Arbutus' LNP Licensee Alnylam Announces FDA Approval of ONPATTRO™ (patisiran), for the Treatment of ATTR Amyloidosis

August 13, 2018

ONPATTRO Approval Triggers Royalty to Arbutus

Clinically Validated LNP Technology Now in the Hands of Genevant to Develop RNA-based Products

WARMINSTER, Pa., Aug. 13, 2018 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), an industry-leading Hepatitis B Virus (HBV) therapeutic solutions company, today announced that the Company's lipid nanoparticle (LNP) licensee, Alnylam Pharmaceuticals, Inc. (Nasdaq:ALNY), announced that their new drug application (NDA) for ONPATTRO, an RNAi therapeutic, has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of hereditary ATTR amyloidosis with polyneuropathy.

"ONPATTRO is the first RNA interference therapeutic product to be approved by the FDA and represents a milestone for the technology as well as a revolutionary new treatment with the potential to transform the care of patients with hereditary transthyretin amyloidosis. Because ONPATTRO is enabled by our proprietary LNP technology, this approval triggers a royalty to Arbutus and provides us with important non-dilutive revenue to support our HBV cure mission, through several important clinical milestones next year," said Dr. Mark Murray, Arbutus' President and CEO. Dr. Murray added, "This approval also represents unprecedented clinical validation of our LNP technology which we have improved upon significantly since licensing it to Alnylam, and have recently granted broad rights to Genevant, a company we formed in the second quarter of 2018 that is jointly owned by Arbutus and Roivant Sciences. Genevant aims to advance multiple product candidates into the clinic across RNAi, mRNA, and gene editing modalities using the Arbutus LNP and ligand conjugate delivery platforms."

About Arbutus
Arbutus Biopharma Corporation is a publicly traded (Nasdaq: ABUS) biopharmaceutical company dedicated to discovering, developing and commercializing a cure for patients suffering from chronic Hepatitis B infection. Arbutus is developing multiple drug candidates, each of which have the potential to improve upon the standard of care and contribute to a curative combination regimen. For more information, visit www.arbutusbio.com.

Forward-Looking Statements and Information
This press release contains forward-looking statements within the meaning of the Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and forward looking information within the meaning of Canadian securities laws (collectively, "forward-looking statements"). Forward-looking statements in this press release include statements about the potential for ONPATTRO ™ (patisiran) to transform the care of patients with genetic and other diseases; receiving a royalty from Alnylam; Genevant advancing multiple product candidates into the clinic across RNAi, mRNA, and gene editing modalities using the Arbutus LNP and ligand conjugate platforms; and discovering, developing and commercializing a cure for patients suffering from chronic HBV infection.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the timely receipt of expected payments; the effectiveness and timeliness of preclinical and clinical trials, and the usefulness of the data; the continued demand for Arbutus' assets; the timing of regulatory approvals; the continued availability of key management personnel; and the stability of economic and market conditions. While Arbutus considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies.

Additionally, there are known and unknown risk factors which could cause Arbutus' actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements contained herein. Known risk factors include, among others: anticipated pre-clinical and clinical trials may be more costly or take longer to complete than anticipated, and may never be initiated or completed, or may not generate results that warrant future development of the tested drug candidate; Arbutus and Genevant may not receive the necessary regulatory approvals for the clinical development of their products on a timely basis, if at all; expected payments, financings, and royalties may not be as large or as timely as expected, if at all; key management personnel may become unavailable; economic and market conditions may worsen; and market shifts may require a change in strategic focus.

A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K and Arbutus' continuous disclosure filings, which are available at www.sedar.com and at www.sec.gov. All forward-looking statements herein are qualified in their entirety by this cautionary statement, and Arbutus disclaims any obligation to revise or update any such forward-looking statements or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments, except as required by law.

Contact Information

Investors
Mark J. Murray
President and CEO
Phone: 604-419-3200
Email: ir@arbutusbio.com

Pam Murphy
Investor Relations Consultant
Phone: 604-419-3200

Email: ir@arbutusbio.com

Primary Logo

Source: Arbutus Biopharma Corporation