



Arbutus Presents AB-343 Data at the 36th International Conference on Antiviral Research

March 14, 2023

Antiviral potency, selectivity and favorable PK support further development of AB-343 as potential ritonavir-free oral treatment for COVID-19 and other human coronaviruses

WARMINSTER, Pa., March 14, 2023 (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, today announced that preclinical data for AB-343, our novel oral SARS-CoV-2 M^{Pro} inhibitor, has been presented in poster format at the 36th International Conference on Antiviral Research (ICAR), in Lyon, France.

"We are excited that our preclinical data for AB-343 has been selected for poster presentation at ICAR. We developed AB-343, our newly nominated nsp5 main protease inhibitor, because there is an urgent need for oral antiviral therapies that are potent and active against circulating SARS-CoV-2 variants and do not require ritonavir boosting," said Dr. Michael J. Sofia, Arbutus' Chief Scientific Officer. "AB-343 has demonstrated these characteristics in preclinical studies. We look forward to completing IND-enabling studies and initiating a Phase 1 clinical trial with AB-343 in the second half of 2023."

The poster, titled "[In Vitro Antiviral Profile of AB-343, a Novel, Oral Potent SARS-CoV-2 Mpro Inhibitor with Pan-coronavirus Activity](#)", provided an overview of several *in vitro* preclinical studies conducted with AB-343 to determine its antiviral activity, pan-coronavirus activity and *in-vitro* selectivity profile. Many of the studies compared AB-343 to nirmatrelvir, the active ingredient in Pfizer's Paxlovid™ and ensitrelvir, the active ingredient in Shionogi's Xocova®.

The results showed that AB-343 targets SARS-CoV-2 M^{Pro} and inhibits viral replication *in vitro* (EC₅₀ ~ 20nM). Binding of AB-343 to SARS-CoV-2 M^{Pro} resulted in longer residence times (>99 minutes versus 21.5 minutes for nirmatrelvir and 1.1 minutes for ensitrelvir) indicative of excellent target engagement. AB-343 also demonstrated pan-coronavirus inhibition (K_i 5-45 nM) against M^{Pro} enzymes from multiple human coronaviruses. In enzyme assays against previously reported SARS-CoV-2 M^{Pro} variants isolated in cell culture, AB-343 showed a differentiated *in vitro* resistance profile versus both nirmatrelvir and ensitrelvir, including a lower fold-increase in K_i for certain rare M^{Pro} enzyme variants known to reduce *in vitro* susceptibility. AB-343 maintained potency against naturally prevalent SARS-CoV-2 variants including the Omicron variant. AB-343 also showed high selectivity for SARS-CoV-2 M^{Pro} as it demonstrated little to no inhibition of an enzyme panel comprised of human and other viral proteases.

Based on the antiviral potency, selectivity and favorable PK of AB-343, Arbutus is moving this compound forward into IND-enabling studies and anticipates initiating a Phase 1 clinical trial in the second half of this year.

Some of these studies were conducted in part with [Proteros biostructures GmbH](#) under the discovery research and license agreement entered into in April 2021.

About AB-343

AB-343 is our lead coronavirus drug candidate that inhibits the SARS-CoV-2 main protease (M^{Pro}), a validated target for the treatment of COVID-19 and potential future coronavirus outbreaks. In our pre-clinical research conducted to date, AB-343 has shown pan-coronavirus antiviral activity, no reduction in potency against known SARS-CoV-2 variants, robust activity against SARS-CoV-2 M^{Pro} resistant strains, and a favorable drug-drug interaction profile with no need for ritonavir boosting. We see an opportunity to pursue a potential combination therapeutic strategy focusing on M^{Pro} and nsp12 viral polymerase targets to reduce hospitalizations, achieve better patient treatment outcomes and provide pre-exposure prophylactic therapy.

About Coronaviruses

Coronaviruses are a large family of viruses that range from the common cold to more severe diseases such as severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and COVID-19. COVID-19 has caused approximately 7.2 million deaths globally according to an analysis by the Institute for Health Metrics and Evaluation (IHME). As we strive to identify and develop new antiviral small molecules to treat COVID-19 and future coronavirus outbreaks, we have focused our research efforts on two essential targets critical for replication across all coronaviruses – nsp5 protease and nsp12 polymerase.

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 also 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 our future development plans for our product candidates; the expected cost, timing and results of our clinical development plans and clinical trials with respect to our product candidates; our expectations with respect to the release of data from our clinical trials and the expected timing thereof; our expectations and goals for our collaborations with third parties and any potential benefits related thereto; the potential for our product candidates to achieve success in clinical trials; and our expected financial condition, including our anticipated net cash burn, the anticipated duration of cash runways and timing regarding needs for additional capital.

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: 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; uncertainties associated with litigation generally and patent litigation specifically; 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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