# NCX 470 (bimatoprost grenod)
# Mont Blanc Data and Value Proposition



nicox
visible science

# Positive Topline NCX 470 Mont Blanc results[1,2,3]

## Phase 3 clinical program intended to support U.S. & China NDA submissions

Designed to demonstrate safety and efficacy of NCX 470 0.1% vs. latanoprost 0.005%, studies evaluate reduction of IOP from time-matched baseline at pre-established time points

**MONT BLANC: Primary objective of non-inferiority achieved**

N=691

56 clinical sites in the U.S. & one site in China

Adaptive design selected the 0.1% concentration

NCX 470 was statistically superior to latanoprost 0,005% in intraocular pressure reduction from baseline at 4 of the 6 timepoints, and numerically greater at all 6

Second efficacy objective, statistical superiority to latanoprost, was not achieved

1. Nicox Press release October 31, 2022
2. Mansberg et al., 2023, World Glaucoma Congress, Abstract # P-339
3. Fechtner et al., 2023, World Glaucoma Congress, Abstract # P-288

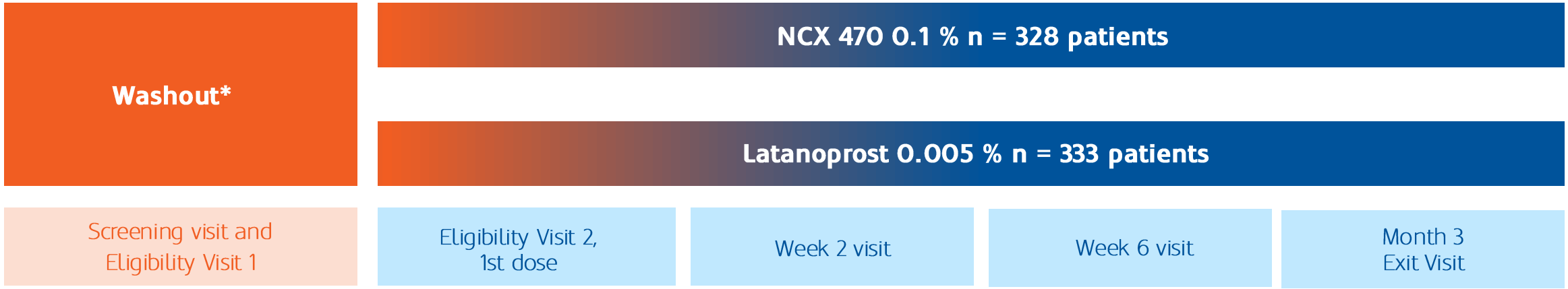
# Mont Blanc Phase 3 efficacy trial design[1]

## Designed to evaluate NCX 470 vs. established therapy, latanoprost

**Randomized, controlled, double-masked, parallel design trial. Patients with open angle glaucoma or ocular hypertension were randomized 1:1 to once-daily treatment with NCX 470 0.1% or latanoprost 0.005%**

**Primary Endpoint:**
Mean IOP reduction from time-matched baseline at 8 AM and 4 PM at the week 2, week 6 and month 3 visits

**Enrollment:**
The trial enrolled 691 patients across all arms (including ~30 patients on NCX 470 0.065% in the adaptive design part)




* Wash-out period according to the patient's previous IOP-lowering treatment

1. This schematic reflects the dosage arms which continued in the trial and do not include the NCX 470 0.065% dose which wasonly in the adaptive design portion of the trial

