June 26, 2020

Allergan, an AbbVie Company, and Molecular Partners Receive Complete Response Letter from FDA on Biologics License Application for Abicipar pegol

NORTH CHICAGO, Ill., June 26, 2020 /PRNewswire (http://www.prnewswire.com/) / -- Allergan, an AbbVie Company (NYSE: ABBV), and Molecular Partners (SIX: MOLN), a clinical-stage biotechnology company developing a new class of custom-built protein therapeutics known as DARPin® therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter to the Biologics License Application (BLA) for Abicipar pegol, a novel, investigational DARPin® therapy for patients with neovascular (wet) age-related macular degeneration (nAMD).

The letter from the FDA indicates that the rate of intraocular inflammation observed following administration of Abicipar pegol 2mg/0.05 mL results in an unfavorable benefit-risk ratio in the treatment of neovascular (wet) age-related macular degeneration (AMD). AbbVie plans to meet with the FDA to discuss their comments and determine next steps.

"We continue to believe in the need for treatment options that provide patients with reliable vision gains and less frequent dosing for the treatment of nAMD," said Michael R. Robinson, M.D., Vice President, Global Therapeutic Area Head, Ophthalmology, AbbVie. "We are committed to working with the FDA to determine the appropriate next steps for Abicipar pegol."

The global need for eye health services is projected to increase dramatically in the coming decades, posing a considerable challenge to healthcare systems. Through building a strong, active pipeline, which is focused on significant unmet needs in eye care, AbbVie is committed to developing and delivering sustainable solutions that make a remarkable impact on people's lives.

About DARPin®
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 over a dozen additional agents for multiple ocular conditions.

We remain steadfast in helping eye care providers deliver the best in patient care through innovative products and outreach programs.

About AbbVie
AbbVie's mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.com (https://c212.net/c/link/?t=0&l=en&o=2842121-1&h=472145391&u=http%3A%2F%2Fwww.abbvie.com%2F&a=www.abbvie.com). Follow @abbvie (https://c212.net/c/link/?t=0&l=en&o=2842121-1&h=1112371664&u=https%3A%2F%2Ftwitter.com%2Fabbvie&a=%40abbvie) on Twitter (https://c212.net/c/link/?t=0&l=en&o=2842121-1&h=2257815989&u=https%3A%2F%2Ftwitter.com%2Fabbvie&a=Twitter), Facebook (https://c212.net/c/link/?t=0&l=en&o=2842121-1&h=378868189&u=https%3A%2F%2Fwww.facebook.com%2FAbbVieGlobal%2F&a=Facebook), Instagram (https://c212.net/c/link/?t=0&l=en&o=2842121-1&h=1253200891&u=https%3A%2F%2Fwww.instagram.com%2Fabbvie%2F&a=Instagram), YouTube (https://c212.net/c/link/?t=0&l=en&o=2842121-1&h=2405355254&u=https%3A%2F%2Fwww.youtube.com%2Fuser%2FAbbVie&a=YouTube) and LinkedIn (https://c212.net/c/link/?t=0&l=en&o=2842121-1&h=1012577455&u=https%3A%2F%2Fwww.linkedin.com%2Fcompany%2Fabbvie%2F&a=LinkedIn).

Forward-Looking Statements
Some statements in this news release are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, failure to realize the expected benefits from AbbVie's acquisition of Allergan plc ("Allergan"), failure to promptly and effectively integrate Allergan's businesses, competition from other products, challenges to intellectual property, difficulties inherent in the research and development process, adverse litigation or government action, changes to laws and regulations applicable to our industry and the impact of public health outbreaks, epidemics or pandemics, such as COVID-19. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2019 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission, as updated by its subsequent Quarterly Reports on Form 10-Q. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

About Molecular Partners AG
Molecular Partners AG is a clinical-stage biotech company developing a new class of custom-built proteins known as DARPin® therapeutics, designed to address challenges current modalities cannot. The company has compounds in various stages of clinical and preclinical development with a focus on oncology. Molecular Partners has formed partnerships with leading pharmaceutical companies to advance DARPin® therapeutics across multiple therapeutic areas.

For more information regarding Molecular Partners AG, go to: www.molecularpartners.com (https://c212.net/c/link/?t=0&l=en&o=2842121-1&h=2310468616&u=https%3A%2F%2Fc212.net%2Fc%2Flink%2F%3Ft%3D0%26l%3Den%26o%3D2421451-1%26h%3D1348911057%26u%3Dhttp%253A%252F%252Fwww.molecularpartners.com%252F%26a%3Dwww.molecularpartners.com&a=www.molecularpartners.com).

Disclaimer
This communication does not constitute an offer or invitation to subscribe for or purchase any securities of Molecular Partners AG. This publication may contain certain forward-looking statements and assessments or intentions concerning the company and its business. Such statements involve certain risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of the company to be materially different from those expressed or implied by such statements. Readers should therefore not place reliance on these statements, particularly not in connection with any contract or investment decision. The company disclaims any obligation to update these forward-looking statements, assessments or intentions.

SOURCE AbbVie

For further information: AbbVie Contacts: U.S. Media: Lisa Kim, +1 (714) 246-3843, or Investors: Liz Shea, (847) 935-2211, or Contacts Molecular Partners AG, Seth Lewis, SVP IR, Comms, & Strategy, Seth.Lewis@molecularpartners.com, Tel.: +1 781-420-2361, or Thomas Schneckenburger, EU IR & Media, thomas.schneckenburger@molecularpartners.com, Tel: +41 44 755 5728, or Tom Donovan, U.S. Media, tom@tenbridgecommunications.com, Tel: +1 857-559-3397

The information in the press releases on these pages was factually accurate on the date of publication. These press releases remain on AbbVie's website for historical purposes only. AbbVie assumes no duty to update the information to reflect subsequent developments. Readers should not rely upon the information in these pages as current or accurate after their publication dates.

For more information
Contact us » (https://news.abbvie.com/pr-contacts/)

Subscribe for email alerts
Sign up (https://news.abbvie.com/email-alerts)
Subscription management (https://news.abbvie.com/email-alerts)

AbbVie social media

We also welcome the opportunity to hear from you in these social channels, but remember we work in a highly-regulated industry with unique legal considerations. Before engaging, please read and adhere to our established community guidelines for each channel.

View our social media channel guidelines » (https://www.abbvie.com/social-media-community-guidelines.html)

AbbVie.com (https://www.abbvie.com/) | Site Map (https://www.abbvie.com/site-map.html) | Terms of Use (https://www.abbvie.com/termsofuse.html) | Privacy Notice (https://www.abbvie.com/privacy.html) | Consumer Health Data Privacy Notice (https://abbv.ie/PrivacyConsumerHealth) | Cookies Settings | Your Privacy Choices (https://abbviemetadata.my.site.com/AbbvieDSRM) (https://abbviemetadata.my.site.com/AbbvieDSRM)

Copyright © 2025 AbbVie Inc. North Chicago, Illinois, U.S.A.

Unless otherwise specified, all product names appearing in this Internet site are trademarks owned by or licensed to AbbVie Inc., its subsidiaries or affiliates. No use of any AbbVie trademark, trade name, or trade dress in this site may be made without the prior written authorization of AbbVie Inc., except to identify the product or services of the company.

×