Novartis enters into agreement to acquire Xiidra®

May 9, 2019
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Xiidra® strengthens leadership in ophthalmic pharmaceuticals with de-risked asset and attractive economics

1. Xiidra® fits strategically within Novartis’ industry-leading USD 4.6bn\(^1\) ophthalmic pharmaceutical portfolio and pipeline, laying groundwork for future launches

2. Xiidra® is the only prescription treatment approved for both signs and symptoms of dry eye disease with a mechanism of action that targets inflammation

3. De-risked USD 0.4bn\(^1\) in-market asset, with blockbuster potential in a large and growing patient population addressing high unmet need

4. Attractive economics, global rights, accretive to sales in 2019, margin in 2021; closing expected in 2019, subject to satisfaction of customary closing conditions

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1. 2018 calendar year sales
Xiidra® fits strategically within Novartis’ leading ophthalmic portfolio, pipeline and existing infrastructure

- Xiidra® is an innovative treatment approved for signs and symptoms of dry eye
- Xiidra® would provide a bridge from current mature front of the eye portfolio to innovative potential future launches
- Novartis is well positioned to maximize Xiidra® potential by leveraging existing front of the eye marketing expertise and scale, including market access

Existing ophthalmic pharmaceuticals portfolio – indicative brands

1. Ex-US only
Xiidra® helps lay groundwork for potential future innovative launches

Note: timeline is not to scale

Note: UNR844, ECF843, SAF312 all in Phase II development

1 Approved in the US (marketed by Spark Therapeutics) and EU (marketed by Novartis)

2 Pending regulatory approvals. DME and RVO indications are planned

<table>
<thead>
<tr>
<th>Gene therapy &amp; rare diseases</th>
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<tr>
<td>Luxturna¹ (2019) Inherited Retinal Disease (gene therapy)</td>
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<th>Retinal diseases</th>
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<td>RTH258 (2019) nAMD² (anti-VEGF)</td>
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<th>Refractive eye diseases</th>
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<td>Presbyopia (pharmacological agent)</td>
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<th>Ocular surface diseases</th>
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<tr>
<td>Dry Eye (biologic) Ocular Surface Pain (topical agent)</td>
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Transaction Highlights (expected closing H2 2019)

Scope
- Global rights
- Approximately 400 full time employees mostly in the US

Consideration
- Initial payment of USD 3.4 billion and additional contingent payments up to USD 1.9 billion structured to appropriately capture upside value for both companies
- First contingent payment would be due once Xiidra® reaches annual sales of USD 1.2 billion

Financing
- The transaction will be fully financed by cash on hand by Novartis

Financial Benefits
- Expected to contribute to Group sales in 2019
- Expected to be accretive to Group core operating income from 2020
- Expected to be accretive to Group core operating income margin from 2021

Other
- Closing expected in second half of 2019, subject to satisfaction of customary closing conditions, including regulatory approvals
Xiidra® is the first and only Rx treatment approved for signs and symptoms of dry eye disease with a MOA that targets inflammation

- Xiidra® is designed to block the interaction between LFA-1\(^1\) and ICAM-1\(^2\), inhibiting the immunological synapse (IS)
- Inhibits T-cell recruitment and activation and reduces pro-inflammatory cytokine release
- Unique Label:
  - Approved for signs and symptoms
  - Fast onset of action, 2 weeks to 3 months
  - Tolerable safety profile

\(^1\) lymphocyte function-associated antigen-1
\(^2\) intercellular adhesion molecule-1
Summary of clinical data

Scope
Approximately 1,000 patients were treated with Xiidra® in four placebo-controlled 12-week trials

Symptoms
In all four studies, a larger reduction in the Eye Dryness Scale (EDS) score was observed with Xiidra® at six and 12 weeks

Fast onset
In two of the four studies, an improvement in EDS was seen with Xiidra® at two weeks

Signs
At week 12, a larger reduction in inferior corneal staining score (ICSS) favoring Xiidra® was observed in three of the four studies

1 FDA. Xiidra® (lifitegrast ophthalmic solution). Prescribing information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208073s000lbl.pdf
Xiidra® opportunity currently focused on US and Canada; Ex-US opportunities to be explored

Launched

- Xiidra® launched in US in 2016, sales currently in the US and Canada
- Majority of current dry eye prescription demand is in the US and Canada

Rest of world

- Global rights acquired
- Approved and under review in several countries
- Commercialization opportunities will be reviewed following closing
Dry Eye Disease is one of the most common reasons patients visit an eye care professional \(^1\)

### Underdiagnosed and undertreated

<table>
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<th>US dry eye patients (^2,3)</th>
<th>34 million</th>
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<tr>
<td>Diagnosed by ECP (^4)</td>
<td>17m</td>
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<tr>
<td>Prescribed Rx (^5)</td>
<td>1.6m</td>
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- ~50% self diagnose
- ~10% treated with Rx

### Increasing incidence due to

- Aging population
- Digital devices use
- Contact lens wear

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\(^1\) Nichols KK et al. Inv Ophthalmol & Vis Sci. 2016;57:2975-2982
\(^3\) 3. US Census Bureau. Annual estimates of the resident population for selected age groups by sex for the United States, States, Counties, and Puerto Rico Commonwealth and Municiopos: April 1, 2010 to July 1, 2014.
\(^4\) Schaumberg et al, 2013, Prevalence of diagnosed dry eye in the US, Marketscope 2018 report – Diagnosed Dry Eye patients in the US,
\(^5\) Novartis Dry Eye market forecasts in the US, Mar 2019, validated with IQVIA TRx and NBRx claims data

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**Significant unmet need. US prescriptions expected to increase significantly with increasing incidence and use of more effective therapies**
Xiidra® addresses a high unmet need in the dry eye treatment paradigm

1st line
mostly mild patients
- Artificial Tears / OTC drops

2nd line
mostly moderate patients
- Rx Anti-inflammatories drops: incl. cyclosporine and Xiidra®
- Punctal plugs

3rd line
mostly severe patients
- Thermal pulsation
- Permanent punctual occlusion

- Cyclosporine emulsion has its limitations, including onset of action up to 6 months\(^1\)
- Even with the availability of cyclosporine, vast majority of surveyed ophthalmologists desired additional treatment options\(^1\)

Novartis industry leadership and commercial infrastructure setup to continue Xiidra® success & maximize its potential

US Infrastructure:
• 375 FF in-line products
• Market access expertise
• Field medical
• Retina team for expected RTH258 launch in Q4 2019¹

Novartis global ophthalmic 2018 sales²:
#1 in Anti-inflammatory
#1 in Anti-allergy
#1 in Anti-infective
#2 in Glaucoma
#2 in Retina (outside US)

¹ Pending regulatory approval
² Rankings based on 2018 sales from IQVIA
Confident in Xiidra® blockbuster potential with unique profile, growing market and Novartis expertise

Xiidra® US Net sales per quarter (USDm)

- Xiidra® grew +48% in 2018
- High unmet need & unique profile
- Leverage Novartis scale and expertise in eye care, including market access
- Optimize DTC to maximize brand awareness

Source: Shire and Takeda disclosures based on calendar year end  
1. partly benefitting from stock in trade movements
Conclusion

- Fits strategically within Novartis’ industry leading ophthalmic pharmaceutical portfolio and pipeline

- Xiidra® is the first and only Rx treatment approved for signs and symptoms of dry eye disease with a MOA that targets inflammation

- De-risked in-market asset, with blockbuster potential in a large and growing patient population