Allergan and Molecular Partners Announce Acceptance of U.S. FDA Biologics License Application and Validation of EMA Marketing Authorisation for Abicipar pegol in Patients with Neovascular (Wet) Age-related Macular Degeneration

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- *Filing includes data from two Phase 3 trials which evaluated the safety and efficacy of Abicipar quarterly dosing regimen*
- *Approvals in the United States and Europe are anticipated in 2020*

DUBLIN, IRELAND – SEPT 9, 2019 – Allergan plc, (NYSE: AGN), a leading global pharmaceutical company with a heritage of more than 70 years in eye care, and Molecular Partners (SIX: MOLN), a clinical-stage biotechnology company developing a new class of drugs known as DARPin® platform, today announced that the U.S. Food and Drug Administration (FDA) has accepted a Biologics License Application (BLA) and the European Medicines Agency (EMA) has validated a Marketing Authorisation Application (MAA) for Abicipar pegol, a novel, investigational DARPin® therapy, in patients with neovascular (wet) age-related macular degeneration (nAMD). The FDA is expected to take action on the BLA mid-2020. A decision from the European Commission is expected in the second half of 2020.

The BLA and MAA filings are based on data from two Phase 3 trials, CEDAR and SEQUOIA, which supported the non-inferior efficacy of the Abicipar quarterly dosing regimen to maintain vision gains with more than 50 percent fewer injections versus ranibizumab (13 vs. 6) dosed monthly in the first year.

“Acceptance of our marketing applications brings us one step closer to offering physicians and patients a new treatment option that has the potential to reduce patient visits and injections while achieving and maintaining vision gains with quarterly dosing,” said David Nicholson, Chief Research and Development Officer, Allergan. “Today’s announcement reinforces Allergan’s continued commitment to eye care innovation and means patients are one step closer to receiving what we believe to be a transformative treatment that will help address unmet needs for nAMD patients.”

The identical, global Phase 3 head-to-head pivotal trials, CEDAR and SEQUOIA, assessed the efficacy and safety of Abicipar compared with ranibizumab in treatment-naïve patients with nAMD. The primary endpoint measured the proportion of treated patients with stable vision at week 52 and, 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 (Abicipar dosed every 8 weeks, Abicipar dosed every 12 weeks, or ranibizumab dosed monthly).

“The FDA filing acceptance marks an important milestone for the DARPin ® technology as Abicipar becomes our first DARPin® candidate to receive filing acceptance by the FDA,” commented Michael T. Stumpp, COO of Molecular Partners. “We’re excited for the potential Abicipar holds to become a true quarterly dosed anti-VEGF treatment in patients with nAMD to provide vision gains and improved quality of life.”

DARPin® molecules are derived from naturally occurring binding proteins that consist of repeat sequences with capping structures at each end of the protein. DARPin® molecules have three key properties that have made them an important investigational class of binding protein for researchers: high binding affinity, low molecular weight and customizable applications. These three properties make DARPin® molecules candidates for a broad range of therapeutic applications and are currently being investigated in therapeutic categories such as ophthalmology, oncology and immuno-oncology. Allergan and Molecular Partners are committed to advancing patient care through the development of molecules such as Abicipar.

About Allergan Eye Care

As a leader in eye care, Allergan has discovered, developed, and delivered some of the most innovative products in the industry for more than 70 years. Allergan has launched over 125 eye care products and invested billions of dollars in new treatments for the most prevalent eye conditions including glaucoma, ocular surface disease, and retinal diseases such as diabetic macular edema and retinal vein occlusion. Our eye care pipeline includes 13 additional agents for multiple ocular conditions.

Our commitment to the well-being of patients is also reflected in philanthropy. Allergan and The Allergan Foundation support more than 150 organizations around the world working to improve lives and communities. We remain steadfast in helping eye care providers deliver the best in patient care through innovative products and outreach programs.

About Allergan plc

Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a global pharmaceutical leader 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 primarily focused on four key therapeutic areas including medical aesthetics, eye care, central nervous system and gastroenterology. As part of its approach to delivering innovation for better patient care, Allergan has built one of the broadest pharmaceutical and device research and development pipelines in the industry.

With colleagues and commercial operations located 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.

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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 ®, on our financial results; risks associated with divestitures, acquisitions, mergers and joint ventures; risks related to impairments; uncertainty associated with financial projections, projected cost reductions, projected debt reduction, 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, 2018 and Allergan's Quarterly Report on Form 10-Q for the period ended June 30, 2019. Except as expressly required by law, Allergan disclaims any intent or obligation to update these forward-looking statements.

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.

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