Arbutus Biopharma and Genevant Sciences File Patent Infringement Lawsuit Against Moderna

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WARMINSTER, Pa., Feb. 28, 2022 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases, and Genevant Sciences today filed a lawsuit in the U.S. District Court for the District of Delaware against Moderna, Inc. (Nasdaq: MRNA) and a Moderna affiliate seeking damages for infringement of U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,364,435, 9,504,651, and 11,141,378 in the manufacture and sale of MRNA-1273, Moderna's vaccine for COVID-19. The patents relate to nucleic acid-lipid particles and lipid vesicles, as well as compositions and methods for their use. The filed complaint is available on the Arbutus website.

William Collier, President and CEO of Arbutus, stated, "Arbutus and its licensee Genevant do not seek an injunction or otherwise seek to impede the sale, manufacture or distribution of MRNA-1273. However, we seek fair compensation for Moderna's use of our patented technology that was developed with great effort and at great expense, without which Moderna's COVID-19 vaccine would not have been successful."

It is well established in the scientific literature that the most significant technological hurdle to developing and deploying medicines using mRNA is engineering a safe and effective way to deliver the mRNA to human cells. Scientists at Arbutus and Genevant have spent years developing and refining lipid nanoparticle (LNP) delivery technology, which has been licensed for various applications to many different third parties. Arbutus and Genevant's LNP technology relies on microscopic particles built from four carefully selected types of fat-like molecules to shelter and protect RNA molecules. With this technology, the RNA can travel through the human body to a target cell and through the target cell's membrane before releasing the RNA. Without this crucial delivery technology, the RNA would quickly degrade in the body and be ineffective.

In December 2021, the United States Court of Appeals for the Federal Circuit rejected Moderna's appeal of a prior decision of the U.S. Patent Trial and Appeal Board holding all claims of the asserted '069 patent to be patentable and dismissed Moderna's appeal challenging a similar finding of patentability with respect to certain claims of the asserted '435 patent. Moderna had initiated inter partes review (IPR) challenges against these patents in 2018 and 2019.

About Arbutus

Arbutus Biopharma Corporation (Nasdaq: ABUS) is a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases. Our current focus areas include Hepatitis B virus (HBV), SARS-CoV-2, and other coronaviruses. In HBV, we are developing a RNAi therapeutic, capsid inhibitor, PD-L1 inhibitor, and RNA destabilizer that we intend to combine to provide a functional cure for patients with chronic HBV by suppressing viral replication, reducing surface antigen and reawakening the immune system. We believe our lead compound, AB-729 is the only RNAi therapeutic with evidence of immune re-awakening and is currently being evaluated in multiple phase 2 clinical trials. We have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronavirus (including SARS-CoV-2). We also intend to explore possible oncology indications for our internal PD-L1 portfolio. 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 patent infringement lawsuit against Moderna and our future development plans for our product candidates.

With respect to the forward-looking statements contained in this press release, Arbutus has made numerous assumptions regarding, among other things: the effectiveness and timeliness of preclinical studies and clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the continued demand for Arbutus' assets; 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, including uncertainties and contingencies related to the ongoing COVID-19 pandemic and patent litigation matters.

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: uncertainties associated with litigation generally and patent litigation specifically; anticipated pre-clinical studies 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 product candidate; Arbutus may elect to change its strategy regarding its product candidates and clinical development activities; Arbutus may not receive the necessary regulatory approvals for the clinical development of Arbutus' products; economic and market conditions may worsen; Arbutus and its collaborators may never realize the expected benefits of the collaborations; market shifts may require a change in strategic focus; and the ongoing COVID-19 pandemic could significantly disrupt Arbutus' clinical development programs.

A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K, Arbutus' Quarterly Reports on Form 10-Q and Arbutus' continuous and periodic 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.

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