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Pharmaceuticals, Inc.

**Roclatan™**

**Mercury 1 Phase 3 12-month  
Topline Results**

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Any discussion of the potential use or expected success of our product candidates is subject to our product candidates being approved by regulatory authorities.

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# Roclatan™ Achieves Positive 12-Month Safety and Efficacy Results



- Safety data over the 12 months were consistent with previous Roclatan™ 3-month results
- There were no drug-related serious or systemic adverse events
- The main adverse event for Roclatan™ was conjunctival hyperemia, which was reported in ~60% of patients, scored as mild for ~70% of these patients and sporadic
- IOP-lowering effect of Roclatan™ through Month 12 remained stable and consistent with the primary efficacy analysis at Month 3, maintaining superiority over both latanoprost and Rhopressa™
  - 1-3 mmHg greater than monotherapy with either latanoprost or Rhopressa™ throughout the duration of the study (i.e., Week 2, Week 6, Month 3, Month 6, Month 9 and Month 12)
  - At Month 12, Roclatan™ reduced mean diurnal IOPs to 16 mmHg or lower in 60% of patients, a significantly higher percentage than observed in the comparator arms

# Mercury 1 Trial Design

Patients with open angle glaucoma (OAG) or ocular hypertension (OHT)  
with IOP >20 mmHg and < 36 mmHg  
N=718 subjects randomized at 58 US sites



Patients randomized  
1:1:1

**Roclatan™**  
PG324  
(netarsudil/latanoprost)  
QD (PM)

**Rhopressa™**  
Netarsudil  
(AR-13324) 0.02%  
QD (PM)

**Latanoprost**  
0.005%  
QD (PM)



Primary endpoints:

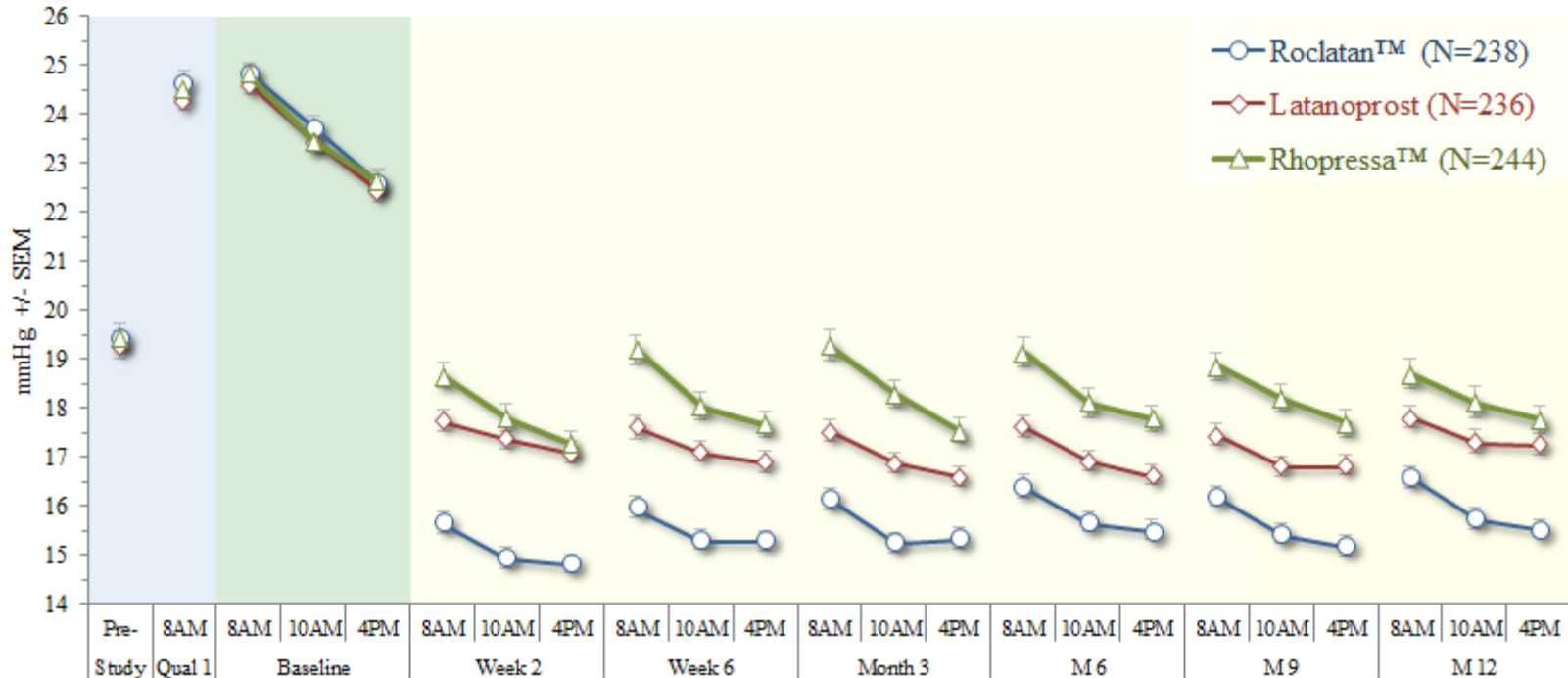
- Efficacy: Mean IOP at nine time points (08:00, 10:00, and 16:00 at Week 2, Week 6, and Month 3)
- Safety: Ocular and systemic safety during a 12-month treatment period