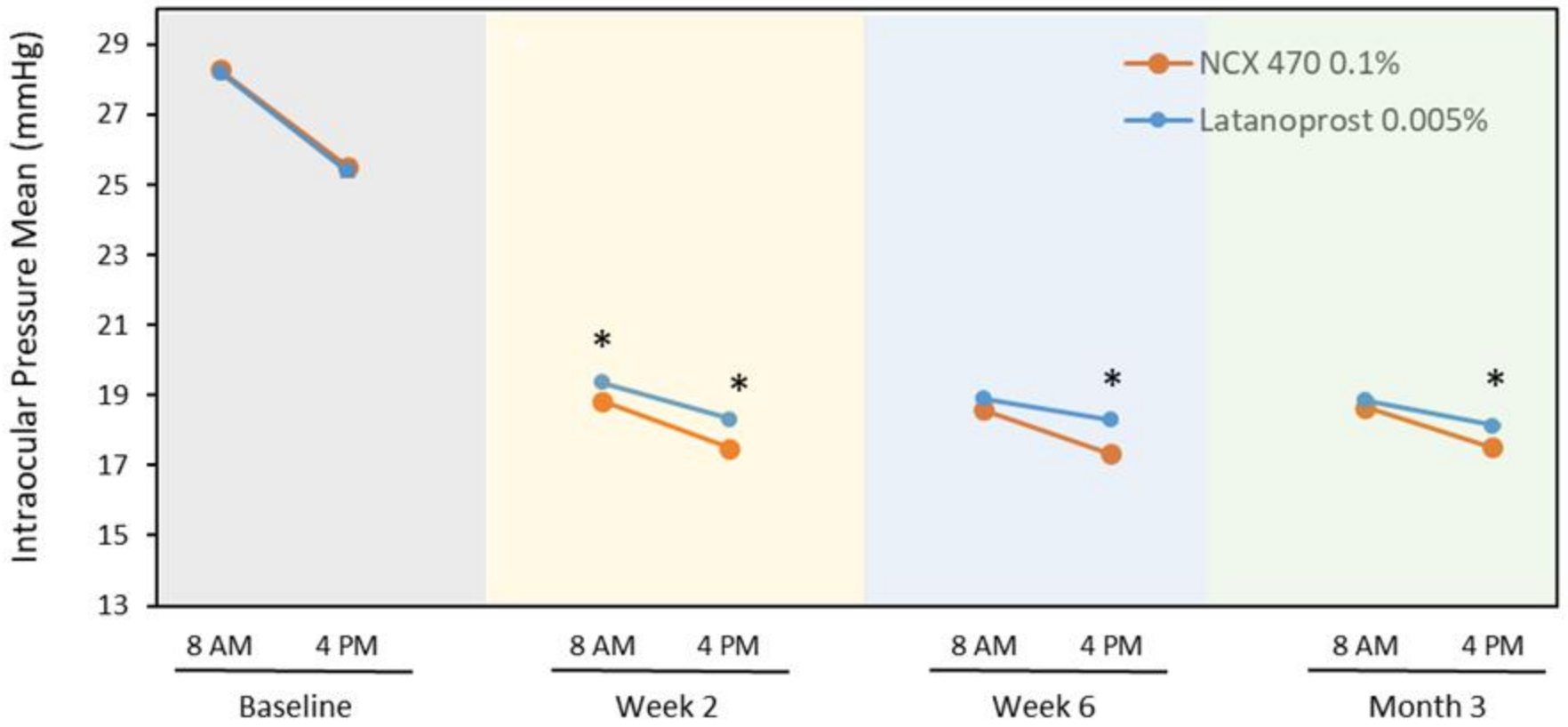
# Mont Blanc Baseline characteristics, demographics and disposition[1]

| | NCX 470 0.1%<br>N = 328 | Latanoprost 0.005%<br>N = 333 |
|---|---|---|
| Mean Diurnal Baseline (8am+4pm) IOP, mmHg, Study Eye (SD) | 26.9 (2.04) | 26.8 (2.02) |
| Gender, n (%)<br>Female<br>Male | <br>200 ( 61.0%)<br>128 ( 39.0%) | <br>188 ( 56.5%)<br>145 ( 43.5%) |
| Age, Years (SD) | 63.6 (10.12) | 62.7 (11.73) |
| Completed the Study | 314 (95.7%) | 316 (94.9%) |
| Discontinued Prior to Study Completion | 14 (4.3%) | 17 (5.1%) |
| Reasons for Discontinuation | | |
| Adverse Event | 8 (57.1%) | 6 (35.3%) |
| Lost to Follow-up | 1 (7.1%) | 4 (23.5%) |
| Physician Decision | 0 | 0 |
| Sponsor or IRB Decision | 1 (7.1%) | 2 (11.8%) |
| Protocol Violation | 0 | 1 (5.9%) |
| Withdrawal by Subject | 3 (21.4%) | 3 (17.6%) |
| IOP greater than 36 mmHg | 0 | 0 |
| Other | 1 (7.1%) | 1 (5.9%) |

1. This data reflects the dosage arms which continued in the trial and do not include the NCX 470 0.065% dose which was only in the adaptive design portion of the trial.

