CASI Pharmaceuticals and BioInvent Announce Dosing of First patient in BI-1206 Phase 1 Clinical Trial for the Treatment of Relapsed/Refractory non-Hodgkin's lymphoma in China

Rockville, MD., and Lund, Sweden, September 7, 2022 – CASI Pharmaceuticals, Inc. ("CASI") (Nasdaq: CASI), a U.S. biopharmaceutical company focused on developing and commercializing innovative therapeutics 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 the first-patient-in in China Phase 1 dose-escalation and expansion study of BI-1206, a first-in-class fully human monoclonal antibody (mAb) that targets FcyRIIB, in combination with rituximab in patients with relapsed/refractory Non-Hodgkin's Lymphoma (NHL). The study design is to assess the safety, tolerability, pharmacology, and clinical activity of BI-1206. The patient was enrolled at Henan Cancer Hospital.

Wei-Wu He, Ph.D., CASI's Chairman, and Chief Executive Officer, commented, "We are excited to dose the first patient in the continued evaluation of BI-1206. BI-1206 has previously shown encouraging early signs of efficacy in Phase 1, a tolerable safety profile, and the potential to be used with multiple therapeutic mAbs that rely on ADCC/CDC for efficacy. This Phase 1 trial in China will generate valuable information and has the potential to provide early evidence of clinical activity in the treatment of relapsed or refractory Non-Hodgkin's Lymphoma."

Martin Welschof, CEO of BioInvent, said: "The initiation of this Phase 1 trial in China is an important milestone for BioInvent as it marks the expansion of the clinical program of our lead drug candidate, BI-1206. The clinical results have been very promising, and we are looking forward to generating additional data together with our partner CASI Pharmaceuticals with the aim of improving treatment for patients with NHL and addressing this significant unmet medical need."

***

About BI-1206 (anti-FcyRIIB antibody)
The National Medical Products Administration (NMPA) granted 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 investigated outside of China in two Phase 1/2 trials. One is evaluating the BI-1206 combination with rituximab for the treatment of non-Hodgkin lymphoma (NHL), which includes patients with follicular lymphoma (FL), mantle cell lymphoma (MCL), and marginal zone lymphoma (MZL) who have relapsed or are refractory to

rituximab. A second Phase 1/2 trial is investigating BI-1206 in combination with anti-PD1 therapy Keytruda® (pembrolizumab) in solid tumors. Earlier this year, the U.S. FDA granted Orphan Drug Designation, for BI-1206, for the treatment of follicular lymphoma, the most common form of slow-growing non-Hodgkin lymphoma.

About BioInvent
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 four drug candidates in five ongoing clinical programs in Phase 1/2 trials for the treatment of hematological cancer and solid tumors, respectively. The Company's validated, proprietary F.I.R.S.T™ technology platform simultaneously identifies both targets and the antibodies that bind to them, generating many promising new drug candidates to fuel the Company's own clinical development pipeline or for additional licensing and partnering.

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 Twitter: @BioInvent.

About CASI Pharmaceuticals
CASI Pharmaceuticals, Inc. is a U.S. 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. The Company has built a commercial team of more than 100 hematology and oncology sales and marketing specialists based in China. More information on CASI is available at www.casipharmaceuticals.com.

Forward-Looking Statements
This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act with respect to the outlook for expectations for future financial or business performance, revenue growth, strategies, expectations and goals. Forward-looking statements are subject to numerous assumptions, risks and uncertainties, which change over time. Forward-looking statements speak only as of the date they are made, and we assume no duty to update forward-looking statements. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Actual results could differ materially from those currently anticipated due to a number of factors.

Disclaimer BioInvent
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.

For further information, please contact:

CASI Pharmaceuticals, Inc.
Rui Zhang
Phone: 240.864.2643
Email: ir@casipharmaceuticals.com

BioInvent International AB (publ)
Cecilia Hofvander, Senior Director Investor Relations
Phone: +46 (0)46 286 85 50
Email: cecilia.hofvander@bioinvent.com

BioInvent International AB (publ)
Co. Reg. No. Org nr: 556537-7263
Visiting address: Ideongatan 1
Mailing address: 223 70 LUND
Phone: +46 (0)46 286 85 50
www.bioinvent.com

Attachments

CASI Pharmaceuticals and BioInvent Announce Dosing of First patient in BI-1206 Phase 1 Clinical Trial for the Treatment of Relapsed/Refractory non-Hodgkin's lymphoma in China