

## **MEDIA & INVESTOR RELEASE**

# **Novartis to acquire Gyroscope Therapeutics, adding a one-time gene therapy that could transform care for geographic atrophy, a leading cause of blindness**

- *There are no currently approved therapies impacting disease progression for the up to 8 million people suffering from geographic atrophy (GA)<sup>1,2</sup>*
- *Acquisition will add GT005 to the Novartis portfolio, an investigational, one-time gene therapy currently in Phase 2 for the treatment of people living with GA*
- *Potential to be the first therapy with sustained efficacy for a broad GA patient population*
- *Acquisition complements Novartis established expertise in retinal diseases and gene therapy and further builds position in ophthalmology gene therapy and optogenetics following acquisitions of Vedere Bio and Arctos Medical*

**Basel, December 22, 2021** — Novartis announced today that it entered into a definitive agreement to acquire all of the outstanding share capital of the UK-based ocular gene therapy company Gyroscope Therapeutics.

Geographic atrophy (GA) is an advanced form of dry age-related macular degeneration (AMD) that leads to progressive and irreversible vision loss<sup>1</sup>. There are no approved treatments for GA, making it one of the most significant unmet needs remaining in retinal diseases<sup>2</sup>.

GT005 is designed as an AAV2-based, one-time investigational gene therapy for GA secondary to AMD that is delivered under the retina. GT005 aims to restore balance to an overactive complement system, a part of the immune system, by increasing production of the CFI protein. Complement overactivation can lead to inflammation that damages healthy tissues, and it has been strongly correlated with the development and progression of AMD<sup>3</sup>. The CFI protein regulates the activity of the complement system. It is believed that increasing CFI production could reduce inflammation, with the goal of preserving a person's eyesight.

The safety and efficacy of GT005 for the treatment of GA secondary to AMD is currently being evaluated in a Phase 1/2 clinical trial and two Phase 2 clinical trials<sup>4,5,6</sup>. GT005 has received Fast Track designation from the U.S. Food and Drug Administration for the treatment of people with GA.

Gyroscope also has several additional assets in its pipeline in early discovery for retinal diseases.

“With our own pioneering research in ocular gene therapies and our experience gained from bringing Luxturna to inherited retinal dystrophy patients outside of the US, Novartis has a well-established expertise in ocular gene therapies that will position us well to continue developing this promising one-time treatment” said Marie-France Tschudin, President, Novartis Pharmaceuticals. “This acquisition is one more step forward in our commitment to delivering innovation in ophthalmology to treat and prevent blindness worldwide.”

Novartis will make an upfront payment of \$800 million and potential additional milestone payments of up to \$700 million. Closing of the transaction is subject to customary closing conditions including regulatory approvals. Until closing, Novartis and Gyroscope Therapeutics will continue to operate as separate and independent companies.

### **About geographic atrophy (GA)**

Dry AMD is a leading cause of permanent vision loss in people over the age of 55 and is a devastating diagnosis<sup>2,7</sup>. As dry AMD advances, it leads to GA, an irreversible degeneration of retinal cells, causing a gradual and permanent loss of central vision. This disease can severely impact a person’s daily life as they lose the ability to drive, read and even see faces<sup>7</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 “potential,” “will,” “plan,” “could,” “commitment,” “investigational,” “to acquire,” “to develop,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for GT005, the acquisition of Gyroscope Therapeutics, or regarding potential future revenues from GT005. 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 GT005 will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Neither can there be any guarantee expected benefits or synergies from this transaction will be achieved in the expected timeframe, or at all, nor can there be any guarantee that GT005 will be commercially successful in the future. In particular, our expectations regarding GT005 or the transaction described in this media update could be affected by, among other things, the satisfaction of customary closing conditions including regulatory approvals, 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**

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 nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <https://twitter.com/novartisnews>  
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](mailto:media.relations@novartis.com)

## References

- <sup>1</sup> Schmitz-Valckenberg S, et al. Natural History of Geographic Atrophy Progression Secondary to Age-Related Macular Degeneration (Geographic Atrophy Progression Study) *Ophthalmology* 2016;123:361-368.
- <sup>2</sup> National Institute of Health. "Age-Related Macular Degeneration". Accessed December 2021. <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/age-related-macular-degeneration>.
- <sup>3</sup> Holz FG, et al. Geographic Atrophy: Clinical Features and Potential Therapeutic Approaches. *Ophthalmology* 2014;121(5):1079-1091.
- <sup>4</sup> U.S. National Library of Medicine. "EXPLORE: A Phase II Study to Evaluate the Safety and Efficacy of Two Doses of GT005 (EXPLORE)". Accessed December 2021. <https://clinicaltrials.gov/ct2/show/NCT04437368?term=geographic+atrophy%2C+GT005&cond=Macular+Degeneration&draw=2&rank=1#contacts>
- <sup>5</sup> U.S. National Library of Medicine. "HORIZON: A Phase II Study to Evaluate the Safety and Efficacy of Two Doses of GT005". Accessed December 2021. <https://clinicaltrials.gov/ct2/show/NCT04566445?term=GT005&draw=2>
- <sup>6</sup> U.S. National Library of Medicine. "FocuS: First in Human Study to Evaluate the Safety and Efficacy of GT005 Administered in Subjects With Dry AMD". Accessed December 2021. <https://clinicaltrials.gov/ct2/show/NCT03846193?term=FOCUS&cond=Geographic+Atrophy&draw=2&rank=1>
- <sup>7</sup> American Macular Degeneration Foundation. "Macular Degeneration". Accessed December 2021. <https://www.macular.org/what-macular-degeneration>.

###

## Novartis Media Relations

E-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

Amy Wolf  
Novartis External Communications  
+41 79 576 0723 (mobile)  
[amy.wolf@novartis.com](mailto:amy.wolf@novartis.com)

Meghan O'Donnell  
Novartis Pharma Communications  
+41 61 324 9123 (direct)  
+41 79 797 9102 (mobile)  
[meghan.odonnell@novartis.com](mailto:meghan.odonnell@novartis.com)

Julie Masow  
Novartis US External Communications  
+1 862 579 8456  
[Julie.masow@novartis.com](mailto:Julie.masow@novartis.com)

## Novartis Investor Relations

Central investor relations line: +41 61 324 7944  
E-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Central		North America	
Samir Shah	+41 61 324 7944	Sloan Simpson	+1 862 345 4440
Thomas Hungerbuehler	+41 61 324 8425	Alina Levchuk	+1 862 778 3372

Isabella Zinck

+41 61 324 7188

Parag Mahanti

+1 973-876-4912