# NCX 470 demonstrated potent IOP-lowering from baseline and statistical superiority vs market leader latanoprost at 4 of 6 timepoints

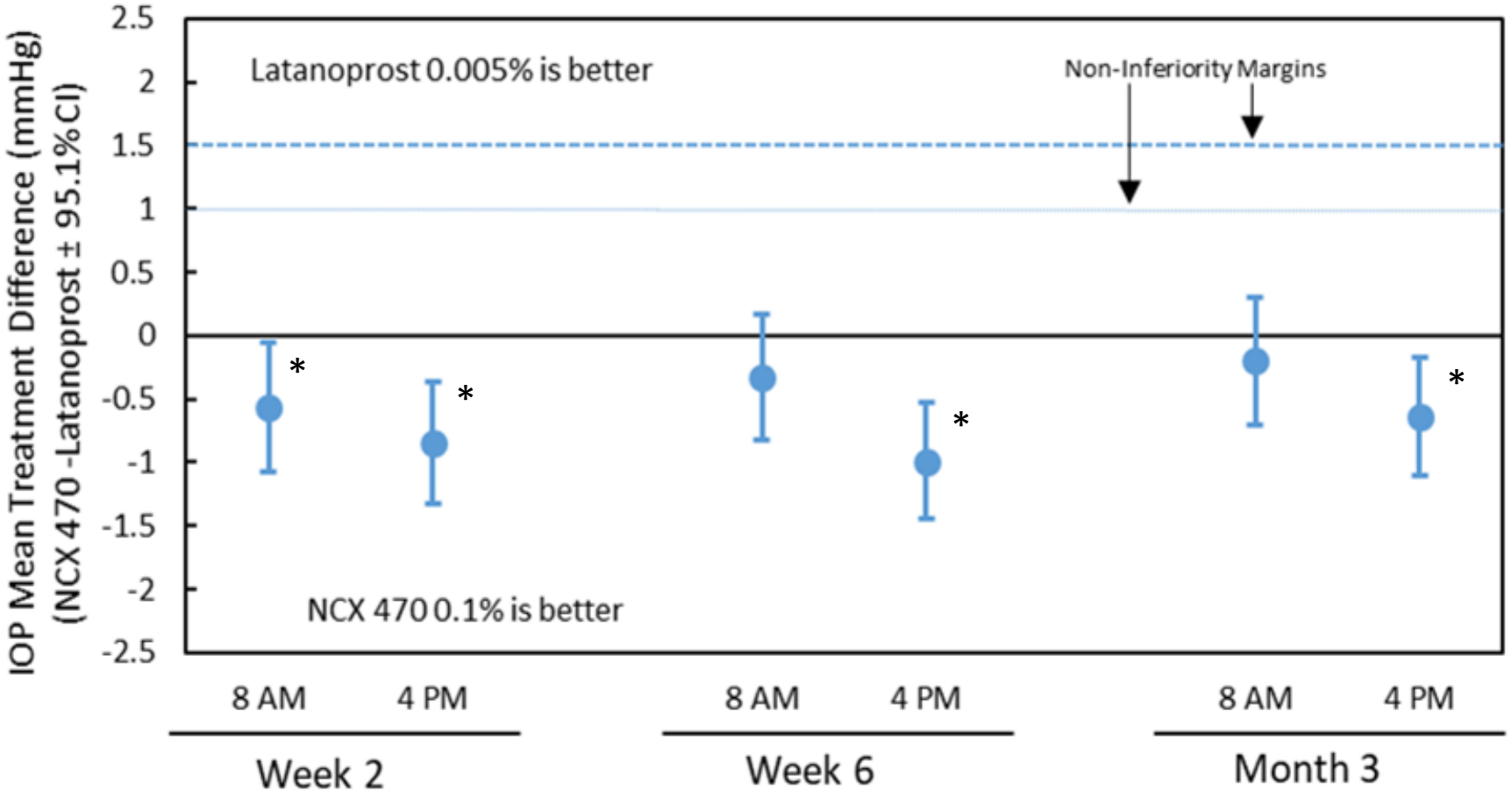
## IOP-lowering from baseline was 8.0 to 9.7 mmHg for NCX 470 vs. 7.1 to 9.4 mmHg for latanoprost




