



Arbutus Announces Multiple Abstracts Accepted for Presentation at AASLD - The Liver Meeting® 2023

October 11, 2023

Imdusiran data will be highlighted in late breaking presentation

WARMINSTER, Pa., Oct. 11, 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 clinical data from the Company's lead HBV focused asset, imdusiran (AB-729), an RNAi therapeutic, and preclinical data from its oral PD-L1 inhibitor program, will be highlighted in oral and poster presentations, including a late breaking poster presentation at The American Association for the Study of Liver Diseases (AASLD) – The Liver Meeting® 2023, taking place from November 10-14, 2023 in Boston, MA.

Late-Breaking Abstract Acceptance:

Title: Preliminary Pharmacodynamics and Safety of Repeat Dosing of Imdusiran (AB-729) Followed by VTP-300 or Placebo in Virally-Suppressed, Non-Cirrhotic Subjects with Chronic Hepatitis B (CHB)

Authors: Man-Fung Yuen, Kosh Agarwal, Stuart K. Roberts, Gin-Ho Lo, Chao-Wei Hsu, Wan-Long Chuang, Chi-Yi Chen, Pei-yuan Su, Sam Galhenage, Sheng-Shun Yang, Deana Antonello, Emily Thi, Susanne O'Brien, Louise Bussey, Elina Medvedeva, Timothy Eley, Deepa Patel, Tilly Varughese, Christine Espiritu, Sharie Ganchua, Christina Iott, Mark Anderson, Tiffany Fortney, Gavin Cloherty, Tom Evans, Karen Sims

Regular Abstract Acceptances:

Abstract Number: 45559

Title: Baseline Nucleotide Polymorphisms Within HBV Target Site in Chronic Hepatitis B Subjects Do Not Impact HBsAg Reductions Mediated by RNA Interference Therapeutic AB-729

Presentation Type: Poster #1459-C

Presentation Time: Friday, November 10: 12:00 – 1:00 PM ET – Poster Hall C

Authors: Christine Espiritu, Holly Micolochick Steuer, Andrzej Ardzinski, Varun Sharma, Timothy Eley, Karen D. Sims, Amy C.H. Lee, Rene Rijnbrand, Andrea Cuconati, Nagraj Mani, Angela M. Lam, Michael J. Sofia, and Emily P. Thi

Data Summary: Single nucleotide polymorphisms (SNPs) in the imdusiran (AB-729) HBV target site were identified in sequences obtained from a publicly available database and were observed at baseline in some chronic HBV subjects in AB-729-001. In vitro testing in an HBV cell-based model confirm retention of AB-729 activity against tested variants suggesting that these SNPs have no apparent influence on individual or mean HBsAg declines observed in subjects treated with AB-729.

Abstract Number: 46646

Title: Oral Small-Molecule Liver-Tropic PD-L1 Inhibitor Pharmacokinetics for the Treatment of Hepatocellular Carcinoma

Presentation Type: Poster #4209A

Presentation Time: Monday, November 13: 1:00 – 2:00 PM ET

Authors: Arpita Mondal, Emily P Thi, Ingrid Graves, Gavin Heffernan, Fran Xu, Seyma Ozturk, Amanda Pohl, Kristi Y Fan, Andrew Cole, Troy O Harasym, Angela M Lam, and Michael J Sofia

Data Summary: Treatment with oral small-molecule PD-L1 inhibitors possessing liver-tropic pharmacokinetic profiles was associated with increased efficacy and tumor clearance in a novel humanized orthotopic HCC mouse model. These data suggest that development of small-molecule PD-L1 inhibitors with biodistribution to the liver may provide benefit in the treatment of HCC.

Abstract Number: 40653

Title: Preliminary off-treatment responses following 48 weeks of vebicorvir, nucleos(t)ide reverse transcriptase inhibitor, and AB-729 combination in virologically suppressed patients with hepatitis B e antigen negative chronic hepatitis B: Analysis from an open-label Phase 2 study

Presentation Type: Oral Presentation

Session: Hepatitis B: New Therapies for HBV and HDV

Presentation Time: Sunday, November 12: 8:30 AM

Authors: Gerry MacQuillan, Magdy Elkhashab, Krasimir Antonov, Zina Valaydon, Scott Davison, Scott Fung, Catherine Vincent, Robert Bailey, Fei Chen, Curtis Cooper, Stuart Roberts, Marie-Louise Vachon, Carla S. Coffin, Gail Matthews, Mariana Radicheva, Steven J. Knox, Ran Yan, Emily P. Thi, Calvin Chan, Jieming Liu, Katie Zomorodi, Timothy Eley, Luisa M. Stamm, Karen Sims, Michele Anderson, Gaston Picchio, Grace Wang, Rozalina Balabanska, Radoslava Tsrancheva, Jacob George

Data Summary: Treatments were well tolerated. Available data indicate that adding VBR to AB-729+Nrtl does not result in significantly greater on- or post-treatment improvements in markers of active HBV infection vs AB-729+Nrtl.