# Disposition

	Roclatan™ N = 238	Rhopressa™ N = 244	Latanoprost N = 236
<b>Completed Month 12</b>	<b>159 (66.8%)</b>	<b>148 (60.7%)</b>	<b>203 (86.0%)</b>
<b>Discontinued Prior to Month 12</b>	<b>79 (33.2%)</b>	<b>96 (39.3%)</b>	<b>33 (14.0%)</b>
<b>Reasons for Discontinuation</b>			
Adverse Event	47 (19.7%)	53 (21.7%)	4 (1.7%)
Withdrawal of Consent	13 (5.5%)	9 (3.7%)	8 (3.4%)
Non-Compliant	0	1 (0.4%)	3 (1.3%)
Lost to Follow-up	5 (2.1%)	5 (2.0%)	4 (1.7%)
Lack of Efficacy	0	13 (5.3%)	1 (0.4%)
Disallowed Concurrent Medication	6 (2.5%)	7 (2.9%)	5 (2.1%)
Investigator Decision	2 (0.8%)	2 (0.8%)	0
Protocol Violation	6 (2.5%)	3 (1.2%)	8 (3.4%)
Other	0	3 (1.2%)	0

# Roclatan™ Maintained Superior Efficacy Over Individual Components for 12 Months

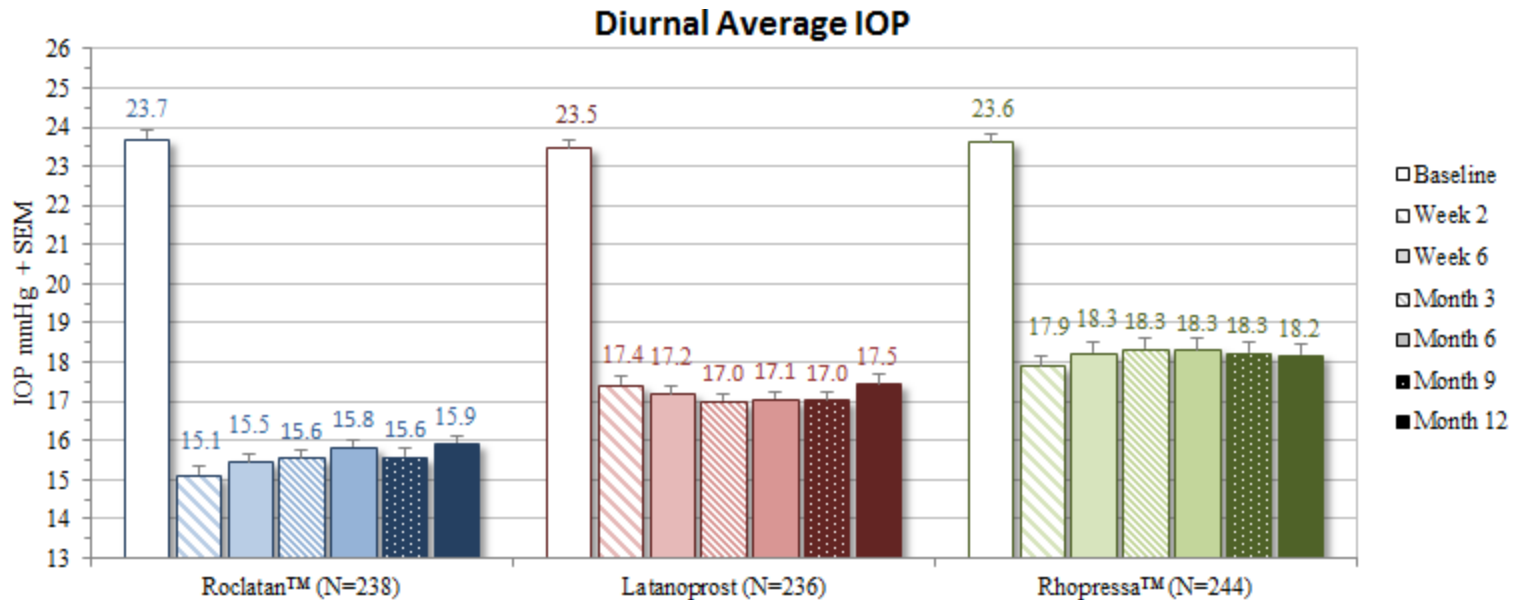
## Mean IOP at Each Time Point (ITT)