NCX 470 0.1%: N = 328
Latanoprost 0.005%: N = 333

- Denotes statistically significant differences vs latanoprost (p<0.049)
- Fechtner et al., AJO, 2024 Aug;264:66-74

# NCX 470 achieved non-inferiority for IOP-lowering vs latanoprost, meeting the efficacy requirement in a pivotal study for FDA approval




To be non-inferior, the treatment difference between NCX 470 and latanoprost had to meet BOTH criteria:

- For all 6 timepoints, the upper limit of all confidence intervals (95.1%) were required to be less than or equal to 1.5 mmHg and
- At least 4 of the 6 timepoints were required to be less than or equal to 1.0 mmHg
- NCX 470 0.1% demonstrated an IOP lowering effect greater than latanoprost 0.005% of up to 1.0 mmHg

* Denotes statistically significant differences vs latanoprost ($p<0.049$)

# NCX 470 topline results demonstrate robust efficacy and safety[1]

## All comparisons are based on NCX 470 0.1% and latanoprost 0.005%

Topline results from this pivotal trial:

- **IOP-lowering effect from baseline was 8.0 to 9.7 mmHg for NCX 470** vs. 7.1 to 9.4 mmHg for latanoprost
- **Statistical non-inferiority was met vs. latanoprost** in the primary efficacy analysis. This trial therefore met the efficacy requirements for approval in the U.S.
- While NCX 470 failed to meet statistical superiority to latanoprost in a pre-specified secondary efficacy analysis of time-matched change from baseline IOP, NCX 470 was numerically superior to latanoprost at all time points and **statistically significant ($p<0.049$) at 4 of 6 timepoints**

**Data from the post hoc analysis:**

- Statistically significant percentage of patients **achieve ≤ 18mmHg intraocular pressure (IOP) on NCX 470** compared to latanoprost
- Mean **percentage reduction in IOP greater on NCX 470** than on latanoprost
- **In eyes with an initial IOP of ≤ 28 mmHg the IOP-lowering effect from baseline was statistically significantly greater for NCX 470 compared to latanoprost** at the majority of timepoints measured
- **NCX 470 demonstrates a consistent lowering of IOP regardless of the baseline IOP,** whereas the reduction in IOP with latanoprost is dependent on the baseline IOP
- **A statistically significant greater proportion of patients who received NCX 470 showed an IOP reduction of greater than 10 mmHg from baseline**, compared to those on latanoprost

### NCX 470 was well tolerated

- The most common adverse event was ocular hyperemia in 11.9% of NCX 470 patients vs. 3.3% of latanoprost patients
- There were no ocular serious adverse events and no treatment-related non-ocular serious adverse events
- 4.3% of patients on NCX 470 discontinued compared to 5.1% on latanoprost

1. This data reflects the dosage arms which continued in the trial and do not include the NCX 470 0.065% dose which was only in the adaptive design portion of the trial.

