

# Arbutus Announces 2022 Corporate Objectives and Provides Financial Update

January 24, 2022

Multiple AB-729 and AB-836 HBV clinical data readouts anticipated to guide future clinical development and regulatory strategies

### Complete IND-enabling studies for oral PD-L1 inhibitor, AB-101, for the treatment of HBV

### Complete IND-enabling studies for next generation oral RNA destabilizer, AB-161, for the treatment of HBV

#### Advance an nsp5 main protease (M<sup>pro</sup>) inhibitor candidate into IND-enabling studies for treatment of SARS-CoV-2

#### Financial position significantly strengthened; cash runway into Q2 2024

WARMINSTER, Pa., Jan. 24, 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, today announced its 2022 corporate objectives and provided a financial update.

William Collier, President and CEO, stated, "This year is an important one for Arbutus and the HBV patient community based on the many accomplishments we achieved in 2021. With five clinical trials on-going in HBV that include either AB-729 or AB-836, we are now poised for several key data readouts throughout this year that we anticipate will support Phase 2b clinical development. In addition, we intend to advance AB-101, our oral PD-L1 inhibitor compound for HBV which is designed to re-awaken the immune system, through IND-enabling studies this year. Similarly, this year we intend to complete IND-enabling studies for our RNA destabilizer, AB-161."

Mr. Collier continued, "As the COVID-19 pandemic lingers, we are expediting our efforts to advance novel oral pan-coronavirus compounds against viral protease and polymerase targets. We intend to advance an M<sup>pro</sup> candidate into IND-enabling studies for the treatment of SARS-CoV-2 this year.

"Lastly, we are entering 2022 from a position of financial strength, with a cash runway expected to extend into the second quarter of 2024. I am thrilled with the company's accomplishments and execution in 2021 and look forward to providing further updates over the course of this coming year."

# Summary of 2022 Anticipated Key Milestones:

HBV Franchise:

- Announce preliminary AB-729 data in the second half of 2022 from the following three on-going Phase 2a proof-of-concept clinical trials in patients with chronic hepatitis B (HBV) infection:
  - AB-729 in combination with ongoing standard-of-care nucleos(t)ide analogues ("NA") therapy and short courses of PEG-IFNα-2a.
  - AB-729 plus vebicorvir ("VBR"), Assembly Bio's lead investigational HBV core inhibitor (capsid inhibitor) candidate, and a NA.
  - AB-729 plus ATI-2173, Antios' proprietary Active Site Polymerase Inhibitor Nucleotide (ASPIN), and Viread <sup>®</sup> (tenofovir disoproxil fumarate).
- Initiate a triple combination Phase 2a proof-of-concept clinical trial in the first half of 2022 to evaluate AB-729, combined with VTP-300, Vaccitech's therapeutic vaccine, and a NA.
- Present at a medical conference the long-term on- and off-treatment follow-up data from our Phase 1a/1b clinical trial evaluating multiple doses and dosing schedules of AB-729.
- Announce data from our Phase 1a/1b clinical trial evaluating AB-836 in patients with chronic HBV in the first half of 2022.
- Complete IND-enabling studies with our oral PD-L1 inhibitor compound, AB-101, in the second half of 2022.
- Complete IND-enabling studies for AB-161, our next-generation oral HBV specific RNA destabilizer, in the second half of 2022. Arbutus has conducted extensive non-clinical safety evaluations with AB-161 that gives us confidence in this molecule's ability to circumvent the peripheral neuropathy findings seen in non-clinical safety studies with the Company's first-generation oral RNA destabilizer, AB-452.

COVID-19 & Pan-Coronavirus Franchise

• Nominate a candidate that inhibits the SARS-CoV-2 nsp5 main protease (M<sup>pro</sup>) in the first half of 2022 and advance into IND-enabling studies.

• Continue lead optimization activities for an Nsp12 viral polymerase candidate.

## Other Opportunities

• Explore potential oncology applications for internal PD-L1 portfolio.

