BioInvent International: CASI Pharmaceuticals Report Positive Interim Phase 1 Data For BI-1206 In The Treatment Of Relapsed/Refractory Indolent Non-Hodgkin's Lymphoma In China

BEIJING, China and LUND, Sweden, March 5, 2024 – CASI Pharmaceuticals, Inc. (Nasdaq: CASI), a biopharmaceutical company specializing in the development and commercialization of innovative therapeutic and pharmaceutical products, and BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV), a biotech company focused on the discovery and development of novel and first-in-class immune-modulatory antibodies for cancer immunotherapy, today announced preliminary encouraging efficacy data for BI-1206 in combination with rituximab in patients with relapsed/refractory (R/R) indolent Non-Hodgkin's Lymphoma (iNHL) in the ongoing development program in China.

BI-1206 is a first-in-class fully human monoclonal antibody (mAb) that targets FcγRIIB. It is being evaluated in combination with rituximab in patients with R/R iNHL. The Phase 1 study is designed to assess the safety, tolerability, pharmacology, and clinical activity of BI-1206, administered though intravenous (IV) infusion.

The Phase 1 dose-escalation study showed impressive signs of clinical efficacy, with 4 partial responses (PR) and 1 complete response (CR) out of 8 evaluable patients. The results are consistent with the clinical data that have been previously reported by BioInvent. Among the responders in the study being conducted in China, one patient with relapsed Marginal Zone Lymphoma (MZL) patient who achieved CR has maintained a durable complete remission for 20+ weeks. The preliminary results demonstrated a manageable safety profile across all patients.

Dr. Wei-Wu He, CEO of CASI, said "These initial BI-1206 data showed promising response for patients with difficult-to-treat disease. The data are especially notable as they demonstrated strong and durable responses at lower dose levels. We believe these results represent important steps toward validating BI-1206 as a potential treatment as well as de-risk our plan for future development."

Dr. He continued, "Further developing BI-1206 to help treat more patients with iNHL is an important goal we share with our partner BioInvent. The interim results further strengthen our confidence in progressing BI-1206 into the next stage of clinical development as a potential treatment option for patients with R/R iNHL."

Dr. Martin Welschof, CEO of BioInvent commented, "We are encouraged by the promising new interim Phase 1 data reported today by our partner, CASI. BI-1206 is being developed to re-establish the clinical efficacy of cancer therapies such as rituximab by addressing

fundamental resistance mechanisms to cancer treatments. The clinical efficacy results reported today, including a long-lasting complete response, reinforce previously reported data. We continue to be enthusiastic about the development of BI-1206 in NHL and look forward to reporting data from additional studies in the first half of 2024."

About BI-1206 (Anti-FcyRIIB antibody)

The National Medical Products Administration (NMPA) granted the BI-1206 Clinical Trial Application (CTA) approval in December 2021. Ethics committee approval from a leading investigational site was granted in January 2022. BI-1206 is currently being evaluated in the US, the EU, Brazil and China in three Phase 1/2 trials. Two studies are evaluating BI-1206 in combination with rituximab for the treatment of indolent non-Hodgkin lymphoma (NHL), which includes patients with follicular lymphoma (FL), mantle cell lymphoma (MCL), and MZL who have relapsed or are refractory to rituximab. The third Phase 1/2 trial is investigating BI-1206 in combination with the anti-PD1 therapy KEYTRUDA® (pembrolizumab) in solid tumors. The U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for BI-1206 for the treatment of follicular lymphoma, the most common form of slow-growing non-Hodgkin lymphoma. BioInvent has licensed the rights for BI-1206 to CASI for China, Hong Kong, Macau, and Taiwan.

About CASI Pharmaceuticals

CASI Pharmaceuticals, Inc. is a biopharmaceutical company focused on developing and commercializing innovative therapeutics and pharmaceutical products in China, the United States, and throughout the world. The Company is focused on acquiring, developing, and commercializing products that augment its hematology oncology therapeutic focus as well as other areas of unmet medical need. The Company intends to execute its plan to become a leader by launching medicines in the Greater China market, leveraging the Company's China-based regulatory and commercial competencies and its global drug development expertise. The Company's operations in China are conducted through its wholly owned subsidiary, CASI Pharmaceuticals (China) Co., Ltd., located in Beijing, China. More information on CASI is available at www.casipharmaceuticals.com.