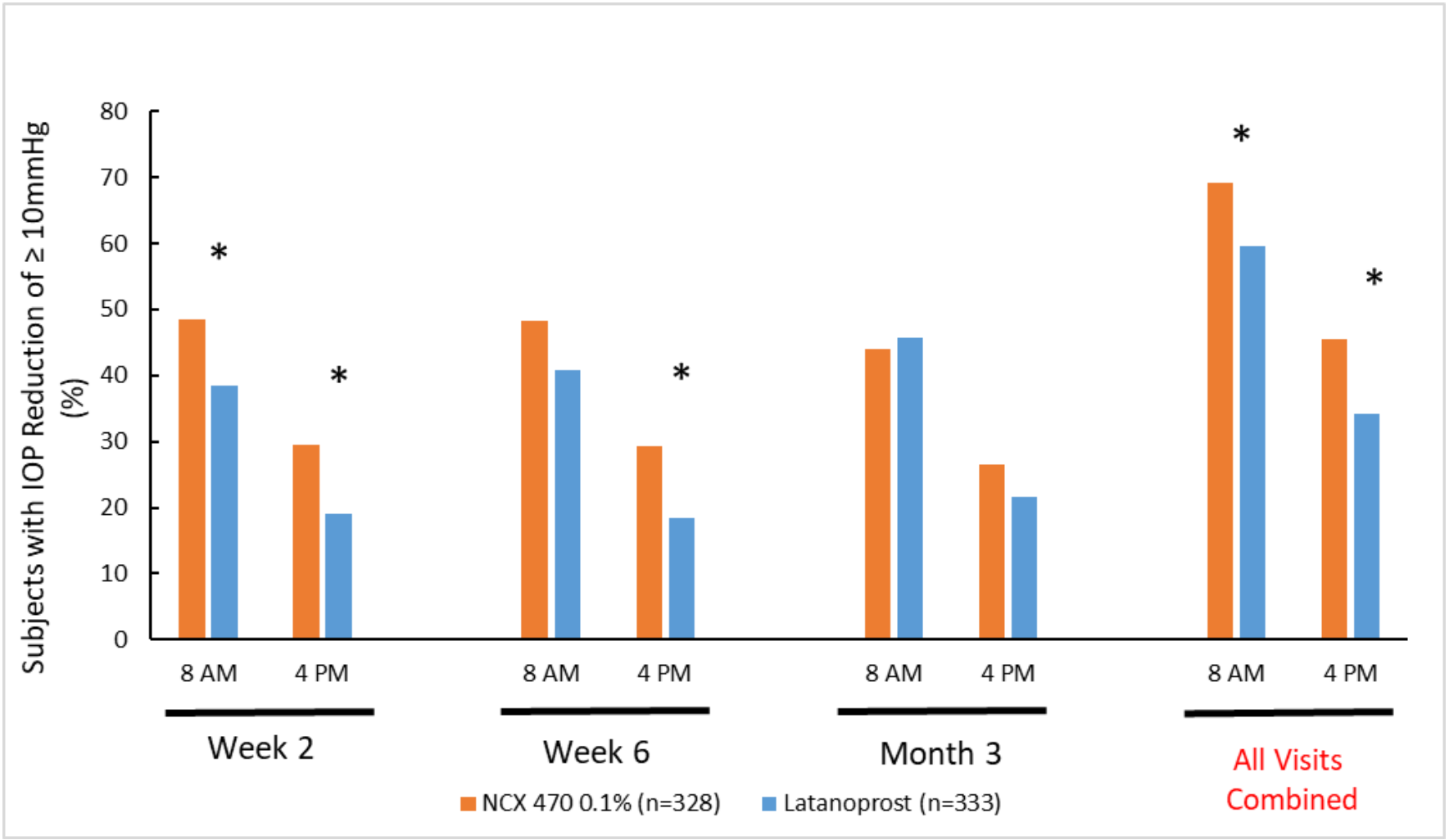
# Mont Blanc post-hoc analysis supports robust differentiated NCX 470 efficacy

## Consistent IOP lowering after 3 months' treatment regardless of baseline unlike latanoprost

- In subjects with baseline pressures < 28 mmHg, NCX 470 lowered IOP from baseline more than latanoprost and, that difference was greater at lower baselines.
- A greater proportion of subjects on NCX 470 achieved IOP lowering from baseline by ≥ 10 mmHg compared to those on latanoprost.
- Statistically significantly more subjects on NCX 470 were able to achieve target IOP of ≤ 18 mmHg compared to those on latanoprost.
- After 3 months' treatment, NCX 470 lowered IOP by ~ 8.2 mmHg regardless of the starting IOP. This predictable IOP lowering was not seen with latanoprost