# Financial Update:

- We had cash, cash equivalents and investments in marketable securities totaling \$191 million as of December 31, 2021. This amount does not include a \$40 million upfront payment and \$15 million of proceeds resulting from the sale of common stock to Qilu Pharmaceutical as part of the exclusive licensing agreement and strategic partnership to develop and commercialize AB-729 in mainland China, Hong Kong, Macau and Taiwan. These amounts were received in January 2022.
- For the full year of 2021 we received \$135 million of net proceeds from the issuance of common shares under Arbutus's "at-the-market" offering program. As of December 31, 2021, we had approximately 145 million common shares issued and outstanding, and approximately 11.4 million stock options outstanding.
- We expect our net cash burn to range from \$90 to \$95 million in 2022. We believe our cash, cash equivalents and investments in marketable securities of \$191 million as of December 31, 2021, plus the amounts received from Qilu Pharmaceutical in January 2022 are sufficient to fund the Company's operations into the second quarter of 2024.
- The preliminary cash, cash equivalents and investments, the amount received from the issuance of common shares under Arbutus's "at-the-market" offering program and the common shares and stock options outstanding as of December 31, 2021 were calculated prior to the completion of an audit by Arbutus' independent registered public accounting firm and are therefore subject to adjustment.

# **COVID-19 Impact**

In December 2019 an outbreak of a novel strain of coronavirus (COVID-19) was identified in Wuhan, China. This virus has been declared a pandemic by the World Health Organization and has spread to nearly every country in the world. The impact of this pandemic has been, and will likely continue to be, extensive in many aspects of society. The pandemic has resulted in and will likely continue to result in significant disruptions to businesses. A number of countries and other jurisdictions around the world have implemented extreme measures to try and slow the spread of the virus. These measures include the closing of businesses and requiring people to stay in their homes, the latter of which raises uncertainty regarding the ability to travel to hospitals in order to participate in clinical trials. Additional measures that have had, and will likely continue to have, a major impact on clinical development, at least in the near-term, include shortages and delays in the supply chain, and prohibitions in certain countries on enrolling subjects and patients in new clinical trials. While we have been able to progress with our clinical and pre-clinical activities to date, it is not possible to predict if the COVID-19 pandemic will materially impact our plans and timelines in the future.

## About AB-729

AB-729 is an RNA interference (RNAi) therapeutic specifically designed to reduce all HBV viral proteins and antigens, including hepatitis B surface antigen, which is thought to be a key prerequisite to enable reawakening of a patient's immune system to respond to the virus. AB-729 targets hepatocytes using Arbutus' novel covalently conjugated N-acetylgalactosamine (GalNAc) delivery technology that enables subcutaneous delivery. Clinical data generated thus far has shown single- and multi-doses of AB-729 to be generally safe and well-tolerated while providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. AB-729 is currently in multiple Phase 2a clinical trials.

## About AB-836

AB-836 is a next generation oral hepatitis B virus (HBV) capsid inhibitor that interacts with HBV core protein, which in turn is required for viral replication. The current standard-of-care therapy for HBV is primarily nucleos(t)ide analogues that inhibit the viral polymerase and significantly reduce, but do not eliminate viral replication. AB-836 in combination with nucleos(t)ide analogues is designed to completely eliminate viral replication in infected cells by preventing the assembly of functional viral capsids. In addition, AB-836 has been shown to inhibit the replenishment of covalently closed circular DNA (cccDNA), the viral genetic reservoir which the virus needs to replicate itself. Preliminary data from an on-going Phase 1a/1b clinical trial has shown that AB-836 is generally safe and well-tolerated and provides robust antiviral activity.

## About HBV

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). HBV can cause chronic infection which leads to a higher risk of death from cirrhosis and liver cancer. Chronic HBV infection represents a significant unmet medical need. The World Health Organization estimates that over 250 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2 million people in the United States suffer from chronic HBV infection. Approximately 900,000 people die every year from complications related to chronic HBV infection despite the availability of effective vaccines and current treatment options.

## **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) and coronaviruses. In HBV, we are developing a RNAi therapeutic, oral capsid inhibitor, oral PD-L1 inhibitor, and oral RNA destabilizer that we intend to combine to improve the outcomes of patients with chronic HBV by suppressing viral replication, reducing surface antigen and reawakening the immune system. 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 COVID-19). 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 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; our expected financial condition, including the anticipated duration of cash runways and timing regarding needs for additional capital; and our expectations regarding the impact of the COVID-19 pandemic on our business and clinical trials.

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.

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; 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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