- Roclatan™ statistically superior to latanoprost and Rhopressa™ at all time points
- Roclatan™ IOP-lowering 1-3 mmHg greater than monotherapy through Month 12

# Roclatan™ Maintained Superior Efficacy Over Individual Components for 12 Months

## Mean Diurnal IOP at Each Visit (ITT)

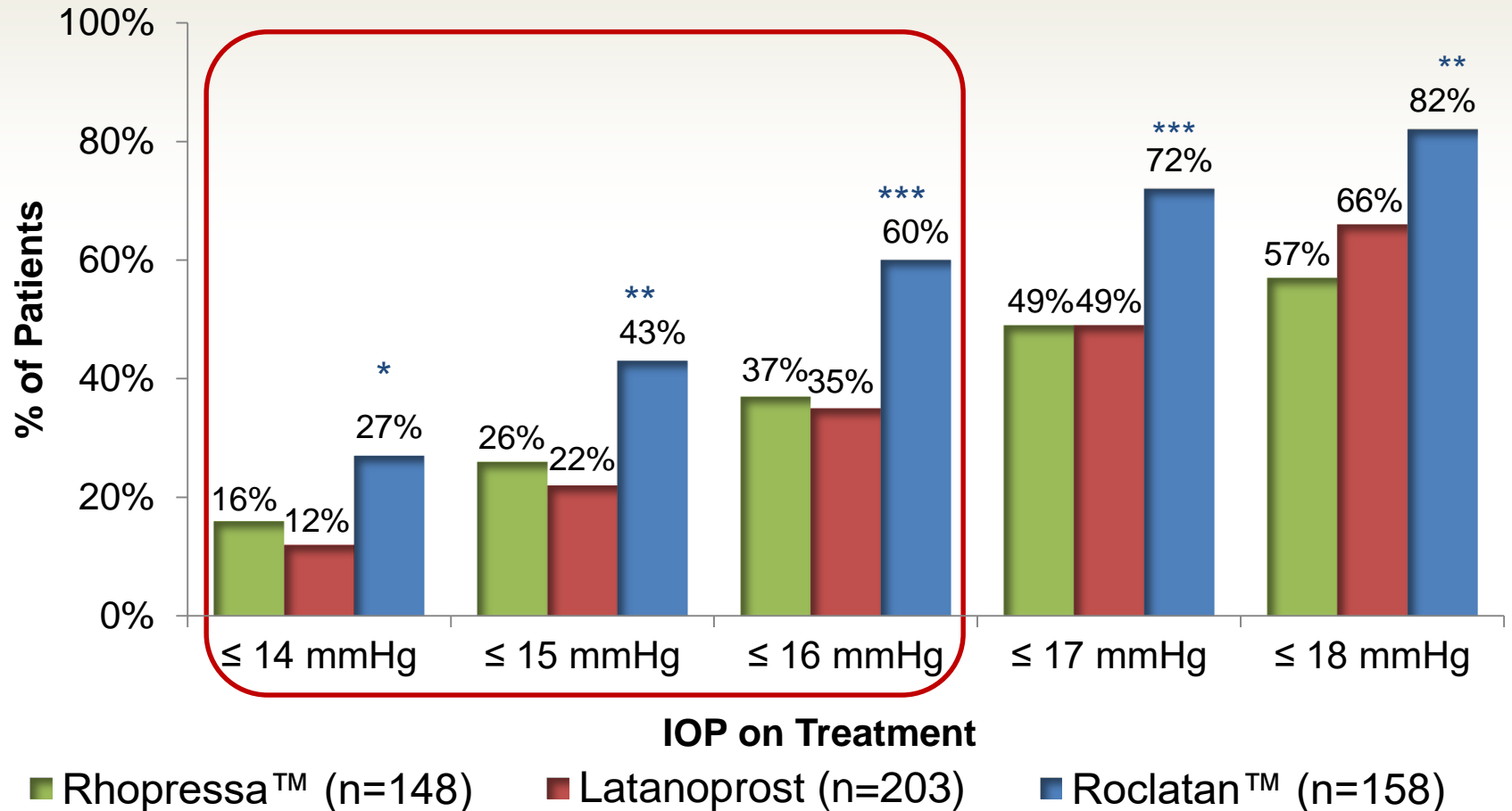


$p < 0.0001$  at All Visits vs. Latanoprost and Rhopressa™

# Roclatan™ Phase 3 Month 12 Responder Analysis: Goal is to Achieve Lowest IOP Possible



At Month 12: % of Patients with IOP Reduced to 18 mmHg or Lower

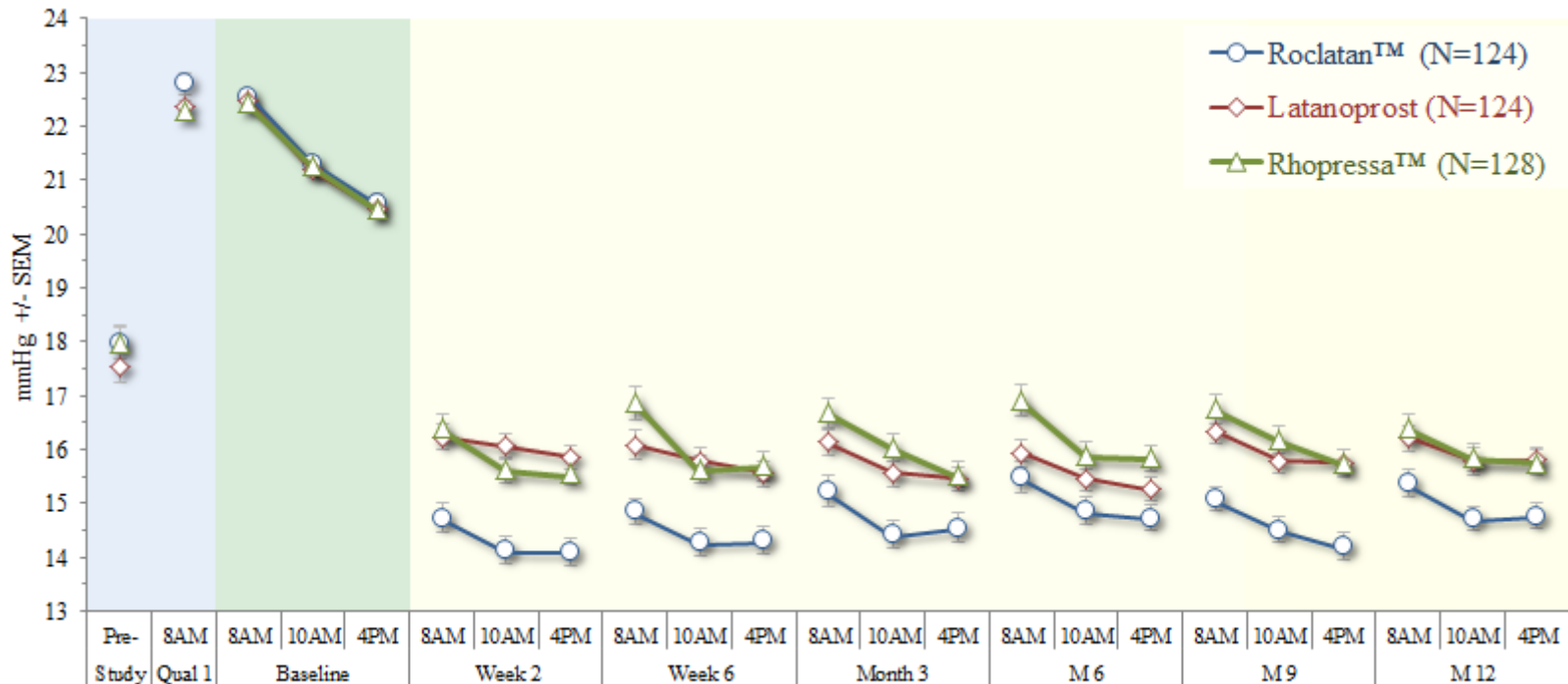


\*p<0.05, \*\*p<0.01, \*\*\*p<0.0001



# Efficacy in Subjects with Baseline IOP <25 mmHg

## Mean IOP at Each Time Point (ITT)

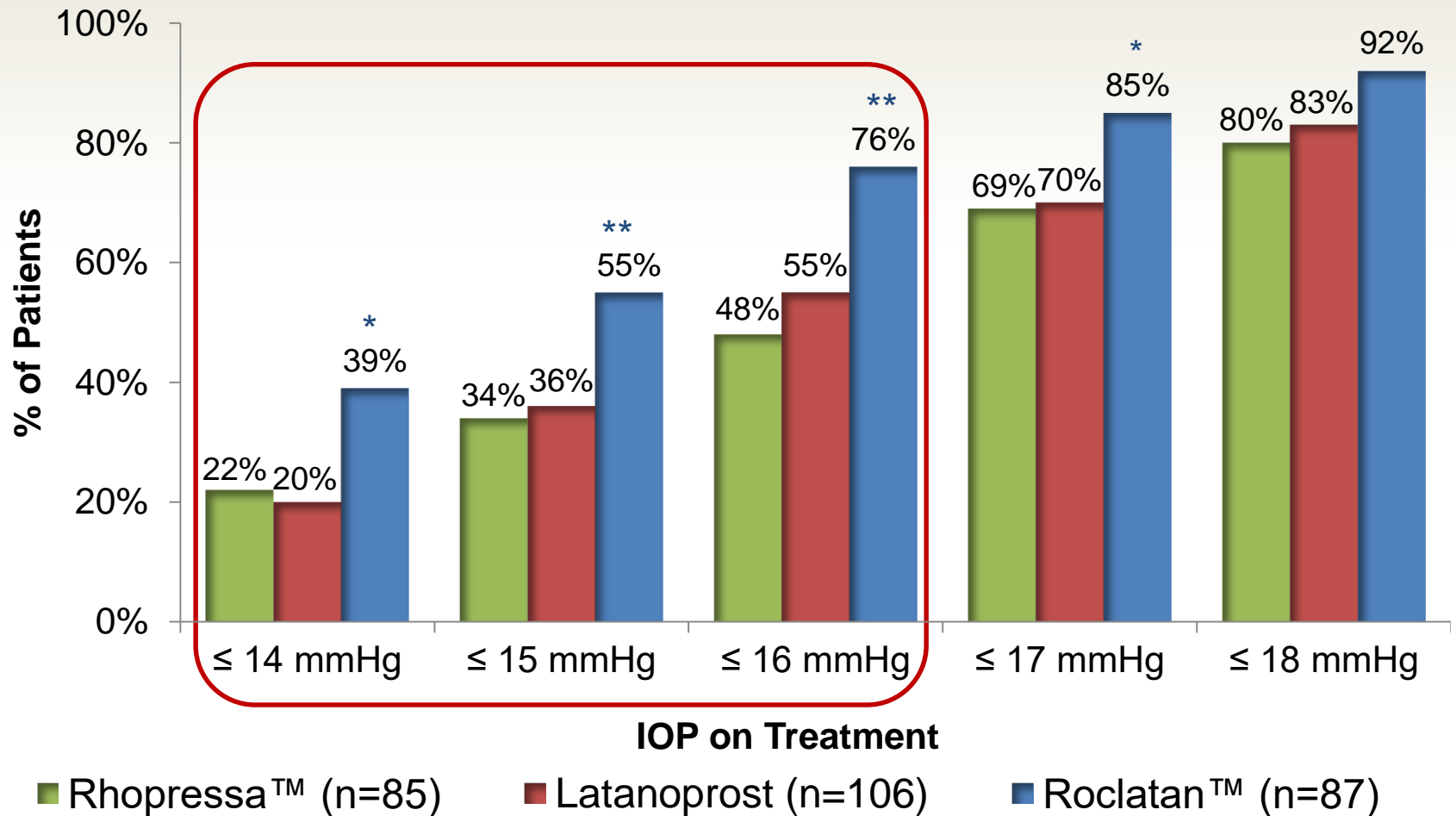


- Rhopressa™ efficacy similar to latanoprost and stable for 12 months