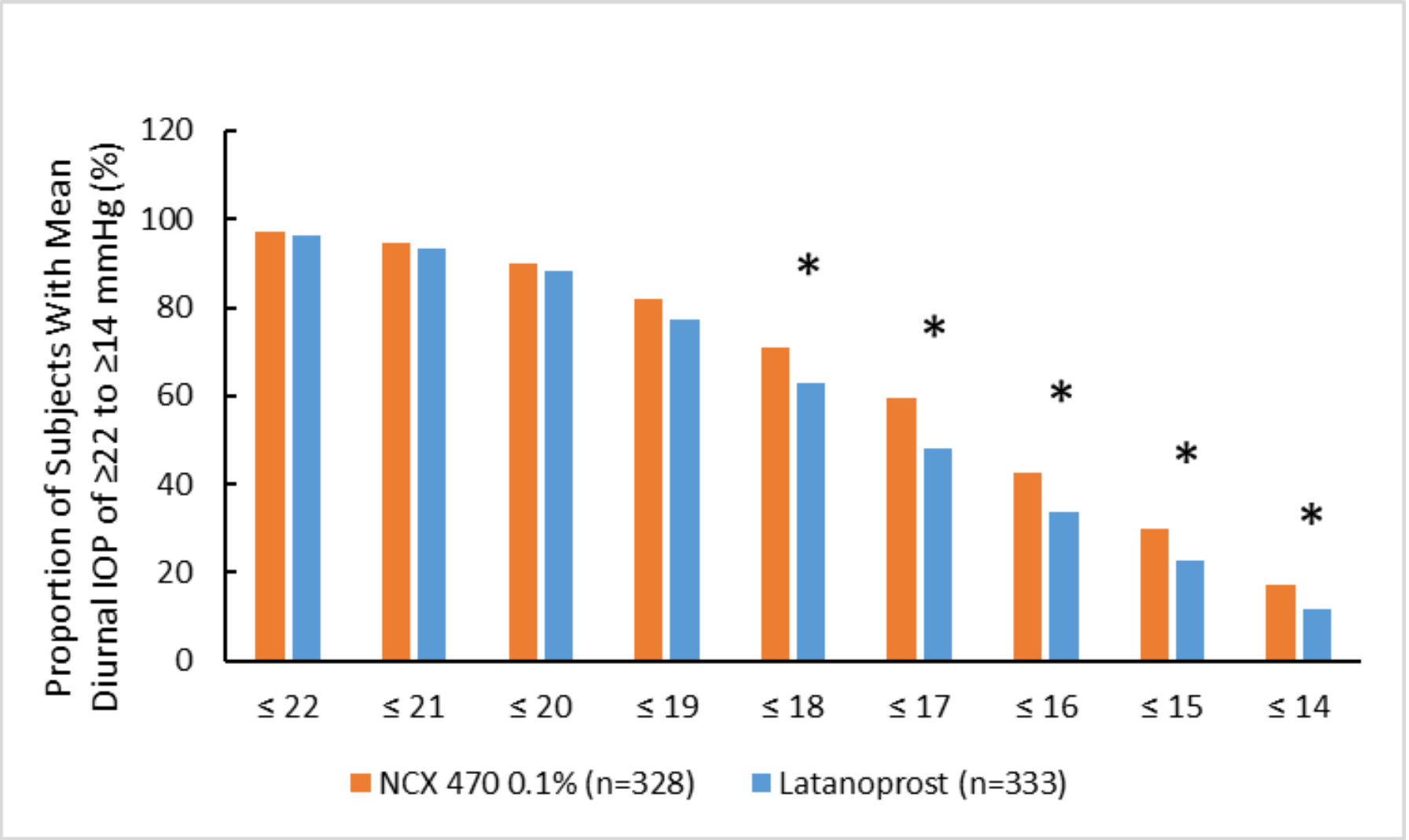
# Significantly more patients achieved ≥ 10 mmHg Time-Matched IOP Reduction from Baseline on NCX 470 vs latanoprost for all study visits combined and for 3 individual timepoints

Proportion of Subjects Achieving Time-Matched IOP Reduction from Baseline of ≥ 10 mmHg (Observed Data from 8AM and 4PM) Intent-to-Treat Population



