Onset was variable, and duration was typically 1-3 weeks
- Conjunctival hemorrhage was mild in 90% of cases and self-resolving with continued dosing
- Resulted in discontinuation in 1% of patients treated with RHOPRESSA® (netarsudil ophthalmic solution) 0.02% QD

QD, once daily.
Rocklatan® and Rhopressa® Usage

- Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% is a new combination drug product and has a white cap
- Rocklatan® is available in a 1-month supply (2.5 mL)
- Protect from light. Must remain refrigerated

- Rhopressa® (netarsudil ophthalmic solution) 0.02% is a new class of drug and has a white cap
- Rhopressa® is available in a 1-month supply (2.5 mL)
- Refrigerate until opened. After opening, the product may be kept at room temperature for up to 6 weeks
Rocklatan

- The FDA approval of Rocklatan™ is based on data from two Phase 3 registration trials, MERCURY 1 and MERCURY 2.
- In these studies, Rocklatan™ achieved its primary 90-day efficacy endpoint as well as positive 12-month safety and efficacy results, demonstrating statistically superior IOP reduction over latanoprost and netarsudil at every measured time point.
- More than 60% of patients taking Rocklatan™ in the two MERCURY studies achieved an IOP reduction of 30% or more, a frequency that was nearly twice that achieved by participants taking latanoprost alone.
- Rocklatan™ also helped more patients get to low target pressures. Nearly twice as many patients taking Rocklatan™ reached 16 mmHg or lower and nearly three times as many reached 14 mmHg or lower compared to latanoprost.

Rocklatan® Achieved the Primary Endpoint of Superiority vs Both Individual Components Over 3 Months¹

- Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% was compared to its individual components Rhopressa® QD and latanoprost QD to establish statistical superiority in MERCURY-1 and MERCURY-2²,³
- Primary efficacy endpoint for both trials was mean IOP at 8 AM, 10 AM, and 4 PM at Week 2, Week 6, and Month 3, respectively. Primary safety endpoint was ocular and systemic AEs over the treatment period²,³

<table>
<thead>
<tr>
<th>n</th>
<th>PRIMARY EFFICACY ANALYSIS</th>
<th>SAFETY ANALYSIS</th>
<th>PRIMARY EFFICACY POPULATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>MERCURY-1²</td>
<td>n=238 (Rocklatan® QD)</td>
<td>3 months</td>
<td>&gt;20 mmHg @ 08:00 AM,</td>
</tr>
<tr>
<td></td>
<td>n=244 (Rhopressa® QD)</td>
<td></td>
<td>&gt;17 mmHg @ 10:00 AM and</td>
</tr>
<tr>
<td></td>
<td>n=236 (latanoprost QD)</td>
<td></td>
<td>16:00 AM, and &lt;36 mmHg any time prior to randomization</td>
</tr>
<tr>
<td>MERCURY-2³</td>
<td>n=245 (Rocklatan® QD)</td>
<td>3 months</td>
<td>&gt;20 mmHg @ 08:00 AM,</td>
</tr>
<tr>
<td></td>
<td>n=255 (Rhopressa® QD)</td>
<td></td>
<td>&gt;17 mmHg @ 10:00 AM and</td>
</tr>
<tr>
<td></td>
<td>n=250 (latanoprost QD)</td>
<td>3 months</td>
<td>16:00 AM, and &lt;36 mmHg any time prior to randomization</td>
</tr>
</tbody>
</table>

Over 60% of Rocklatan® Patients Achieved ≥30% Mean IOP Reduction at 3 Months¹

Pooled MERCURY Studies: Proportion of Patients Achieving Prespecified Percentage of Mean Diurnal IOP Reduction at Month 3 (ITT Population)

Vyzulta
(Latanoprostene Bunod)
Nitric Oxide and Glaucoma

- Patients with primary open-angle glaucoma (POAG) have lower levels of NO synthase activity in the trabecular meshwork (TM), Schlemm’s canal, and ciliary muscle.
- NO donors lower IOP in normal and POAG eyes.
- A major site of action for NO donors is the TM.
  - NO relaxes the TM and ciliary muscle.
  - NO donors increase outflow facility in anterior segments, mediated by a decrease in TM cell volume.
  - Endothelial NO synthase (eNOS) overexpression increases conventional outflow and lowers IOP in a mouse eye model.

Latanoprostene Bunod: NO-Donating Latanoprost

- NO plays key roles in both health and disease throughout the body, including the eye.
How Does Nitric Oxide, as Released by VYZULTA, Contribute to Reduction in IOP?