The poster presentations will be available on Arbutus' website on November 10, 2023 and can be accessed through the Publications section at <https://www.arbutusbio.com/publications/>.

About imdusiran (AB-729)

Imdusiran 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. Imdusiran targets hepatocytes using Arbutus' novel covalently conjugated N-Acetylgalactosamine (GalNAc) delivery technology enabling subcutaneous delivery. Clinical data generated thus far has shown single and multiple doses of imdusiran to be generally safe and well-tolerated, while also providing meaningful reductions in hepatitis B surface antigen and hepatitis B DNA. Imdusiran is currently in multiple Phase 2a clinical trials.

About AB-101

AB-101 is our oral PD-L1 inhibitor candidate that we believe will allow for controlled checkpoint blockade while minimizing the systemic safety issues typically seen with checkpoint antibody therapies. Immune checkpoints such as PD-1/PD-L1 play an important role in the induction and maintenance of immune tolerance and in T-cell activation. Preclinical data generated thus far indicates that AB-101 mediates re-activation of exhausted HBV-specific T-cells from cHBV patients. We believe AB-101, when used in combination with other approved and investigational agents, could potentially lead to a functional cure in patients chronically infected with HBV. AB-101 is currently being evaluated in a Phase 1a/1b clinical trial. We have identified compounds in our internal PD-L1 portfolio that could also be used in oncology indications.

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 290 million people worldwide suffer from chronic HBV infection, while other estimates indicate that approximately 2.4 million people in the United States suffer from chronic HBV infection. Approximately 820,000 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 identify and develop novel therapeutics with distinct mechanisms of action, which can be combined to provide a functional cure for patients with chronic hepatitis B virus (cHBV). We believe the key to success in developing a functional cure involves suppressing HBV DNA, reducing surface antigen, and boosting HBV-specific immune responses. Our pipeline of internally developed, proprietary compounds includes an RNAi therapeutic, imdusiran (AB-729), and an oral PD-L1 inhibitor, AB-101. Imdusiran is the only RNAi that has generated meaningful clinical data demonstrating an impact on both surface antigen reduction and reawakening of the HBV-specific immune response. Imdusiran is currently in two Phase 2a combination clinical trials. AB-101 is currently being evaluated in a Phase 1a/1b clinical trial. We are also exploring oncology applications for our internal PD-L1 portfolio. For more information, visit www.arbutusbio.com.

Forward-Looking Statements

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 belief that AB-101 will allow for controlled checkpoint blockade while minimizing the systemic safety issues typically seen with checkpoint antibody therapies; our belief that development of small-molecule PD-L1 inhibitors with biodistribution to the liver may provide benefit in the treatment of HCC; our belief that AB-101, when used in combination with other approved and investigational agents, could potentially lead to a functional cure in patients chronically infected with HBV; our belief that the key to success in developing a functional cure for cHBV involves suppressing HBV DNA, reducing surface antigen, and boosting HBV-specific immune responses; our future development plans for our product candidates; our program updates; our belief that checkpoint inhibitors may play a key role in antiviral immune tolerance in cHBV; 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 clinical trial design and 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 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 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: the risk that the program updates may not materially extend the cash runway and may create a distraction or uncertainty that may adversely affect our operating results, business, or investor perceptions; 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; it may take considerable time and expense to resolve the clinical hold that has been placed on AB-101 by the FDA, and no assurance can be given that the FDA will remove the clinical hold; Arbutus and its collaborators may never realize the expected benefits of the collaborations; and market shifts may require a change in strategic focus; and risks related to the sufficiency of Arbutus' cash resources and its ability to obtain adequate financing in the future for its foreseeable and unforeseeable operating expenses and capital expenditures.

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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Investors and Media

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