Amgen Licenses AMG 634, An Investigational Treatment For Tuberculosis And Leprosy, To Medicines Development for Global Health

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THOUSAND OAKS, Calif. and MELBOURNE, Australia, Dec. 22, 2020 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Medicines Development for Global Health (MDGH), a non-profit biopharmaceutical company, today announced that the companies have entered into a license agreement for AMG 634, a phosphodiesterase type 4 (PDE4) inhibitor being investigated for the treatment of tuberculosis (TB) and erythema nodosum leprosum (ENL), an inflammatory cutaneous and systemic complication of leprosy. The compound is in Phase 2 development with studies led by the Aurum Institute NPC (TB study) and The Leprosy Mission Nepal (ENL study). Amgen had acquired AMG 634 (formerly CC-11050) as part of its acquisition of Otezla® (apremilast) from Celgene in 2019. Under the terms of the agreement, MDGH will assume full responsibility for the further development and commercialization of AMG 634.

"Since tuberculosis and erythema nodosum leprosum remain challenging diseases in many countries around the world, Amgen sought an organization that could support the development of AMG 634 to address the global health unmet need," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "MDGH's track record and experience in product development, global health, and neglected infectious diseases makes them an ideal company to further develop AMG 634 for the benefit of patients."

Amgen will continue to support the two Phase 2 clinical trials in ENL and TB set to begin in 2021 by providing study drug to both studies and funding the ENL study. This support will help ensure a seamless transition in development to MDGH.

"We are excited by the potential of AMG 634 for patients with ENL and TB and are honored to take over the stewardship of this compound from Amgen," said Mark Sullivan, founder and managing director of MDGH. "MDGH is dedicated to developing and delivering medicines for diseases that disproportionally affect people in low- and middle-income countries. We broke new ground as the first not-for-profit biopharmaceutical company to achieve FDA approval for a treatment for river blindness in 2018 and we will now undertake full development of AMG 634 in hopes of bringing it to patients in need of a treatment for their disease."

According to the World Health Organization (WHO), in 2019, an estimated 10 million people were infected with TB, including over 1 million children, and 1.4 million people died of TB.[1] Leprosy, also known as Hansen's disease, affects the skin, peripheral nerves mucosal surfaces of the upper respiratory tract and the eyes.[2] ENL is an autoimmune complication that can occur many years after being cured of leprosy, and can cause permanent nerve damage and disability.[3]

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 Medicines Development for Global Health
MDGH is an independent not-for-profit biopharmaceutical company headquartered in Melbourne, Australia. Established in 2005, this unique organization is dedicated to the development of affordable medicines and vaccines for infectious and neglected diseases prevalent in low- and middle-income countries.

For additional information about MDGH, please visit www.medicinesdevelopment.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 BeiGene, Ltd. or any collaboration or potential collaboration in pursuit of therapeutic antibodies against COVID-19 (including statements regarding such collaboration's, or our own, ability to discover and develop fully-human neutralizing antibodies targeting SARS-CoV-2 or antibodies against targets other than the SARS-CoV-2 receptor binding domain, and/or to produce any such antibodies to potentially prevent or treat COVID-19), or the Otezla® (apremilast) 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. 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, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

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. 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. 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.

The scientific information discussed in this news release related to our 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, any scientific information discussed in this news release relating to new indications for our 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.

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[1] World Health Organization website https://www.who.int/tb/publications/factsheet_global.pdf?ua=1 (last accessed Dec. 15, 2020)

[2] World Health Organization website https://www.who.int/health-topics/leprosy#tab=tab_1 (last accessed Dec. 15, 2020)

[3] 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

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