LBN Relaxed Human Trabecular Meshwork Cells Through Activation of cGMP in In Vitro Models

Each LBN dose significantly increased mean cGMP in primary HTMCs4


In vitro studies showed that LBN increased HTMC cGMP signaling and relaxation of trabecular meshwork

The clinical significance of in vitro data is unknown.

ET-1 = Endothelin-1; HTMC = human trabecular meshwork cells; LBN = latanoprostene bunod.

Efficacy Results: Primary Endpoint Voyager Study

At highest doses, lowered IOP 1-1.5 mmHg more than latanoprost  
Most common AE: pain upon instillation

REDUCTION IN MEAN DIURNAL IOP ON VISIT 6 (DAY 28)


Statistically Superior Efficacy vs Xalatan 0.005%1,2

VYZULTA delivered significantly greater mean IOP reduction from baseline vs Xalatan 0.005% at Day 281

~69% of VYZULTA patients achieved ≤18 mmHg mean diurnal IOP vs ~47% of Xalatan 0.005% patients*  

*Secondary endpoint. P<0.05.
Statistically Superior Efficacy vs Xalatan 0.005%¹,²

VYZULTA delivered significantly greater mean IOP reduction vs Xalatan 0.005%²

42% of VYZULTA patients achieved ≥2 mmHg IOP reduction vs Xalatan 0.005% mean diurnal IOP reduction²†

Percentage of VYZULTA patients that achieved even greater IOP reductions than the Xalatan 0.005% mean diurnal IOP reduction²:

- 30% achieved ≥3 mmHg
- 19% achieved ≥4 mmHg
- 12% achieved ≥5 mmHg

²Data on File. Bausch & Lomb Incorporated.

Only 6 out of 811 Patients Discontinued VYZULTA Due to Ocular Adverse Events in APOLO and LUNAR¹

Less than 1% of patients treated with VYZULTA discontinued due to ocular adverse reactions in the APOLO and LUNAR clinical studies¹

- These included ocular hyperemia, conjunctival irritation, eye irritation, eye pain, conjunctival edema, vision blurred, punctate keratitis, and foreign body sensation

Most Common Ocular Adverse Reactions in ≥2% of Study Eyes*¹,²

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>VYZULTA (n=811)</th>
<th>TIMOLOL 0.5% (n=271)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conjunctival Hyperemia</td>
<td>5.9%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Eye Irritation</td>
<td>4.6%</td>
<td>2.6%</td>
</tr>
<tr>
<td>Eye Pain</td>
<td>3.6%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Ocular Hyperemia</td>
<td>2.0%</td>
<td>0.7%</td>
</tr>
<tr>
<td>Instillation Site Pain</td>
<td>2.0%</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

*Pooled data from all tested time points in the APOLO and LUNAR studies: ocular adverse reactions occurring in ≥2% of study eyes.

JUPITER: Sustained IOP-lowering Efficacy through One Year

- IOP was reduced by ≥22% with LBN at each post-treatment visit vs. baseline ($P<0.001$ for all).

![Graph showing IOP changes over time](image)


THE LANCET
THE “LIGHT” STUDY

VOLUME 393, ISSUE 10180, P1505-1516, APRIL 13, 2019

- Selective laser trabeculoplasty versus eye drops for first-line treatment of ocular hypertension and glaucoma (LiGHT): a multicentre randomised controlled trial

- [Gus Gazzard, FRCOphth](#)
- [Evgenia Konstantakopoulou, PhD](#)
- [Prof David Garway-Heath, MD](#)
- [Anurag Garg, FRCOphth](#)
- [Victoria Vickerstaff, MSc](#)
- [Rachael Hunter, MSc](#)
- et al.
LIGHT Study

- Standardization of laser delivery was achieved by protocol-defined settings and clinical endpoints.14
- Selective laser trabeculoplasty was delivered to 360° of the trabecular meshwork. 100 non-overlapping shots (25 per quadrant) were used, with the laser energy varied from 0.3 to 1.4 mJ by the clinician, using an appropriate laser gonioscopy lens.
- One re-treatment with selective laser trabeculoplasty was allowed, provided there had been a reduction in intraocular pressure after the initial treatment; the next escalation was medical therapy.
- Significant complications of selective laser trabeculoplasty (eg, a spike in intraocular pressure) precluded repetition of selective laser trabeculoplasty.

