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Alnylam and Vir Form Strategic Alliance to Advance RNAi Therapeutics for Infectious Diseases

- Agreement Includes Investigational RNAi Therapeutic Program for Hepatitis B Virus Infection and Discovery Collaboration on Additional Development Candidates for Treatment of Infectious Diseases -

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), the leading RNAi therapeutics company, today announced an exclusive licensing agreement with Vir Biotechnology, a company dedicated to transforming the care of people with serious infectious diseases, for the development and commercialization of RNAi therapeutics for infectious diseases, including chronic hepatitis B virus (HBV) infection. As part of this agreement, the companies will advance Alnylam's HBV program and also initiate a research collaboration for the development and advancement of up to four additional RNAi therapeutic programs for the treatment of other infectious diseases with high unmet needs.

"This agreement represents another step toward bringing RNAi therapeutics to patients with limited or inadequate therapeutic options. Partnering with the exceptional, experienced team at Vir to advance investigational RNAi therapeutics in infectious diseases will expedite the development path for these medicines, while enabling Alnylam to maintain operational focus on our robust pipeline of later-stage programs," said John Maraganore, Ph.D., Chief Executive Officer of Alnylam. "We believe the innovative structure of this deal, including the right for Alnylam to opt into a profit-sharing arrangement prior to the start of Phase 3 for HBV, gives us both strategic flexibility in our committed spend and retention of significant product value."

"We are excited to partner with Alnylam to bring scientific innovation to infectious diseases, such as hepatitis B, that impact global health and currently have significant unmet needs," said George Scangos, Ph.D., Chief Executive Officer of Vir. "This collaboration is a key step forward toward our goal of leveraging discovery and development to better control, or even cure, infectious diseases, thereby benefitting those patients most in need around the world."

Alnylam is developing ALN-HBV for the treatment of chronic HBV infection. A Phase 1/2 clinical trial of ALN-HBV was initiated in July 2016. Alnylam plans to discontinue further development of this investigational compound and to advance a new Development Candidate, ALN-HBV02, utilizing the Company's Enhanced Stabilization Chemistry-Plus (ESC+) GalNAc conjugate technology. As recently reported, ESC+ conjugates have the potential to improve target specificity with an expanded therapeutic index.

As part of the agreement, Alnylam will lead ALN-HBV02 to IND filing, with Vir then progressing ALN-HBV02 through human proof of concept (POC); the companies will co-fund the program through this point. Subsequently, Vir will fund and conduct all development through completion of Phase 2 studies. Thereafter, Alnylam retains the right to opt into a profit-sharing arrangement prior to the start of Phase 3. In connection with the companies' research collaboration for up to four additional infectious disease programs, Vir will fund all research and development costs, while Alnylam retains a product-by-product option on each program to opt into a profit-sharing arrangement following human POC.

Under the terms of the agreement, Alnylam will receive an upfront payment, comprised of cash and shares of Vir common stock. Alnylam is also eligible to receive more than $1 billion in potential milestone payments related to the successful advancement of ALN-HBV02 and other infectious disease programs, as well as tiered royalties on products ultimately commercialized by Vir under the collaboration, should Alnylam elect to decline its co-development and profit share option on a per-product basis.

About HBV Infection

Worldwide, 2 billion people - or one out of three - are infected with HBV, and more than 250 million people are chronically infected, including 1 to 2 million people in the U.S. An estimated 1 million people die each year from HBV and its complications worldwide, of whom about 5,000 are in the U.S. Worldwide, chronic infection with hepatitis causes 80 percent of all cases of hepatocellular carcinoma (HCC), which kills more than 500,000 people each year. About 5 percent of the population is a chronic carrier of HBV, and nearly 25 percent of all carriers develop serious liver diseases such as chronic hepatitis, cirrhosis or HCC. Current treatment options include long-term antiviral therapies, which permit low levels of virus cells to replicate, leading to HBV viral persistence and affecting therapeutic outcomes. There is a significant need for safe and convenient novel therapeutics that restore the host immune response through targeted hepatitis B surface antigen (HBsAg) knockdown, thereby offering HBV patients the potential for functional cures by eliminating virus-producing cells.

About Alnylam Pharmaceuticals, Inc.

Alnylam (Nasdaq: ALNY) is leading the translation of RNA interference (RNAi) into a whole new class of innovative medicines with the potential to transform the lives of people afflicted with rare genetic, cardio-metabolic, and hepatic infectious diseases. Based on Nobel Prize-winning science, RNAi therapeutics represent a powerful, clinically validated approach for the treatment of a wide range of severe and debilitating diseases. Founded in 2002, Alnylam is delivering on a bold vision to turn scientific possibility into reality, with a robust discovery platform and deep pipeline of investigational medicines, including four product candidates that are in late-stage development. Looking forward, Alnylam will continue to execute on its "Alnylam 2020" strategy of building a multi-product, commercial-stage biopharmaceutical company with a sustainable pipeline of RNAi-based medicines to address the needs of patients who have limited or inadequate treatment options. Alnylam employs over 600 people in the U.S. and Europe and is headquartered in Cambridge, MA. For more information about our people, science and pipeline, please visit www.alnylam.com and engage with us on Twitter at @Alnylam or on LinkedIn.

Alnylam Forward-Looking Statements

Various statements in this release concerning Alnylam's future expectations, plans and prospects, including without limitation, Alnylam's views with respect to the development of ALN-HBV02 and the potential development of investigational RNAi therapeutics for up to four additional infectious disease programs, the potential of ESC+ conjugates to improve target specificity with an expanded therapeutic index, the potential for Alnylam to earn milestones and royalties under its collaboration with Vir, Alnylam's right to opt into a profit sharing arrangement under the Vir collaboration, and expectations regarding its "Alnylam 2020" guidance for the advancement and commercialization of RNAi therapeutics, constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Actual results and future plans may differ materially from those indicated by these forward-looking statements as a result of various important risks, uncertainties and other factors, including, without limitation, Alnylam's ability to discover and develop novel drug candidates and delivery approaches, successfully demonstrate the efficacy and safety of its product candidates, the pre-clinical and clinical results for its product candidates, which may not be replicated or continue to occur in other subjects or in additional studies or otherwise support further development of product candidates for a specified indication or at all, actions or advice of regulatory agencies, which may affect the design, initiation, timing, continuation and/or progress of clinical trials or result in the need for additional pre-clinical and/or clinical testing, delays, interruptions or failures in the manufacture and supply of its product candidates, obtaining, maintaining and protecting intellectual property, Alnylam's ability to enforce its intellectual property rights against third parties and defend its patent portfolio against challenges from third parties, obtaining and maintaining regulatory approval, pricing and reimbursement for products, progress in establishing a commercial and ex-United States infrastructure, competition from others using technology similar to Alnylam's and others developing products for similar uses, Alnylam's ability to manage its growth and operating expenses, obtain additional funding to support its business activities, and establish and maintain strategic business alliances and new business initiatives, Alnylam's dependence on third parties for development, manufacture and distribution of products, the outcome of litigation, the risk of government investigations, and unexpected expenditures, as well as those risks more fully discussed in the "Risk Factors" filed with Alnylam's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings that Alnylam makes with the SEC. In addition, any forward-looking statements represent Alnylam's views only as of today, and should not be relied upon as representing its views as of any subsequent date. Alnylam explicitly disclaims any obligation, except to the extent required by law, to update any forward-looking statements.

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