About BioInvent International AB

BioInvent International AB (Nasdaq Stockholm: BINV) is a clinical-stage biotech company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapy, with currently five drug candidates in six ongoing clinical programs in Phase 1/2 trials for the treatment of hematological cancer and solid tumors. The Company's validated, proprietary F.I.R.S.T™ technology platform identifies both targets and the antibodies that bind to them, generating many promising new immune-modulatory candidates to fuel the Company's own clinical development pipeline and providing licensing and partnering opportunities.

The Company generates revenues from research collaborations and license agreements with multiple top-tier pharmaceutical companies, as well as from producing antibodies for third parties in the Company's fully integrated manufacturing unit. More information is available at www.bioinvent.com. Follow on the social media platform X: @BioInvent.

CASI Forward-Looking Statements:

This announcement contains forward-looking statements. These statements are made under the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as "will," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," "confident" and similar statements. Among other things, the business outlook and quotations from management in this announcement, as well as the Company's strategic and operational plans, contain forward-looking statements. The Company may also make written or oral forward-looking statements in its periodic reports to the U.S. Securities and Exchange Commission (the "SEC"), in in its annual report to shareholders, in press releases and other written materials and in oral statements made by its officers, directors or employees to third parties. Statements that are not historical facts, including statements about the Company's beliefs and expectations, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties. A number of factors could cause actual results to differ materially from those contained in any forward-looking statement, including but not limited to the following: the risk that we may be unable to continue as a going concern as a result of our inability to raise sufficient capital for our operational needs; the possibility that we may be delisted from trading on The Nasdaq Capital Market if we fail to satisfy applicable continued listing standards; the volatility in the market price of our ordinary shares; the risk of substantial dilution of existing shareholders in future share issuances; the difficulty of executing our business strategy on a global basis including China; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; legal or regulatory developments in China that adversely affect our ability to operate in China, our lack of experience in manufacturing products and uncertainty about our resources and capabilities to do so on a clinical or commercial scale; risks relating to the commercialization, if any, of our products and proposed products (such as marketing, safety, regulatory, patent, product liability, supply, competition and other risks); our inability to predict when or if our product candidates will be approved for marketing by the U.S. Food and Drug Administration, European Medicines Agency, PRC National Medical Products Administration, or other regulatory authorities; our inability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or future candidates; the risks relating to the need for additional capital and the uncertainty of securing additional funding on favorable terms; the risks associated with our product candidates, and the risks associated with our other early-stage products under development; the risk that result in preclinical and clinical models are not necessarily indicative of clinical results; uncertainties relating to preclinical and clinical trials, including delays to the commencement of such trials; our ability to protect our intellectual property rights; the lack of success in the clinical development of any of our products; and our dependence on third parties;

the risks related to our dependence on Juventas to conduct the clinical development of CNCT19 and to partner with us to co-market CNCT19; risks related to our dependence on Juventas to ensure the patent protection and prosecution for CNCT19; risks relating to the commercialization, if any, of our proposed products (such as marketing, safety, regulatory, patent, product liability, supply, competition and other risks); risks relating to interests of our largest shareholder and our Chairman and CEO that differ from our other shareholders; and risks related to the development of a new manufacturing facility by CASI Pharmaceuticals (Wuxi) Co., Ltd. Further information regarding these and other risks is included in the Company's filings with the SEC. All information provided herein is as of the date of this announcement, and the Company undertakes no obligation to update any forward-looking statement, except as required under applicable law.

BioInvent disclaimer: The press release contains statements about the future, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as the date they are made and are, by their very nature, in the same way as research and development work in the biotech segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios described in this press release. This press release is published in Swedish and English. In the event of any difference between the English version and the Swedish original, the Swedish version shall prevail. For a more detailed description of risk factors, see section "Risks and Risk Management," page 47, in the Company's annual report 2022.

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Attachments

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