



## **Allergan and Molecular Partners Announce Two Positive Phase 3 Clinical Trials for Abicipar pegol 8 and 12-week Regimens for the Treatment in Patients with Neovascular Age-Related Macular Degeneration**

July 19, 2018

**Abicipar, the first and only anti-VEGF to maintain stable vision in greater than 91 percent of patients on a fixed 12-week regimen, achieved the primary endpoint of non-inferiority to monthly ranibizumab at week 52**

**Two pivotal head-to-head trials demonstrate the efficacy of Abicipar 12-week fixed dosing regimen with 50 percent fewer injections versus ranibizumab**

**DUBLIN, IRELAND – July 19, 2018** – Allergan plc, (NYSE: AGN), a leading global pharmaceutical company and Molecular Partners (SIX: MOLN), a clinical-stage biopharmaceutical company developing a new class of drugs known as DARPIn® therapies, today announced the release of two positive clinical trials, SEQUOIA and CEDAR for abicipar, demonstrating that both the 8-week and 12-week treatment regimens met the pre-specified primary endpoint of non-inferiority to ranibizumab. SEQUOIA and CEDAR are identical global phase 3 studies designed to assess the efficacy and safety of abicipar compared with ranibizumab in treatment-naïve patients with neovascular age-related macular degeneration (AMD). The primary endpoint measured the proportion of treated patients with stable vision at week 52.

In both studies abicipar demonstrated similar efficacy after 6 or 8 injections, compared to 13 ranibizumab injections in the first year of this study. The overall adverse events were similar among the three treatment arms. The incidence of intraocular inflammation was higher in the abicipar arms compared to ranibizumab-treated patients in both trials. We are further analyzing these results. SEQUOIA and CEDAR clinical trials continue on a masked basis for a second year.

The filing for abicipar is planned for the first half of 2019. Allergan will be requesting a meeting with the Food and Drug Administration (FDA) to discuss our BLA submission.

In the SEQUOIA study, the proportion of patients with stable vision in abicipar dosed Q8 was 94.8 percent, in Q12 was 91.3 percent compared to ranibizumab dosed Q4 96.0 percent.

In CEDAR, the proportion of patients with stable vision in the abicipar dosed Q8 was 91.7 percent, in Q12 was 91.2 percent compared to ranibizumab dosed Q4 95.5 percent.

“In both studies abicipar demonstrated remarkable efficacy in the 8-week and 12-week regimens,” said David Nicholson, Chief Research and Development Officer, Allergan. “We are pleased with the outcome of these trials. We believe the SEQUOIA and CEDAR studies demonstrated what we set out to achieve, strong efficacy and duration of effect which shows the potential of abicipar as a treatment for AMD patients. We have generated important findings in these trials to address a serious unmet need. We will continue to review these data including inflammation findings and are working on further optimizing the abicipar formulation.”

“Abicipar could transform the way physicians manage AMD with anti-VEGF therapy. Today’s anti-VEGFs were designed for monthly or bimonthly dosing. In the real world, patients have difficulty adhering to the schedule, which places their vision at risk. The adopted treat-and extend approach, while practical, is supported by limited data and in certain cases shows sub-optimal visual outcomes. Treat-and-extend amounts to a compromise for most patients who are unable or unwilling to comply with frequent injections. Abicipar could be the first and only 12-week anti-VEGF treatment that improves visual outcomes in a real world setting for a large number of AMD patients,” said Raj Maturi, MD, Midwest Eye Institute & Associate Professor Ophthalmology, Indiana University School of Medicine.

“We are very excited to see that the most advanced DARPIn® molecule, abicipar, reaches its primary endpoint in phase 3. This is a very important milestone for Molecular Partners and the DARPIn® technology in general,” said Patrick Amstutz, PhD, CEO of Molecular Partners. “We are very pleased to see that abicipar can indeed help patients in need with less frequent dosing which was the key point when we generated abicipar in the first place,” added Michael T. Stumpp, PhD, COO of Molecular Partners.

In the SEQUOIA study, overall treatment-emergent adverse events were similar among the 3 treatment arms, reported in 78.3 percent, 78.0 percent and 74.0 percent of patients receiving abicipar Q8, abicipar Q12 and ranibizumab Q4, respectively.

Incidence of intraocular inflammation events was similar among the two abicipar treatment groups but higher than the ranibizumab arm and reported at 15.7 percent and 15.3 percent of patients in the abicipar Q8 and Q12 arms compared to 0.6 percent in the ranibizumab Q4 arm.

In the CEDAR study, overall treatment-emergent adverse events were similar among the 3 treatment arms reported in 73.7 percent, 81.1 percent and 73.2 percent of patients receiving abicipar Q8, abicipar Q12 and ranibizumab Q4, respectively.

Incidence of intraocular inflammation events was similar among the two abicipar treatment groups but higher than ranibizumab arm and reported at 15.1 percent and 15.4 percent of patients in the abicipar Q8 and Q12 arms compared to 0 percent in the ranibizumab Q4.

Allergan is continuing to review these data. The full data details of the primary endpoints and the secondary endpoints will be presented at an upcoming scientific conference.