# Roclatan™ Responder Analysis

## Baseline IOP <25 mmHg

At Month 12: % of Patients with IOP Reduced to 18 mmHg or Lower

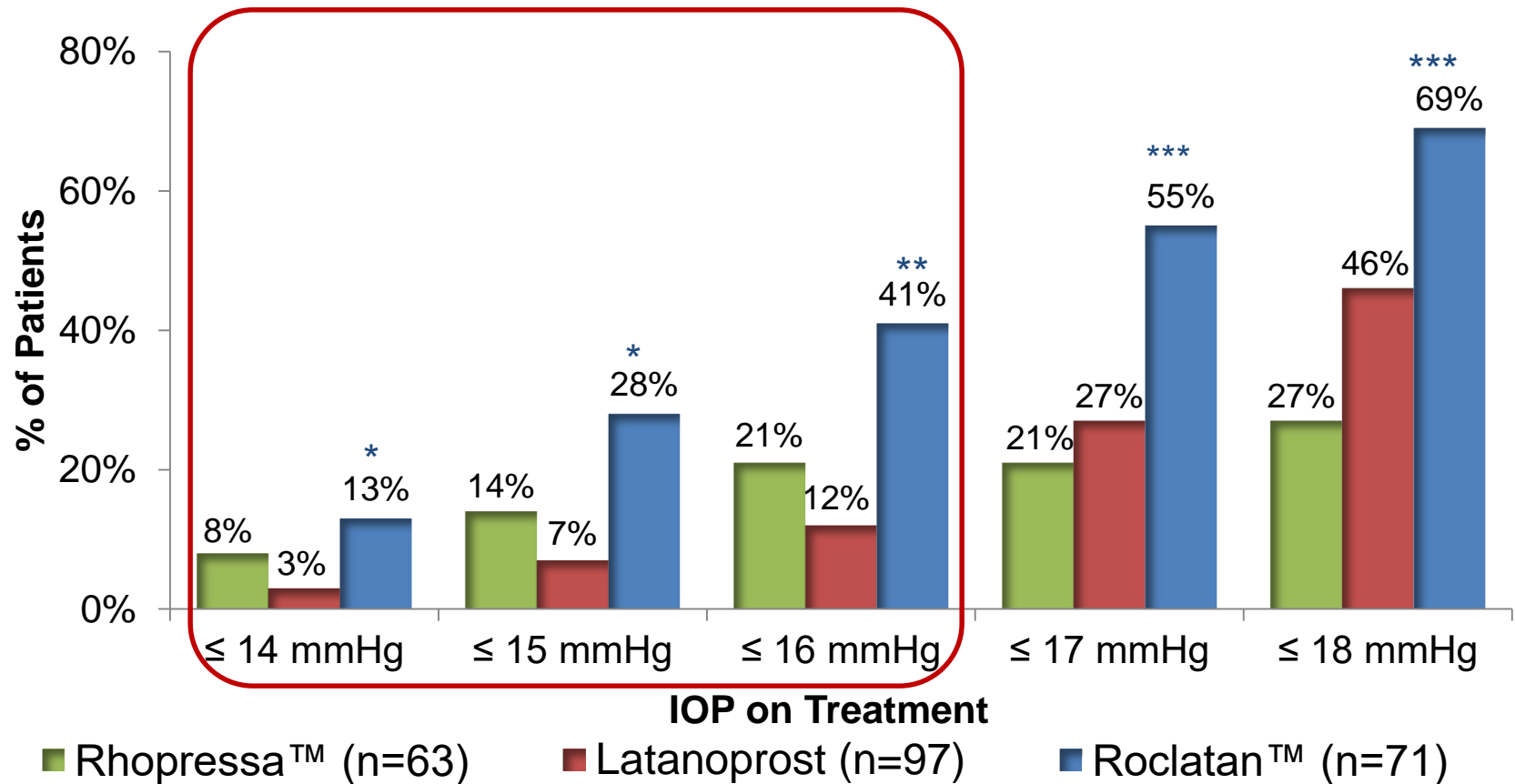


\*p<0.05, \*\*p<0.01

# Roclatan™ Responder Analysis

## Baseline IOP ≥25 mmHg

At Month 12: % of Patients with IOP Reduced to 18 mmHg or Lower



\*p<0.05 vs Latanoprost

\*\*p<0.05 vs Rhopressa™, p<0.0001 Latanoprost

\*\*\*p<0.0001 vs Rhopressa™, p<0.01 Latanoprost

\*\*Data on File

Based on Mercury 1 Topline 12-month

Product candidates have not approved by the FDA

For Investor Use

# Safety/Tolerability Overview of Roclatan™



- There were no drug-related serious adverse events (SAEs) and no evidence of treatment-related systemic effects
- The most common adverse event was conjunctival hyperemia with ~60% incidence, scored as mild on biomicroscopy for ~70% of these patients and sporadic
- Other ocular AEs
