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# **Arbutus Reports Topline Results from TKM-PLK1 HCC Clinical Trial**

Promising Anti-Tumor Activity Observed
Arbutus to Explore Partnership Options to Enable Further Study

VANCOUVER, B.C. and DOYLESTOWN, Pa., July 19, 2016 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq:ABUS), an industry-leading hepatitis B virus (HBV) therapeutic solutions company, today reported topline results from the completed Phase I/II TKM-PLK1 clinical study in patients with advanced Hepatocellular Carcinoma (HCC). Arbutus intends to explore partnership opportunities to enable further study of TKM-PLK-1 in HCC.

Arbutus today reported the following topline results from the Phase I/II study of TKM-PLK1 in HCC:

- TKM-PLK1 was well-tolerated at all dose levels;
- 51% of subjects showed overall stable disease (SD) according to RECIST criteria;
- 22% of subjects showed an overall partial response (PR) according to Choi response criteria;
- Tumor density reduction of up to 59% was observed;

"We are encouraged by the results from the TKM-PLK1 clinical trial in HCC patients and believe it supports further evaluation of this candidate as a potential treatment for HCC," said Dr. Mark Kowalski, Arbutus' Chief Medical Officer. "The observed radiographic tumor density changes are consistent with tumor necrosis in a significant proportion of subjects, warranting further study of TKM-PLK1 for HCC, alone and in combination with other therapies."

"We are very pleased to report the positive results of this study of TKM-PLK1 in HCC, which we view as further validation of our capability to develop promising product candidates using our proprietary LNP delivery technology," said Dr. Mark J. Murray, Arbutus' President and CEO. "Given Arbutus' focus on HBV, we look forward to finding the right partner to advance the development of TKM-PLK1 for HCC and maximize the value of this asset for our shareholders."

## **Trial Design**

The Phase I/II TKM-PLK1 HCC clinical study was an open-label, multi-center, study in patients with advanced HCC conducted in the US, Asia, and Canada. The trial was designed to assess the safety, tolerability, pharmacokinetics, and preliminary efficacy of the product. TKM-PLK1 was administered weekly with each four-week cycle consisting of three onceweekly doses followed by a rest week. The study included a total of 43 subjects (12 subjects in the dose escalation arm, followed by 31 subjects in the expansion cohort). The HCC efficacy endpoint of the study was tumor response rate.

### About TKM-PLK1

TKM-PLK1 (TKM-080301) is a lipid nanoparticle (LNP) encapsulated small interfering RNA (siRNA) directed against polo-like kinase 1 (PLK1), a protein involved in tumor cell proliferation and a validated oncology target. Inhibition of PLK1 expression prevents the tumor cell from completing cell division, resulting in cell cycle arrest and death of the cancer cell. TKM-PLK1 has been evaluated in clinical trials with patients who have HCC, gastrointestinal neuroendocrine tumors (GI-NET), and adrenocortical carcinoma (ACC).

#### About Arbutus

Arbutus Biopharma Corporation is a biopharmaceutical company dedicated to discovering, developing and commercializing a cure for patients suffering from chronic HBV infection. Arbutus is headquartered in Vancouver, BC, Canada with offices in Doylestown, PA, USA. For more information, visit <a href="https://www.arbutusbio.com">www.arbutusbio.com</a>.

## 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 exploring partnership opportunities to enable further study of TKM-PLK-1 in HCC.

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 and clinical trials, and the usefulness of the

data; 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.

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 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 drug candidate; Arbutus may not receive the necessary regulatory approvals for the clinical development of Arbutus' products; economic and market conditions may worsen; and market shifts may require a change in strategic focus.

A more complete discussion of the risks and uncertainties facing Arbutus appears in Arbutus' Annual Report on Form 10-K and Arbutus' continuous disclosure filings, which are available at <a href="https://www.sedar.com">www.sedar.com</a> and at <a href="https://www.sec.gov">www.sec.gov</a>. 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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