**About the Abicipar SEQUOIA (006) AND CEDAR (005) Study Design**

These multicentered, randomized studies were conducted as global Phase 3 studies designed to assess the efficacy and safety of abicipar pegol compared with ranibizumab in treatment-naïve patients with neovascular age-related macular degeneration (AMD). The primary endpoint was based on a proportion of patients with stable vision at Week 52. Stable vision is defined as the proportion of patients with vision loss of fewer than or equal to 15 letters in best-corrected visual acuity (BCVA) from baseline. The study included 3 treatment arms: one arm was Q8: 2 mg abicipar pegol. 3 monthly doses followed by a dose every 8 weeks. 8 doses total for the primary analysis.

The second arm was Q12: 2 mg abicipar pegol with 2 monthly doses, followed by a dose after 8 weeks, followed by every 12 weeks dosing with 6 doses total for the primary analysis. The third arm was RQ4: 0.5 mg ranibizumab monthly doses and 13 doses total for the primary analysis.

#### **ALLERGAN CONFERENCE CALL AND WEBCAST**

Allergan will host a conference call and webcast today, Thursday, July 19, at 8:30 a.m. Eastern Time to discuss the results of the Abicipar study. The dial-in number to access the call is U.S./Canada (877) 251-7980, International (706) 643-1573, and the conference ID is **2267319**.

A taped replay of the conference call will also be available beginning approximately two hours after the call's conclusion, and will remain available through 11:30 p.m. Eastern Time on August 19, 2018. The replay may be accessed by dialing (855) 859-2056 or (404) 537-3406, and entering the conference ID **2267319**.

To access the webcast, please visit Allergan's Investor Relations website at <https://www.allergan.com/investors/events-presentations>. A replay of the webcast will also be available on Allergan's Investor Relations website.

#### **MOLEULAR PARTNERS CONFERENCE CALL AND WEBCAST**

Molecular Partners will host a conference call and webcast today, Thursday, July 19, at 4:00 p.m. Central European Time (CET) / 10:00 a.m. Eastern Time (ET) to discuss the results of the Abicipar study from a Molecular Partners corporate perspective.

The dial-in numbers to access the conference call are Switzerland / Europe +41 58 310 5000, UK +44 207 107 0613, U.S./Canada +1 (1) 631 570 5613.

In order to register for the corresponding conference call, please dial the following numbers approximately 10 minutes before the start of the event.

The corresponding [audio webcast](#) will be accessible, both live and as a replay, on the Investors section of the company's website [www.molecularpartners.com](http://www.molecularpartners.com), along with the accompanying presentation slides.

#### **About Allergan plc**

Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a bold, global pharmaceutical leader. Allergan is focused on developing, manufacturing and commercializing branded pharmaceutical, device, biologic, surgical and regenerative medicine products for patients around the world.

Allergan markets a portfolio of leading brands and best-in-class products for the central nervous system, eye care, medical aesthetics and dermatology, gastroenterology, women's health, urology and anti-infective therapeutic categories.

Allergan is an industry leader in Open Science, a model of research and development, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. With this approach, Allergan has built one of the broadest development pipelines in the pharmaceutical industry.

Allergan's success is powered by our global colleagues' commitment to being Bold for Life. Together, we build bridges, power ideas, act fast and drive results for our customers and patients around the world by always doing what is right.

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives every day.

For more information, visit Allergan's website at [www.Allergan.com](http://www.Allergan.com).

#### **About Molecular Partners AG**

Molecular Partners AG is a clinical-stage biopharmaceutical company that is developing a new class of therapies known as DARPIn® therapies. With a management team that includes many of the founding scientists, the company continues to attract talented individuals who share the passion to develop breakthrough medicines for serious diseases. Molecular Partners has compounds in various stages of clinical and preclinical development and several more in the research stage, with a current focus on ophthalmology and oncology. The company establishes research and development partnerships with leading pharmaceutical companies and is backed by established biotech investors.

For more information regarding Molecular Partners AG, go to: [www.molecularpartners.com](http://www.molecularpartners.com).

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**Forward-Looking Statement**

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Allergan's current perspective on existing trends and information as of the date of this release. Actual results may differ materially from Allergan's current expectations depending upon a number of factors affecting Allergan's business. These factors include, among others, the difficulty of predicting the timing or outcome of FDA approvals or actions, if any; the impact of competitive products and pricing; market acceptance of and continued demand for Allergan's products; the impact of uncertainty around timing of generic entry related to key products, including RESTASIS<sup>®</sup>, on our financial results; risks associated with divestitures, acquisitions, mergers and joint ventures; uncertainty associated with financial projections, projected cost reductions, projected synergies, restructurings, increased costs, and adverse tax consequences; difficulties or delays in manufacturing; and other risks and uncertainties detailed in Allergan's periodic public filings with the Securities and Exchange Commission, including but not limited to Allergan's Annual Report on Form 10-K for the year ended December 31, 2017 and Allergan's Quarterly Report on Form 10-Q for the period ended March 31, 2018. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

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