Amgen And Provention Bio Announce Co-Development Collaboration In Celiac Disease

Provention to Lead Phase 2b Stage of Development for Anti-IL-15 Antibody AMG 714

Amgen Will Invest $20 Million in Provention Equity

Amgen Will be Responsible for Clinical Trial Supply and Manufacturing

PRVB

THOUSAND OAKS, Calif. and OLDWICK, N.J., Nov. 5, 2018 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Provention Bio, Inc. (NASDAQ:PRVB), a clinical-stage biopharmaceutical company focused on immune-mediated diseases, today announced a licensing and co-development agreement for AMG 714, identified by Provention as PRV-015. AMG 714 is a novel anti-IL-15 monoclonal antibody being developed for the treatment of gluten-free diet non-responsive celiac disease (NRCD). Development efforts at Provention will be led by researchers with previous experience developing AMG 714.

Under the terms of the agreement, Provention will conduct and fund a Phase 2b trial in NRCD and lead the next phase of development and regulatory activities for the program. Amgen will make a $20 million investment coincident with Provention's next financing event, subject to certain terms and conditions. Amgen is also responsible for the manufacturing of AMG 714. Upon completion of the Phase 2b trial, Provention will be eligible to receive a $150 million milestone payment, as well as additional regulatory milestone payments and royalties if Amgen continues AMG 714 development.

"Celiac disease impacts millions of people around the world and remains the only common autoimmune disease with no approved therapeutic treatment," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "We are pleased to collaborate with Provention, given their expertise and familiarity with AMG 714, in advancing a potential new treatment option for patients living with this life-interrupting illness."

"Our AMG 714 co-development collaboration with Amgen is a significant milestone in the growth and advancement of Provention. AMG 714 has the potential to be the first FDA-approved treatment for celiac disease and aligns with Provention's mission to prevent and intercept immune-mediated disease," said Ashleigh Palmer, co-founder and chief executive officer of Provention.

"Data presented at Digestive Disease Week 2018 from two Phase 2a clinical trials of AMG 714 demonstrated the drug's potential in celiac disease and refractory celiac disease type II (RCD-II), an in situ gastrointestinal T cell lymphoma, and confirmed that IL-15 plays a central role in non-responsive celiac disease and RCD-II," said Francisco Leon, M.D., Ph.D., co-founder and chief scientific officer of Provention. "We are delighted to be collaborating with Amgen to advance AMG 714 by way of the planned Phase 2b NRCD study."

About AMG 714
AMG 714 (PRV-015) is a human immunoglobulin monoclonal antibody that binds to IL-15. AMG 714 was initially developed by Amgen in rheumatoid arthritis and later investigated for possible use in celiac disease. In 2015, Amgen outlicensed AMG 714 to Celimmune LLC, a clinical development-stage immunotherapy company founded by Ashleigh Palmer and Francisco Leon, M.D., Ph.D. Celimmune conducted two separate

AMG 714 Phase 2a clinical trials in celiac disease and refractory celiac disease type II, after which Amgen acquired Celimmune in 2017. Data from both clinical trials were presented at Digestive Disease Week 2018.

About Celiac Disease
Celiac disease is a chronic hereditary systemic autoimmune and inflammatory disease triggered by gluten consumption that results in damage to the lining of the small intestine, causing gastrointestinal dysfunction and debilitating symptoms. Nutritional malabsorption can lead to a failure to thrive in children, and anemia and osteopenia in children and adults. Over the course of a lifetime, untreated or poorly managed celiac disease is often associated with deteriorating general health, multiple serious intestinal and extra-intestinal medical complications, and increased morbidity and mortality. It is estimated that currently one percent of Western and .5 percent of Asian populations suffer from celiac disease and diagnosed prevalence is expected to increase with improved diagnostic tools and clinical awareness. There are no approved medications for celiac disease.

About Amgen
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

About Provention Bio, Inc.
Provention Bio, Inc. is a clinical-stage biopharmaceutical company leveraging a transformational drug development strategy that is focused on the prevention or interception of immune-mediated disease. Provention's diverse portfolio was assembled with product candidates that have undergone clinical testing but may have been underdeveloped or deprioritized assets at other companies. Provention's mission is to in-license, transform and develop clinical-stage, or nearly clinical-stage, therapeutic candidates targeting the high morbidity, mortality and escalating costs of autoimmune and inflammatory diseases including: type 1 diabetes (T1D), Crohn's disease, ulcerative colitis, lupus, and certain life-threating viral diseases.

For more information on Provention Bio, please visit www.proventionbio.com.

Amgen Forward-Looking Statements
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including its most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed, and actual results may differ materially from those Amgen project. Amgen's results may be affected by its ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing its products and global economic conditions. In addition, sales of Amgen's products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify safety, side effects or manufacturing problems with its products, including its devices, after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. In addition, Amgen's business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. While Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors, or Amgen may fail to prevail in present and future intellectual property litigation. Amgen performs a substantial amount of its commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depends on third parties for a portion of its manufacturing activities, and limits on supply may constrain sales of certain of its current products and product candidate development. In addition, Amgen competes with other companies with respect to many of its marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. Certain of Amgen's distributors, customers and payers have substantial purchasing leverage in their dealings with Amgen. The discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on its business and results of operations. Amgen's efforts to acquire other companies or products and to integrate the operations of companies Amgen has acquired may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of Amgen's systems and Amgen's data. Amgen's stock price may be volatile and may be affected by a number of events. Amgen's business performance could affect or limit the ability of the Amgen Board of Directors to declare a dividend or its ability to pay a dividend or repurchase its common stock. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Further, the scientific information discussed in this news release relating to new indications for Amgen's products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

Provention Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-

looking statements are based on Provention's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to failure to obtain FDA approvals or clearances and noncompliance with FDA regulations; uncertainties of patent protection and litigation; limited research and development efforts and dependence upon third parties; substantial competition; our need for additional financing and the factors listed under "Risk Factors" in our quarterly report on Form 10-Q for the quarter ended June 30, 2018 and any subsequent filings with the Securities and Exchange Commission (SEC). As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Provention does not undertake an obligation to up-date or revise any forward-looking statement. The information set forth herein speaks only as of the date hereof.

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