Amgen Is Supporting Advancement Of AMG 634 For Global Health Diseases In Developing Countries

June 22, 2020

THOUSAND OAKS, Calif., June 22, 2020 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced it is supporting the further study of AMG 634, a phosphodiesterase type 4 (PDE4) inhibitor, for the treatment of tuberculosis (TB) and erythema nodosum leprosum (ENL), an inflammatory cutaneous and systemic complication of leprosy. Amgen acquired AMG 634 (formerly CC-11050) as part of its acquisition of Otezla® (apremilast) from Celgene in 2019. AMG 634 is currently in Phase 2 studies led by The Aurum Institute NPC (TB study) and The Leprosy Mission Nepal (ENL study).

"AMG 634 could have potential for patients suffering from ENL and TB, two diseases that continue to challenge many countries around the world," said David M. Reese, M.D. executive vice president of Research and Development at Amgen. "We believe that the right organization focused on global health will be able to help further develop the molecule and get it directly into the hands of those patients in need of treatment options."

Approximately 225,000 new cases of leprosy are identified every year[1], and a significant number of leprosy patients suffer from ENL, an autoimmune complication that can occur many years after being cured of leprosy and can cause permanent nerve damage and disability[2]. Tuberculosis affects 10.4 million patients every year and causes over one million deaths. Current treatments are often inadequate and can leave patients with permanent, clinically significant lung damage[3].

While intending to support the two Phase 2 clinical trials in ENL and TB set to begin in 2021 by providing study drug, Amgen is interested in partnering these programs with a non-government organization (NGO) for further development.

More information about the clinical trial in ENL can be found here and in TB can be found here.

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.

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 any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company, including Adaptive Biotechnologies (including statements regarding such collaboration's ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 to potentially prevent or treat COVID-19), BeiGene, Ltd., or the Otezla acquisition, including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion, as well as 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, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, outcomes, progress, or effects relating to studies of Otezla as a potential treatment for COVID-19, 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 our 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 we project. Our results may be affected by our 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 our products and global economic conditions. In addition, sales of our 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, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our

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 our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

CONTACT: Amgen, Thousand Oaks
Megan Fox, 805-447-1423 (media)
Trish Rowland, 805-447-5631 (media)
Arvind Sood, 805-447-1060 (investors)

---

[1] World Health Organization website https://www.who.int/news-room/fact-sheets/detail/leprosy (last accessed June 15, 2020)

[2] Saunderson P, Gebre S, Byass P. ENL reactions in the multi bacillary cases of the AMFES cohort in central Ethiopia: incidence and risk factors. *Lepr Rev* (2000) 71, 3 1 8-324

[3] Bloom BR, Atun R, Cohen T, et al. Tuberculosis. In: Holmes KK, Bertozzi S, Bloom BR, et al., editors. Major Infectious Diseases. 3rd edition. Washington (DC): The International Bank for Reconstruction and Development / The World Bank; 2017 Nov 3. Chapter 11. Available from: https://www.ncbi.nlm.nih.gov/books/NBK525174/ doi: 10.1596/978-1-4648-0524-0_ch11

View original content to download multimedia:http://www.prnewswire.com/news-releases/amgen-is-supporting-advancement-of-amg-634-for-global-health-diseases-in-developing-countries-301081303.html

SOURCE Amgen