LIGHT Study

- Drug classes for first, second, or third line treatment were defined by NICE15 and European Glaucoma Society19 guidance
  - First line was prostaglandin analogues, second line was β blockers, third or fourth line was topical carbonic anhydrase inhibitors or α agonists. Fixed combination drops were allowed.
  - Systemic carbonic anhydrase inhibitors were only permitted while awaiting surgery. Maximum tolerated medical therapy was defined by the treating clinician as the most intensive combination of drops an individual could reasonably, reliably, and safely use and thus varied between patients.
  - A need for treatment escalation beyond maximum tolerated medical therapy triggered an offer of surgery.
The Light study

• Methods
  • In this observer-masked, randomized controlled trial treatment-naive patients with open angle glaucoma or ocular hypertension and no ocular comorbidities were recruited between 2012 and 2014 at six UK hospitals.
  • They were randomly allocated (web-based randomization) to initial selective laser trabeculoplasty or to eye drops.
  • An objective target intraocular pressure was set according to glaucoma severity.
  • The primary outcome was health-related quality of life (HRQoL) at 3 years (assessed by EQ-5D). Secondary outcomes were cost and cost-effectiveness, disease-specific HRQoL, clinical effectiveness, and safety.
  • Analysis was by intention to treat. This study is registered at controlled-trials.com (ISRCTN32038223).

The Light study

• Findings
  • Of 718 patients enrolled, 356 were randomised to the selective laser trabeculoplasty and 362 to the eye drops group. 652 (91%) returned the primary outcome questionnaire at 36 months.
  • Average EQ-5D score was 0·89 (SD 0·18) in the selective laser trabeculoplasty group versus 0·90 (SD 0·16) in the eye drops group, with no significant difference (difference 0·01, 95% CI −0·01 to 0·03; p=0·23).
  • At 36 months, 74·2% (95% CI 69·3–78·6) of patients in the selective laser trabeculoplasty group required no drops to maintain intraocular pressure at target.
  • Eyes of patients in the selective laser trabeculoplasty group were within target intraocular pressure at more visits (93·0%) than in the eye drops group (91·3%), with glaucoma surgery to lower intraocular pressure required in none versus 11 patients.
  • Over 36 months, from an ophthalmology cost perspective, there was a 97% probability of selective laser trabeculoplasty as first treatment being more cost-effective than eye drops first at a willingness to pay of £20 000 per quality-adjusted life-year gained.
Efficacy of Repeat Selective Laser Trabeculoplasty in Medication-Naive Open-Angle Glaucoma and Ocular Hypertension during the LiGHT Trial

Anurag Garg FRCOphth; Victoria Vickerstaff MSc; Neil Nathwani BSc; David Garrison MD; Evgenia Konstantakopoulou PhD; Gareth Ambler PhD; Catey Bunce DSc; Richard Wormald FRCOphth; Keith Barton FRCS; Gus Gazzard MD; Laser

Repeat SLT

- **Results**
  - A total of 115 eyes of 90 patients received repeat SLT during the first 18 months of the trial. Pretreatment IOP before initial SLT was significantly higher than before retreatment IOP of repeat SLT (mean difference, 3.4 mmHg; 95% confidence interval [CI], 2.6–4.3 mmHg; \( P < 0.001 \)).
  - Absolute IOP reduction at 2 months was greater after initial SLT compared with repeat SLT (mean difference, 1.0 mmHg; 95% CI, 0.2–1.8 mmHg; \( P = 0.02 \)).
  - Adjusted absolute IOP reduction at 2 months (adjusting for IOP before initial or repeat laser) was greater after repeat SLT (adjusted mean difference, −1.1 mmHg, 95% CI, −1.7 to −0.5 mmHg; \( P = 0.001 \)).
  - A total of 34 eyes were early failures (retreatment 2 months after initial SLT) versus 81 later failures (retreatment >2 months after initial SLT). No significant difference in early absolute IOP reduction at 2 months after repeat SLT was noted between early and later failures (mean difference, 0.3 mmHg; 95% CI, −1.1 to 1.8 mmHg; \( P = 0.655 \)).
  - Repeat SLT maintained drop-free IOP control in 67% of 115 eyes at 18 months, with no clinically relevant adverse events.
Repeat SLT

• Conclusions
• These exploratory analyses demonstrate that repeat SLT can maintain IOP at or below target IOP in medication-naive OAG and OHT eyes requiring retreatment with at least an equivalent duration of effect to initial laser.