Arbutus Biopharma and Genevant Sciences File Patent Infringement Lawsuit Against Pfizer/BioNTech

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Companies seek compensation for Pfizer's and BioNTech's unlicensed use of patented technologies in COVID-19 mRNA-LNP vaccines

WARMINSTER, Pa., April 04, 2023 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq: ABUS) ("Arbutus"), a clinical-stage biopharmaceutical company leveraging its extensive virology expertise to develop novel therapeutics that target specific viral diseases, and Genevant Sciences (Genevant) today filed a lawsuit in the U.S. District Court for the District of New Jersey against Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) seeking damages for infringement of U.S. Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098 in the manufacture and sale of any COVID-19 mRNA-LNP vaccines. The patents relate to nucleic acid-lipid particles and their composition, manufacture, delivery and methods of use. The filed complaint is available on the Arbutus website.

With this suit, Arbutus and its licensee Genevant seek compensation for Pfizer's and BioNTech's unlicensed use of patented lipid nanoparticle (LNP) delivery technologies without which Pfizer-BioNTech's COVID-19 vaccines would not have been successful.

William Collier, President and CEO of Arbutus, stated, "During the pandemic, there was an urgent need for LNP technologies to deliver mRNA-based COVID-19 vaccines to cells in the human body. We believe that Pfizer and BioNTech could not have created and manufactured effective vaccines at such an unprecedented speed without the existing, proven and patented LNP technologies owned by Arbutus and licensed to Genevant. Therefore, we are pursuing legal action against both Pfizer and BioNTech for the unlicensed use of our patented technologies in their COVID-19 vaccines."

While scientists have been able to easily create mRNA molecules, they struggled to develop a delivery mechanism to ensure the mRNA molecule engages safely and effectively with human cells. This delivery challenge persisted for decades until a team of Arbutus scientists, many of whom are now at Genevant, developed and refined LNP delivery technologies, for which they were awarded many patents. Arbutus' LNP technologies rely on microscopic particles built from four carefully selected types of fat-like molecules that are stable enough to shelter and protect fragile RNA molecules as they move through the human body to a target cell, and then through the target cell's membrane, before finally releasing the RNA. These particles are called lipid nanoparticles and their invention was widely recognized as a major achievement that is essential for mRNA vaccines. Without these crucial delivery technologies, the RNA would quickly degrade in the body and be ineffective.

Arbutus also developed the technologies needed to manufacture these LNPs. Previously, methods of manufacturing lipid encapsulants for RNAs used harsh and extreme conditions that would damage the fragile RNA payload. Arbutus developed new, sophisticated manufacturing methods that avoided these deleterious effects.

Arbutus remains committed to taking all legal actions necessary to defend and protect its intellectual property.

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. To address HBV, we are developing a RNAi therapeutic, an oral PD-L1 inhibitor, and an oral RNA destabilizer to potentially identify a combination regimen with the aim of providing 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. AB-729 is currently being evaluated in multiple phase 2 clinical trials. We also have an ongoing drug discovery and development program directed to identifying novel, orally active agents for treating coronaviruses, (including SARS-CoV-2), for which we have nominated a compound and have begun IND-enabling pre-clinical studies. In addition, we are exploring oncology applications 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 Pfizer and BioNTech 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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