

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**

**Novartis to acquire Xiidra<sup>®</sup>, expanding front-of-eye portfolio and strengthening leadership in eye care**

- *Xiidra (lifitegrast ophthalmic solution) 5% fits strategically within industry-leading USD 4.6 billion Novartis ophthalmic pharmaceutical portfolio, laying groundwork for front-of-the-eye pipeline products currently in development<sup>1</sup>*
- *Xiidra is the first and only prescription treatment approved for both signs and symptoms of dry eye disease with a mechanism of action that targets inflammation<sup>2</sup>*
- *Xiidra achieved USD 0.4 billion of revenue in 2018 and is well positioned for blockbuster potential; closing expected in second half of 2019, subject to satisfaction of customary closing conditions, including regulatory approvals*
- *Deal terms include a USD 3.4 billion upfront payment with potential milestone payments of up to USD 1.9 billion*

**Basel, May 9, 2019** – Novartis announced today that it has entered into an agreement with Takeda Pharmaceutical Company Limited to acquire the assets associated with Xiidra<sup>®</sup> (lifitegrast ophthalmic solution) 5% worldwide. Xiidra is the first and only prescription treatment approved to treat both signs and symptoms of dry eye by inhibiting inflammation caused by the disease<sup>2</sup>. The transaction would bolster the Novartis front-of-the-eye portfolio and ophthalmic leadership. Closing of the transaction is expected in second half of 2019, subject to customary closing conditions including regulatory approvals. On closing, Novartis plans a smooth transition of operations and integration of Xiidra into its pharmaceuticals portfolio.

Dry eye is a common inflammatory disease that, left untreated, can become extremely painful and lead to permanent damage to the cornea and vision<sup>3</sup>. This damage manifests in the form of signs that can be objectively measured by eye care professionals through various clinical tests (such as corneal staining), and symptoms (such as pain and discomfort). Xiidra, with its anti-inflammatory mechanism of action, is the first dry eye treatment approved to treat both the signs of eye damage and the physical symptoms experienced by patients. Additional benefits of Xiidra, exhibited in phase III studies, include a timely onset of action and well-tolerated safety profile.

“Xiidra, with its unique dual benefits, is an example of the type of innovative advances we invest in for the benefit of patients,” said Paul Hudson, CEO Novartis Pharmaceuticals. “We look forward to leveraging our well-established commercial infrastructure to bring this medicine to more patients.”

In addition to powering Novartis’ ability to serve more patients suffering from eye disease, the additional commercial experience established with Xiidra is expected to better position the company for front-of-the-eye pipeline products currently in development.

Deal terms include a USD 3.4 billion upfront payment with potential milestone payments of up to USD 1.9 billion. As part of the agreement, Novartis will be taking on approximately 400 employees associated with the product.

### **About dry eye disease**

Dry eye disease is a multifactorial disease of the tears and ocular surface<sup>3</sup>. In the US, it is estimated that more than 34 million people are impacted by the disease<sup>3</sup>. It is diagnosed by an eye care professional based on patient-reported symptoms such as eye dryness, overall eye discomfort, stinging, burning, a gritty feeling or fluctuating blurry vision, as well as signs of damage to the eye's surface, which include redness and corneal damage that can be objectively evaluated by an eye care professional through various tests<sup>4</sup>. Dry eye disease can interrupt daily activities such as reading, driving, working, using technology and spending time outside in bright light and cold or windy conditions<sup>3</sup>. Aging and gender (more prevalent in females) are recognized as traditional risk factors of dry eye disease while modern risk factors include prolonged digital/computer screen time, contact lens wear and cataract or refractive surgery<sup>4,5</sup>. Dry eye may be progressive and is one of the most common reasons people visit eye care professionals<sup>6</sup>.

### **About Xiidra**

Xiidra is a prescription eye drop solution designed to treat the signs and symptoms of dry eye disease<sup>2</sup>. It is dosed twice per day, approximately 12 hours apart, in each eye<sup>2</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>2</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>2</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>2</sup>. In two of the four studies, an improvement in EDS was seen with Xiidra at two weeks<sup>2</sup>. At week 12, a larger reduction in inferior corneal staining score (ICSS) favoring Xiidra was observed in three of the four studies<sup>2</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>2</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 "to acquire," "expanding," "strengthening," "strategically," "laying groundwork," "pipeline," "in development," "well positioned," "potential," "expected," "subject to," "closing conditions," "would," "plans," "look forward to," "position," "aim," or similar terms, or by express or implied discussions regarding potential completion of the announced acquisition of Xiidra, 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 the proposed acquisition of Xiidra will be completed in the expected form or within the expected time frame or at all. Nor can there be any 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, including an unexpected failure to obtain necessary government approvals for the acquisition of Xiidra, or unexpected delays in obtaining such approvals; the potential that any other closing conditions for acquisition of Xiidra might not be met; 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; uncertainties regarding actual or potential legal proceedings, including, among others, potential legal proceedings with respect to the proposed acquisition; 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](http://www.novartis.com).

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