

Amgen And Arrowhead Pharmaceuticals Announce Two Cardiovascular Collaborations

September 29, 2016

Amgen to Receive Worldwide Exclusive License to Arrowhead's RNAi ARC-LPA Program Amgen Receives Exclusive License Option to RNAi Therapy for Undisclosed Cardiovascular Target Arrowhead to Receive \$56.5 Million in Upfront Payments and Initial Equity Investment and up to an Additional \$617 Million in Potential Milestone and Equity Payments Arrowhead Will Hold a Webcast Today at 9 a.m. ET

THOUSAND OAKS, Calif. and PASADENA, Calif., Sept. 29, 2016 /PRNewswire/ -- Amgen (NASDAQ: AMGN) and Arrowhead Pharmaceuticals Inc. (NASDAQ: ARWR) today announced two license and collaboration agreements to develop and commercialize RNA interference (RNAi) therapies for cardiovascular disease. These are the first programs to utilize Arrowhead's proprietary subcutaneous RNAi delivery platform. RNAi molecules may be designed to target and shut down specific gene products that contribute to various diseases.

Under one agreement, Amgen receives a worldwide, exclusive license to Arrowhead's novel, RNAi ARC-LPA program. These RNAi molecules are designed to reduce elevated lipoprotein(a), which is a genetically validated, independent risk factor for atherosclerotic cardiovascular disease. Under the second agreement, Amgen receives an option to a worldwide, exclusive license for a RNAi therapy for an undisclosed genetically validated cardiovascular target. In both agreements, Amgen will be wholly responsible for clinical development and commercialization.

Under the terms of the agreements taken together, Arrowhead will receive \$35 million in upfront payments; \$21.5 million in the form of an equity investment by Amgen in Arrowhead common stock; and up to \$617 million in option payments, and development, regulatory and sales milestone payments. Arrowhead is further eligible to receive single digit royalties for sales of products against the undisclosed target and up to low double digit royalties for sales of products under the ARC-LPA agreement. Additional financial terms of the agreements are not disclosed.

"Arrowhead's expertise in RNAi makes them a valuable partner as we translate genetic discoveries into potential therapies that can improve health outcomes for patients," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "This collaboration builds upon our commitment to cardiovascular disease with targets that we believe are uniquely suited for RNAi-based therapy."

"We have made great advances to our proprietary subcutaneous RNAi delivery vehicle and in RNAi trigger modification and stabilization that enable rapid development of new RNAi therapeutics across multiple disease areas," said Christopher Anzalone, Ph.D., president and chief executive officer at Arrowhead. "Our capabilities and platform technologies are becoming increasingly validated, so we feel that now is a great time to expand the reach of our technologies and partner with other companies to maximize the value of our assets. We are thrilled to be working with Amgen, one of the world's leading biotechnology companies, on this collaboration. Amgen's extensive development, regulatory, and commercial expertise makes them an ideal partner, and we look forward to a long and productive relationship."

The closing of the ARC-LPA transaction is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and is expected to close before the end of the fourth quarter of 2016.

Arrowhead Conference Call and Webcast Details

Arrowhead will host a conference call today, Sept. 29, 2016, at 9 a.m. ET. Investors may access a live audio webcast on Arrowhead's website at http://ir.arrowheadpharma.com/events.cfm. For analysts that wish to participate in the conference call, please dial 855-215-6159 or 315-625-6887 and enter Conference ID 88684368.

A replay of the webcast will be available on the Arrowhead website approximately two hours after the conclusion of the call and will remain available for 90 days. An audio replay will also be available approximately two hours after the conclusion of the call and will be available for 3 days. To access the audio replay, dial 404-537-3406 and enter Conference ID 88684368.

About ARC-LPA

ARC-LPA is designed to reduce production of apolipoprotein A, a key component of lipoprotein(a), which has been genetically linked with increased risk of cardiovascular diseases, independent of cholesterol and LDL levels. ARC-LPA is Arrowhead's first drug candidate to use a subcutaneously administered delivery construct.

About Amgen Cardiovascular

Building on more than three decades of experience in developing biotechnology medicines for patients with serious illnesses, Amgen is dedicated to addressing important scientific questions to advance care and improve the lives of patients with cardiovascular disease, the leading cause of morbidity and mortality worldwide.¹ Amgen's research into cardiovascular disease, and potential treatment options, is part of a growing competency at Amgen that utilizes human genetics to identify and validate certain drug targets. Through its own research and development efforts, as well as partnerships, Amgen is building a robust cardiovascular portfolio consisting of several approved and investigational molecules in an effort to address a number of today's important unmet patient needs, such as high cholesterol and heart failure.

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 Arrowhead Pharmaceuticals

Arrowhead Pharmaceuticals develops medicines that treat intractable diseases by silencing the genes that cause them. Using a broad portfolio of RNA chemistries and efficient modes of delivery, Arrowhead therapies trigger the RNA interference mechanism to induce rapid, deep, and durable knockdown of target genes. RNA interference, or RNAi, is a mechanism present in living cells that inhibits the expression of a specific gene, thereby affecting the production of a specific protein. Arrowhead's RNAi-based therapeutics leverage this natural pathway of gene silencing. The company's pipeline includes ARC-520 and ARC-521 for chronic hepatitis B virus infection, ARC-AAT for liver disease associated with alpha-1 antitrypsin deficiency, ARC-F12 for hereditary angioedema and thromboembolic disorders, ARC-LPA for cardiovascular disease, and ARC-HIF2 for renal cell carcinoma.

For more information please visit <u>www.arrowheadpharma.com</u>, or follow us on Twitter <u>@ArrowheadPharma</u>. To be added to the Company's email list and receive news directly, please visit <u>http://ir.arrowheadpharma.com/alerts.cfm</u>.

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 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 projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products after they are on the market.

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 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. If Amgen fails to meet the compliance obligations in the corporate integrity agreement between it and the U.S. government, Amgen could become subject to significant sanctions. Further, 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 manufacturing facilities 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. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third-party suppliers. 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. Amgen may not be able to access the capital and credit markets on terms that are favorable to it, or at all. Amgen is increasingly dependent on information technology systems, infrastructure and data security. 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.

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.

Arrowhead Safe Harbor Statement under the Private Securities Litigation Reform Act:

This news release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements are based upon our current expectations and speak only as of the date hereof. Our actual results may differ materially and adversely from those expressed in any forward-looking statements as a result of various factors and uncertainties, including the success of the Amgen collaboration, as well as actual amounts received under that collaboration. Arrowhead's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q discuss some of the important risk factors that may affect our business, results of operations and financial condition. Arrowhead assumes no obligation to update or revise forward-looking statements to reflect new events or circumstances.

DYNAMIC POLYCONJUGATES is a trademark of Arrowhead Pharmaceuticals, Inc.

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¹ World Health Organization. Cardiovascular diseases (CVDs) fact sheet. <u>http://www.who.int/mediacentre/factsheets/fs317/en/</u>. Accessed August 2016.



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