

Press Release

Nicox's NCX 470 Demonstrates Sustained Efficacy through 12 Months in Denali Clinical Trial with no new Safety Observations

- **Additional pre-planned analysis of the NCX 470 Denali trial completed**
- **NCX 470 maintains robust intraocular pressure lowering at 6, 9 and 12 months**
- **Other analyses broadly in line with the trends seen for Mont Blanc**
- **Data presentations planned for upcoming ophthalmology conferences**

October 2, 2025 – release at 7:30 am CET

Sophia Antipolis, France

Nicox SA (Euronext Growth Paris: FR0013018124, ALCOX), an international ophthalmology company, today announced that it has completed the additional pre-planned analyses of the NCX 470 Denali Phase 3 clinical trial data. These analyses confirm an efficacy profile similar to that seen in subgroup analysis of the Mont Blanc trial. In addition, reduction in intraocular pressure (IOP) was measured in the long-term safety extension period of the Denali trial from 6 months through to 12 months. NCX 470 maintained robust IOP reduction during this period with no additional safety signals seen.

New Drug Applications (NDAs) for NCX 470 are in preparation for the U.S. and China. A full summary of the status of NCX 470 was given in our [Press Release](#) of September 4, 2025.

The Company plans to publish further data at upcoming ophthalmology conferences.

Key Future Milestones

- **NCX 470 NDA submission in the United States:** expected in H1 2026.
- **NCX 470 NDA submission in China:** expected shortly after submission in the U.S.
- **NCX 470 Phase 3 clinical program in Japan:** Program initiated in summer 2025. Managed and financed by Kowa.

Denali Trial Design

Similar to Mont Blanc, Denali is a randomized, multi-regional, double-masked, parallel group trial that evaluated the safety and efficacy of NCX 470 ophthalmic solution, 0.1% compared to latanoprost ophthalmic solution, 0.005% in 696 patients in 90 sites in the U.S. and China. Latanoprost is the most widely prescribed first-line therapy for open-angle glaucoma or ocular hypertension.

The primary efficacy evaluation was based on reduction from baseline in mean time-matched IOP at 6 timepoints: 8 AM and 4 PM at week 2, week 6 and month 3. The Denali trial also

included a long-term safety extension from 6 months through to 12 months and was jointly conducted and equally financed with our Chinese partner, Ocumension Therapeutics.

About Nicox

Nicox SA is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. Nicox's lead late-stage development program is NCX 470 (bimatoprost grenod), a novel nitric oxide-donating bimatoprost eye drop, for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension, licensed to Ocumension Therapeutics for the Chinese, Korean and Southeast Asian markets and to Kowa in the rest of the world. Nicox also has a preclinical research program on NCX 1728, a nitric oxide-donating phosphodiesterase-5 inhibitor, with Glaukos. Nicox's first product, VYZULTA® in glaucoma, licensed exclusively worldwide to Bausch + Lomb, is available commercially in the U.S. and over 15 other territories. Nicox generates revenue from ZERVIAE® in allergic conjunctivitis, licensed in multiple geographies, including to Harrow, Inc. in the U.S., and Ocumension Therapeutics in the Chinese and in the majority of Southeast Asian markets.

Nicox, headquartered in Sophia Antipolis, France, is listed on Euronext Growth Paris (Ticker symbol: ALCOX).

For more information www.nicox.com

Analyst coverage

H.C. Wainwright & Co Yi Chen New York, U.S.



The views expressed by analysts in their coverage of Nicox are those of the author and do not reflect the views of Nicox. Additionally, the information contained in their reports may not be correct or current. Nicox disavows any obligation to correct or to update the information contained in analyst reports.

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Risks factors which are likely to have a material effect on Nicox's business are presented in section 3 of the "Rapport Annuel 2024" which is available on Nicox's website (www.nicox.com).

Finally, this press release may be drafted in the French and English languages. If both versions are interpreted differently, the French language version shall prevail.

Nicox S.A.

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