Vir and Alnylam Identify RNAi Therapeutic Development Candidate, VIR-2703 (ALN-COV), Targeting SARS-CoV-2 for the Treatment of COVID-19

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− Highly Potent and Broadly Cross-Reactive RNAi Therapeutic Development Candidate Selected Only Three Months After Program Initiation −

− Companies Expect to Start Human Clinical Trials at or Around Year-End 2020 –

SAN FRANCISCO & CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 4, 2020-- Vir Biotechnology, Inc. (Nasdaq: VIR) and Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY) today announced the selection of a development candidate (DC) for VIR-2703 (also referred to as ALN-COV), an investigational RNAi therapeutic targeting the SARS-CoV-2 genome. The companies plan to soon meet with the U.S. Food and Drug Administration (FDA) and other regulatory authorities to discuss a potential accelerated path for filing an Investigational New Drug (IND) or IND equivalent application at or around year-end 2020, less than a year since program initiation. The companies plan to advance VIR-2703 as an inhalational formulation for the potential treatment and/or prevention of COVID-19.

In its discovery efforts, Alnylam synthesized over 350 small interfering RNAs (siRNAs) – the molecules that mediate RNAi – targeting highly conserved regions of the SARS-CoV-2 genome, which were then analyzed bioinformatically and assessed in *in vitro* potency assays. Multiple highly potent siRNAs were identified that demonstrated a 3-log reduction of viral replication in an *in vitro* SARS-CoV-2 live virus model conducted by Vir. In dose-response assays, VIR-2703 was shown to have an effective concentration for 50% inhibition (EC50) of less than 100 picomolar and an EC95 of less than 1 nanomolar in the SARS-CoV-2 live virus model measuring inhibition of infectious virion production. Further, VIR-2703 has predicted reactivity against greater than 99.9 percent of the over 4300 SARS-CoV-2 genomes currently available in public databases that meet analysis requirements, and is also predicted to have reactivity toward the SARS-CoV genome from the 2003 SARS outbreak. With this DC selection, Vir and Alnylam will work closely together to generate the data required to enable rapid commencement of clinical studies.

“Vir is committed to applying industry-leading technologies in our fight against COVID-19. Our fruitful and expansive collaboration with Alnylam has rapidly led to identification of a development candidate targeting SARS-CoV-2,” said George Scangos, Ph.D., CEO of Vir. “With this candidate now in hand, we will further accelerate our efforts and plan to begin studies in humans at or around year-end. Our ultimate goal would be to provide rapid worldwide access, if approved, to an effective therapeutic to combat COVID-19.”

“I’m very proud of the quality and pace of work done by our scientists and with our collaborators at Vir to identify an RNAi therapeutic development candidate targeting the SARS-CoV-2 genome. To our knowledge, this is one of the most potent direct-acting antivirals targeting SARS-CoV-2 reported to date,” said John Maraganore, Ph.D., Chief Executive Officer of Alnylam. “As this pandemic continues to unfold, we are committed to acting with the utmost urgency to broaden and accelerate our efforts to develop investigational RNAi therapeutics against COVID-19, and potentially future coronavirus-mediated diseases.”

In addition to the development candidate targeting the SARS-CoV-2 genome, the companies will utilize Alnylam’s recent advances in lung delivery of siRNAs, with widespread silencing of gene targets in the respiratory tract in multiple cell types, including cells in the respiratory tract that may be the targets for SARS-CoV-2 infection. In addition, the companies will employ Vir’s infectious disease expertise and established capabilities to bring forward up to three additional host factor-targeting development candidates to treat COVID-19, and potentially other coronavirus diseases.

About VIR-2703 (ALN-COV)

VIR-2703 is an inhaled SARS-CoV-2-targeting siRNA that may have utility for prevention or for treatment. It leverages Alnylam Pharmaceuticals, Inc.’s latest advances in lung delivery of siRNAs and may have applicability to other coronaviruses as well. VIR-2703 is the first development candidate selected in the company’s expanded collaboration with Alnylam for up to four RNAi potential therapeutics for COVID-19.

About RNAi

RNAi (RNA interference) is a natural cellular process of gene silencing that represents one of the most promising and rapidly advancing frontiers in biology and drug development today. Its discovery has been heralded as “a major scientific breakthrough that happens once every decade or so,” and was recognized with the award of the 2006 Nobel Prize for Physiology or Medicine. By harnessing the natural biological process of RNAi occurring in our cells, a new class of medicines, known as RNAi therapeutics, is now a reality. Small interfering RNA (siRNA), the molecules that mediate RNAi and comprise Alnylam's RNAi therapeutic platform, function upstream of today’s medicines by potently silencing messenger RNA (mRNA) – the genetic precursors – that encode for disease-causing proteins, thus preventing them from being made. This is a revolutionary approach with the potential to transform the care of patients with genetic and other diseases.

