

Novartis acquires Kedalion Therapeutics and its innovative ocular delivery platform that could transform patient experience

Jun 30, 2022

- Novartis acquires AcuStream[™] platform, a novel topical ocular delivery device designed to facilitate dosing precision with the potential to support the delivery of front-of-eye therapies and help patient comfort during therapy administration¹⁻³
- Acquisition underscores Novartis commitment to deliver innovative, customer- and patient-centric ophthalmic advancements for a range of eye conditions

East Hanover, N.J., June 30, 2022 — Novartis today announced that it has acquired Kedalion Therapeutics and its AcuStream[™] technology, an innovative device that may have the potential to facilitate precise dosing and accurate delivery of certain topical ophthalmic medications to the eye^{1,2}. The acquisition enhances the Novartis ophthalmics portfolio, advancing efforts to investigate transformative ophthalmic methods to address unmet patient needs in front-of-eye conditions.

"The acquisition of Kedalion Therapeutics delivers on our commitment to reimagine medicine by potentially enhancing the delivery and patient experience with our medicines," said Jill Hopkins, SVP and Global Development Unit Head, Ophthalmology, Novartis. "We look forward to exploring how AcuStream can advance our approved and investigational front-of-eye therapies and optimize outcomes for patients."

The AcuStream platform is a preservative-free, electromechanical topical ocular delivery device that may facilitate precise dosing and accurate delivery, potentially helping patients' experience 1-5.

Presently, Novartis intends to develop the AcuStream technology for potential use with its existing and future front-of-eye therapies, which could include Xiidra[®] (lifitegrast ophthalmic solution) 5%, a first-in-class prescription LFA 1 antagonist for the treatment of dry eye disease^{6,7}.

Kedalion Therapeutics is a clinical-stage, venture-funded ophthalmic drug company based in Menlo Park, California. In November 2021, Kedalion Therapeutics announced the completion of its Series B financing led by Novartis, which included an exclusive option to acquire the company and its AcuStream technology.

Xiidra Indication

Xiidra (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease.

Xiidra Important Safety Information

Xiidra is contraindicated in patients with known hypersensitivity to liftegrast or to any of the other ingredients.

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge,

eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

For additional safety information, visit Xiidra.com for Full Prescribing Information.

About Novartis in Ophthalmology

At Novartis, our mission is to discover new ways to improve and extend people's lives. In ophthalmology, we develop and deliver life-changing medicines and therapies for diseases and conditions from front to back of the eye, enabled by data and transformative technologies. Our ophthalmic solutions reach more than 150M people per year.

Disclaimer

This media update contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "seek," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this media update, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the investigational or approved products described in this media update will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this media update as of this date and does not undertake any obligation to update any forward-looking statements contained in this media update as a result of new information, future events or otherwise.

About Novartis

Located in East Hanover, NJ Novartis Pharmaceuticals Corporation – an affiliate of Novartis – is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis employs nearly 15,000 people in the United States. For more information, please visit

2/4

https://www.novartis.us.

Novartis and Novartis US is on Twitter. Sign up to follow @Novartis at https://twitter.com/novartisnews and @NovartisUS at https://twitter.com/NovartisUS.

For Novartis multimedia content, please visit https://www.novartis.com/news/media-library.

For questions about the site or required registration, please contact media.relations@novartis.com.

References

- Quiroz-Mercado H, Ivri E, Gonzalez-Salinas R, et al. Clinical evaluation of a novel electromechanical topical ocular drug delivery system: two phase 1 proof of concept studies. *Clin Ophthalmol*. 2020;14:139-147.
- 2. Data on file. AcuStream repetitive acute and real-time delivery study. Novartis, 2022.
- 3. Data on file. Patient Comfort Testing Results. Kedalion Therapeutics, 2021.
- 4. Data on file. Kedalion Report September 2021. Kedalion Therapeutics, 2021.
- 5. Data on file. Device Focus Group. Kedalion Therapeutics, 2019.
- 6. XIIDRA [prescribing information] East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2020.
- 7. US Food and Drug Administration Press Release. https://www.fda.gov/news-events/press-announcements/fda-approves-new-me.... Accessed May 17, 2022.

###

Novartis Media Relations

E-mail: media.relations@novartis.com

Julie Masow

Head, US External Engagement +1 862 579 8456

julie.masow@novartis.com

Vicki Crafton

Director, US & Global Pharma TA Communications

+1 201 213 6338

vicki.crafton@novartis.com

Novartis Investor Relations

E-mail: investor.relations@novartis.com

North America Sloan Simpson +1 862 778 5052

Source URL: https://qa1.novartis.us/news/media-releases/novartis-acquires-kedalion-therapeutics-and-its-innovative-ocular-delivery-platform-could-transform-patient-experience

List of links present in page

- 1. https://qa1.novartis.us/news/media-releases/novartis-acquires-kedalion-therapeutics-and-its-innovative-ocular-delivery-platform-could-transform-patient-experience
- 2. https://qa1.novartis.us/sites/novartis_us/files/xiidra.pdf
- 3. https://www.novartis.us
- 4. https://twitter.com/novartisnews
- 5. https://twitter.com/NovartisUS
- 6. https://www.novartis.com/news/media-library

- 7. mailto:media.relations@novartis.com
- 8. https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-dry-eye-disease
- 9. mailto:media.relations@novartis.com
- 10. mailto:julie.masow@novartis.com
- 11. mailto:vicki.crafton@novartis.com
- 12. mailto:investor.relations@novartis.com