BioInvent and CASI Pharmaceuticals announce CTA approval for clinical studies of BI-1206 in NHL in China

Lund, Sweden – December 10, 2021 – 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 that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA), China's medical product regulator, has approved a Clinical Trial Application (CTA) submitted by BioInvent's licensee in China, CASI Pharmaceuticals (CASI). The CTA is for the initiation of two clinical trials of BioInvent's novel anti-FcγRIIB antibody, BI-1206, in patients with non-Hodgkin's Lymphoma (NHL) in China.

BI-1206 is BioInvent's lead drug candidate and is currently being investigated in two Phase 1/2 trials. One is evaluating the BI-1206 combination with anti-PD1 therapy Keytruda® (pembrolizumab) in solid tumors, and the other in combination with rituximab for the treatment of non-Hodgkin's lymphoma.

CASI is planning Phase 1 trials of BI-1206 as a single agent with the aim to evaluate the PK profile and in combination with rituximab in NHL (mantle cell lymphoma, marginal zone lymphoma and follicular lymphoma) to assess safety and tolerability, select the Recommended Phase 2 Dose and assess early signs of clinical efficacy as part of its development program for BI-1206 in China and associated markets. The studies are expected to start in H1 2022.

BioInvent and CASI have an exclusive licensing agreement for the development and commercialization of BI-1206 in mainland China, Taiwan, Hong Kong and Macau in both liquid and solid cancers, with CASI responsible for commercialization in China and associated markets. BioInvent is eligible to receive up to $83 million in development and commercial milestone payments plus tiered royalties in the high-single to mid-double-digit range on net sales of BI-1206.

"We are very pleased to see the first fruit of our development collaboration with CASI on BI-1206. As BioInvent develops the drug candidate across Europe and the US, our partnership with CASI focusing on China, Hong Kong, Macau and Taiwan, adds significant shareholder value to the company. Our expanding pipeline of first-in-class immunotherapies creates multiple development and commercial opportunities for the company and its partners." said **Martin Welschof, CEO of BioInvent.**

"We are excited to be able to accelerate the development of BI-1206 in China and contribute to its global development. The collaboration has been open, fast, efficient and professional. We believe BI-1206 has great potential to improve NHL treatment in China and elsewhere." said **Wei-Wu He, Ph.D., CASI's Chairman and Chief Executive Officer.**

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 three drug candidates in four ongoing clinical programs in Phase I/II trials for the treatment of hematological cancer and solid tumors, respectively and a fifth program just initiating clinical development. 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.

About CASI Pharmaceuticals
CASI Pharmaceuticals, Inc. (NASDAQ: CASI) 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. ("CASI China"), which is located in Beijing, China. The Company has built a commercial team of over 100 hematology and oncology sales and marketing specialists based in China. More information on CASI is available at www.casipharmaceuticals.com.

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Attachments

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