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# MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

# Novartis successfully completes acquisition of Xiidra®, bolstering ophthalmic portfolio

**Basel, July 1, 2019** – Novartis today announced that it has completed its acquisition of Xiidra® (lifitegrast ophthalmic solution) 5%, the first and only prescription treatment approved to treat both signs and symptoms of dry eye by inhibiting inflammation caused by the disease<sup>1</sup>.

Marie-France Tschudin, President, Novartis Pharmaceuticals, said: "This deal delivers on our ongoing commitment to reimagine medicine for patients suffering from a variety of eye diseases, while also laying critical groundwork for future, potential front-of-the-eye pipeline products we have in development."

#### **About Xiidra**

Xiidra is a prescription eye drop solution designed to treat the signs and symptoms of dry eye disease<sup>1</sup>. It is dosed twice per day, approximately 12 hours apart, in each eye<sup>1</sup>. Xiidra is approved to treat signs and symptoms of dry eye disease in multiple markets including the US, Canada and Australia. It is under regulatory review in a number of additional markets.

Approximately 1000 patients were treated with Xiidra in four vehicle-controlled 12-week trials<sup>1</sup>. Each of the four studies assessed the effect of Xiidra on both the signs and symptoms of dry eye disease at baseline, week two, six and 12<sup>1</sup>.

In three of the four studies, a larger reduction in the eye dryness score (EDS) was observed with Xiidra at six and 12 weeks<sup>1</sup>. In two of the four studies, an improvement in EDS was seen with Xiidra at two weeks<sup>1</sup>. At week 12, a larger reduction in inferior corneal staining score (ICSS) favoring Xiidra was observed in three of the four studies<sup>1</sup>. The most common adverse reactions reported in 5 to 25 percent of patients were instillation site irritation, altered taste sensation (dysgeusia) and reduced visual acuity<sup>1</sup>.

#### **Disclaimer**

This press release 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 "bolstering," "potential," "milestone," "ongoing," "commitment," "future," "pipeline," or similar terms, or by express or implied discussions regarding potential future milestone payments, or regarding potential future revenues from Xiidra or the other products in the Novartis ophthalmic pharmaceutical portfolio and pipeline. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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 Novartis will be required to make any milestone payments for Xiidra in the future. Neither can there be any guarantee that Novartis will be able to realize any of the potential strategic benefits, synergies or opportunities as a result of the acquisition. Nor can there be any guarantee that Xiidra or other products in the Novartis

ophthalmic pharmaceuticals portfolio and pipeline will be commercially successful in the future. In particular, management's expectations regarding these products could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the potential that the strategic benefits, synergies or opportunities expected from the acquisition of Xiidra, including the potential impact of the acquisition of Xiidra on the success of potential future products, may not be realized or may take longer to realize than expected; the uncertainties inherent in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection; safety, quality or manufacturing issues; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; the particular prescribing preferences of physicians and patients; 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 press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

# **About Novartis in ophthalmology**

Novartis is reimagining the treatment and prevention of visual impairment and blindness. By working to push the boundaries of medicine and technology, we aim to develop life-changing gene therapies, next-generation pharmaceuticals, and transformative technologies for diseases and conditions spanning every area of eye disease, including front and back of the eye.

#### **About Novartis**

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 products reach more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 105 000 people of more than 140 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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# References

 FDA. Xiidra (lifitegrast ophthalmic solution). Prescribing information. Available at: https://www.accessdata.fda.gov/drugsatfda\_docs/label/2016/208073s000lbl.pdf. Accessed June 20, 2019.

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