# Proportion of Subjects Achieving a Mean Diurnal IOP of ≤ 22 to ≤ 14 mmHg in 1 mmHg Increments for All Visits Combined

(Observed Data from 8AM and 4PM) Intent-to-Treat Population

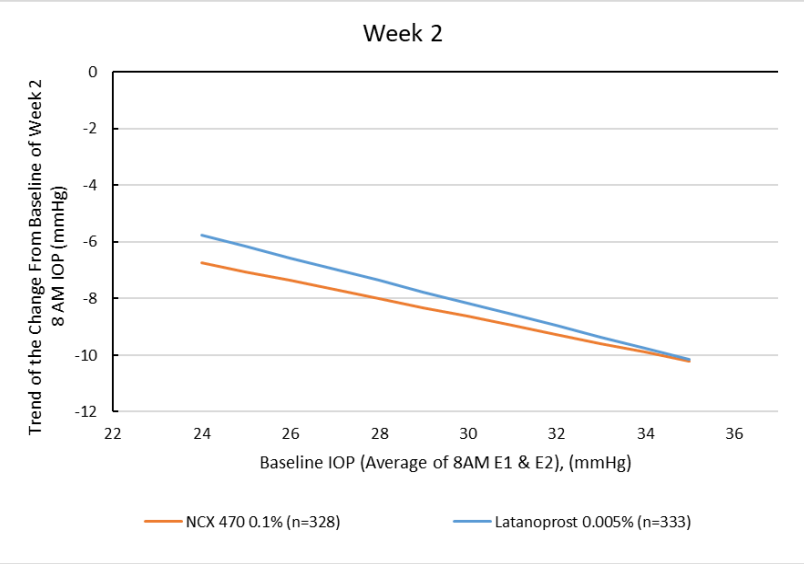


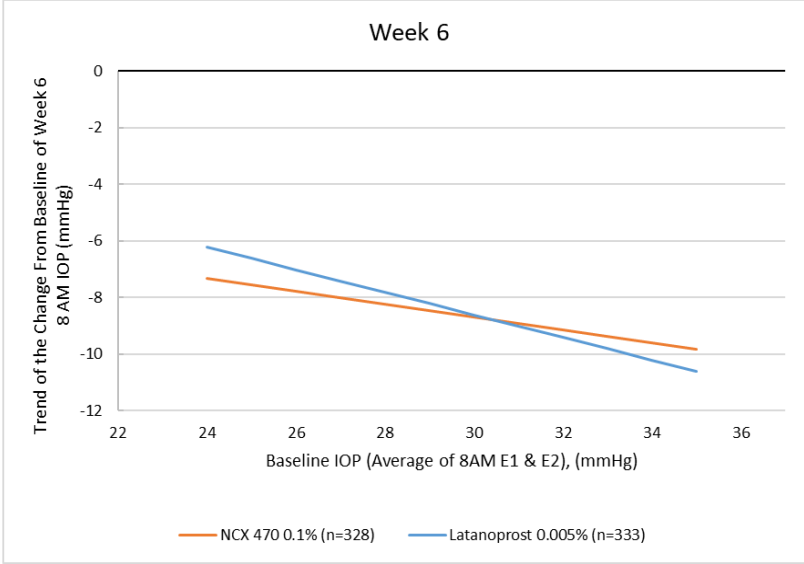


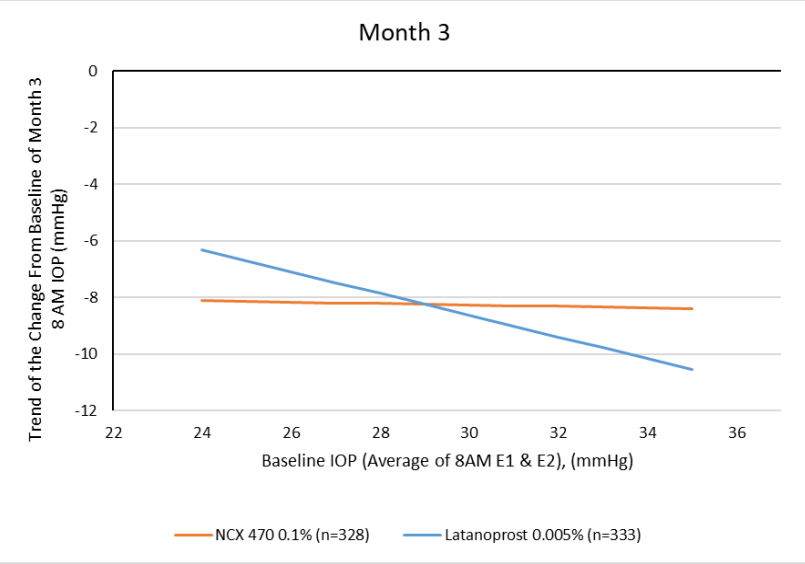

Submitted 2025 American Glaucoma Society Congress

# After 3 months' treatment NCX 470 was able to lower IOP by ~ 8.2 mmHg irrespective of starting IOP. This predictable IOP lowering was not seen with latanoprost

Trends of the Change from Baseline in Response to Treatment by IOP at 8 am on Randomization Visit (Baseline IOP)NCX 470 0.1% (n=328), Latanoprost 0.005% (n=333)






Ad Hoc Analysis

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