  - AEs occurring in ~5-18% of subjects receiving Roclatan™ included: cornea verticillata, conjunctival hemorrhage, eye pruritus, lacrimation increased, visual acuity reduced, blepharitis and punctate keratitis.

# Roclatan™ Phase 3 Safety Profile

Adverse Events (≥5.0% in any group)	Roclatan™ n=238	Rhopressa™ n=243	Latanoprost n=237
<b>Eye Disorders</b>			
Conjunctival Hyperemia	150 (63.0%)	125 (51.4%)	52 (21.9%)
Conjunctival Hemorrhage	31 (13.0%)	44 (18.1%)	3 (1.3%)
Cornea Verticillata	42 (17.6%)	33 (13.6%)	0
Eye Pruritus	27 (11.3%)	22 (9.1%)	3 (1.3%)
Punctate Keratitis	12 (5.0%)	18 (7.4%)	10 (4.2%)
Lacrimation Increased	17 (7.1%)	20 (8.2%)	1 (0.4%)
Visual Acuity Reduced	13 (5.5%)	13 (5.3%)	6 (2.5%)
Vision Blurred	11 (4.6%)	15 (6.2%)	3 (1.3%)
Blepharitis	14 (5.9%)	8 (3.3%)	5 (2.1%)
<b>Administration Site Conditions</b>			
Instillation site pain	55 (23.1%)	60 (24.7%)	18 (7.6%)