About Vir Biotechnology

Vir Biotechnology is a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Vir has assembled four technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. Its current development pipeline consists of product candidates targeting hepatitis B virus, influenza A, SARS-CoV-2, human immunodeficiency virus and tuberculosis. For more information, please visit www.vir.bio.

About Alnylam

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, hepatic infectious, and central nervous system (CNS)/ocular 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 RNAi therapeutics platform. Alnylam's commercial RNAi therapeutic products are ONPATTRO® (patisiran), approved in the U.S., EU, Canada, Japan, Switzerland, and Brazil, and GIVLAARI® (givosiran), approved in the U.S. and EU. Alnylam has a deep pipeline of investigational medicines, including six product candidates that are in late-stage development. Alnylam is executing 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 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.

Vir Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "believe," "estimate," "intend," "potential," "promising," "predict" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Vir's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements regarding the potential benefits of the collaboration with Alnylam, the companies' plans to pursue an accelerated path toward filing an IND application, advance VIR-2703 for the prophylaxis and treatment of COVID-19, and commence studies in humans, the timing of implementation of such plans and commencement of clinical studies, Vir's ability to identify novel host factor-targeting development candidates to treat COVID-19 and other coronavirus diseases, the potential anti-viral effects of siRNAs targeting human host factors, the predicted reactivity of VIR-2703 against SARS-CoV and SARS-CoV-2 genomes, whether or not any DCs will be successfully developed and commercialized, and Vir's ability to address the COVID-19 pandemic. Many factors may cause differences between current expectations and actual results including delays or disruptions on our business or clinical trials due to the COVID-19 pandemic, unexpected safety or efficacy data observed during preclinical or clinical studies, challenges in identifying and selecting DCs, challenges in identifying new host factors pertinent to coronaviral infection, difficulty in collaborating with other companies or government agencies, difficulties in securing meetings with regulatory authorities, challenges in generating the data required to expedite commencement of clinical studies, and challenges in accessing manufacturing capacity and the development of treatments for infectious diseases. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Vir's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as required by law, Vir assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Alnylam Forward-Looking Statements

Various statements in this release concerning Alnylam's future expectations, plans and prospects, including, without limitation, Alnylam's views and plans with respect to the potential for RNAi therapeutics, including the translation to humans of recent pre-clinical progress in delivery of siRNAs to the lung, plans related to inhalational formulations of siRNAs, the potential for siRNAs, including the selected development candidate ALN-COV (VIR-2703), targeting highly conserved regions of SARS-CoV-2 – the virus that causes COVID-19 – and other siRNAs targeting human host factors for COVID-19 and potentially other coronaviruses, its expectations regarding a potential accelerated path for filing an IND for and advancing ALN-COV (VIR-2703) in the clinic, its ability to collaborate with Vir to address the COVID-19 pandemic or other coronavirus outbreaks, and expectations regarding the continued execution on 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: direct or indirect effects on Alnylam's business, activities and prospects as a result of the COVID-19 pandemic, or delays or interruptions resulting therefrom and the success of Alnylam's mitigation efforts; Alnylam's ability in collaboration with Vir, to enable rapid advancement of ALN-COV and other potential development candidates into human trials; Alnylam's ability to discover and develop additional novel drug candidates, including candidates targeting the SARS-CoV-2 genome and/or host factors for SARS-CoV-2 infection, and delivery approaches, including to the lung and using intranasal and/or inhalational formulations; its ability to successfully demonstrate the efficacy and safety of its product candidates, including ALN-COV and other potential candidates targeting the SARS-CoV-2 genome and/or host factors for SARS-CoV-2 infection; 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, including the ability to accelerate the commencement and completion of clinical trials of candidates targeting the SARS-CoV-2 genome and/or host factors for SARS-CoV-2 infection, 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 or its marketed products; obtaining, maintaining and protecting intellectual property; intellectual property matters including potential patent litigation relating to its platform, products or product candidates; obtaining regulatory approval for its product candidates, including lumasiran and any product candidates targeting the SARS-CoV-2 genome and/or host factors for SARS-CoV-2 infection, and maintaining regulatory approval and obtaining pricing and reimbursement for its products, including ONPATTRO and GIVLAARI; progress in continuing to establish a commercial and ex-United States infrastructure; successfully launching, marketing and selling its approved products globally, including ONPATTRO and GIVLAARI, and achieve net product revenues for ONPATTRO within its expected range during 2020; Alnylam's ability to successfully expand the indication for ONPATTRO in the future; 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 within the ranges of its expected guidance and achieve a self-sustainable financial profile in the future without the need for future equity financing; Alnylam's ability to establish and maintain strategic business alliances and new business initiatives; Alnylam's dependence on third parties, including Vir, for development of candidates for the treatment of infectious diseases, including COVID-19, and commercialization of any infectious disease product resulting therefrom; Regeneron, for development, manufacture and distribution of certain products, including eye and CNS products, and Ironwood, for assistance with the education about and promotion of GIVLAARI in the U.S.; 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 Annual Report on Form 10-K 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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