



BioInvent Phase I/IIa data suggest BI-1206 restores activity of rituximab in relapsed non-Hodgkin's lymphoma patients

- **Responses in 6 out of 9 patients evaluated provide exciting evidence that BI-1206 has the potential to restore activity of rituximab in non-Hodgkin's lymphoma patients who have relapsed after treatment with rituximab**
- **Long-lasting complete responses observed in two patients beyond 12 months**
- **Key opinion leader (KOL) call to discuss results today, January 28, at 5.30 p.m. CET (11:30 a.m. ET)**

Lund, Sweden – January 28, 2021 – BioInvent International AB ("BioInvent") (OMXS: BINV), a biotech company focused on the discovery and development of novel and first-in-class immune-modulatory antibodies for cancer immunotherapy, today announces positive interim results from the Phase I/IIa trial of the novel anti-FcγRIIB antibody BI-1206 in combination with rituximab (anti-CD20 monoclonal antibody) in patients with indolent relapsed or refractory B-cell non-Hodgkin's lymphoma (NHL).

"The responses observed in six out of nine patients are very encouraging and clearly suggest that BI-1206 may restore the response to rituximab in patients who have few treatment alternatives. The complete responses we have seen in two patients are particularly impressive and indicate that BI-1206 has the potential to significantly improve the lives of NHL patients who have progressed after several lines of treatment. Based on these results, we will now move to identify the recommended phase II dose for the Phase IIa part of the trial and look forward to further evaluating the exciting potential of BI-1206 to bring much needed innovation to lymphoma patients," said **Martin Welschof, Ph.D., CEO of BioInvent**.

Of the 9 patients who completed the induction cycle, 6 patients have shown either complete or partial responses several of which are still ongoing. Two patients (30 mg and 70 mg dose) achieved a complete response, which continues to be sustained 12 and 24 months later. Another patient who had a blastoid form of MCL achieved a partial response, and a complete depletion of peripheral tumor cells. Readout from two patients is still pending.

A total of 15 patients have been recruited to date in the Phase I dose escalation part of the study, all of whom were late stage and have failed conventional treatments, including several lines of rituximab-containing therapies.

To address dose limiting toxicities seen at higher doses earlier in the trial, a new safety protocol was implemented, enabling higher doses to be administered. No dose-limiting toxicities have been observed in the five patients who have been treated under the current protocol, despite receiving higher doses of BI-1206.

Wei-Wu He, Ph.D., CASI's Chairman and Chief Executive Officer, said: "We continue to be excited about this anti-FcγRIIB antibody's potential in restoring rituximab's activity in NHL patients, and these results provided further encouraging evidence of its potential as a durable and safe treatment alternative. We remain encouraged by its potential application across multiple tumor types in many first line treatments and in refractory settings and are excited to be taking an important step closer to making BI-1206 available to patients and healthcare providers across Greater China."

BioInvent will hold a [key opinion leader \(KOL\) call](#) today, Thursday, January 28 at 5:30 p.m. CET (11:30 a.m. ET) to discuss the results and next steps in clinical development of BI-1206. Renowned lymphoma expert Mats Jerkeman, MD, Lund University, will give a presentation on the current treatment landscape, and unmet medical need for patients with relapsed or refractory NHL. The BioInvent management team will be available for Q&A and partner CASI Pharmaceuticals (NASDAQ: CASI) will provide an update on the development plan and potential for BI-1206 in China.

BI-1206, in clinical development for both hematological and solid tumors, is the lead compound in BioInvent's broad pipeline and one of three products undergoing four clinical trials. BioInvent initiated a Phase I/IIa trial of anti-TNFR2 antibody BI-1808 in January and is ready to initiate a Phase I/IIa study of the novel oncolytic vaccinia virus BT-001, together with partner Transgene.

About the Phase I/IIa study of BI-1206 in NHL

The Phase I/IIa study consists of two parts: i) Phase I, with dose escalation cohorts using a 3+3 dose-escalation design and selection of the recommended Phase IIa dose (RP2D); and ii) Phase IIa, an expansion cohort at the RP2D, enriched with patients with mantle cell lymphoma (MCL). Subjects in each phase receive 1 cycle (4 doses) of induction therapy with BI-1206 in combination with rituximab. Subjects who show clinical benefit at week 6 continue onto maintenance therapy and receive BI-1206 and rituximab once every 8 weeks for up to 6 maintenance cycles, or up to 1 year from first dose of BI-1206.

About BioInvent

BioInvent International AB (OMXS: BINV) is a clinical stage company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapies, with four programs in 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.

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This information is information that BioInvent International AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 7.45 a.m. CET, on 28 January, 2021.