Patients with known contraindications or hypersensitivity to latanoprost were **excluded**

\*\*Data on File

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# Roclatan™ Conjunctival Hyperemia Was Sporadic And Severity Did Not Increase With Continued Dosing



- Hyperemia severity did not increase with continued dosing
- Hyperemia was sporadic
  - Only ~10% of patients had hyperemia on each study visit day from week 2 to month 12 (~7% Rhopressa™, ~3% latanoprost)
- Only ~8% of all patients discontinued due to hyperemia (~7% of all patients at Month 3)

# Roclatan™ Once-Daily Performance Summary



Consistent statistically superior efficacy over both latanoprost and Rhopressa™ at all time points demonstrated in 2 Phase 3 trials (Mercury 1 and Mercury 2)

IOP-lowering effect was greater (1-3 mmHg) than monotherapy with either latanoprost or Rhopressa™ throughout the duration of the study

Stable efficacy through 12 months

Well tolerated with no evidence of treatment-related serious or systemic effects

# Rhopressa™ Once-Daily Performance Summary



Rhopressa™ efficacy similar to latanoprost with baseline IOP < 25 mmHg

Rhopressa™ maintained consistent IOP lowering across all baseline IOPs including  $\geq 25$  mmHg

Stable efficacy through 12 months

Adverse event profile consistent with previous studies



# Key Upcoming Milestones

## Rhopressa™

- PDUFA February 28, 2018
  - Expected FDA Advisory Committee
- Initiating clinical program for Japan market (Phase 1 and 2 to be conducted in the U.S. in Japanese patients)
  - To commence in Q3/Q4 2017

## Roclatan™

- NDA filing expected 1H 2018
- Mercury 3 (Europe): 6-month study, comparing to Ganfort®
  - To commence in Q3 2017