

# BioInvent: The FDA grants Orphan Drug Designation to BI-1206 for the treatment of follicular lymphoma

- **Clinical data clearly suggest BI-1206 may restore the response to rituximab**

**Lund, Sweden – January 19, 2022 – 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 announces that its anti-FcγRIIB antibody BI-1206 has been granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA) for the treatment of follicular lymphoma (FL), the most common form of slow-growing Non-Hodgkin lymphoma.

The FDA's Office of Orphan Drug Products grants orphan status to support the development of medicines for rare disorders that affect fewer than 200,000 people in the U.S. ODD provides benefits, including market exclusivity upon regulatory approval, exemption of FDA biologic license application fee and tax credits for qualified clinical trials. BI-1206 previously received ODD from the FDA for the treatment of mantle cell lymphoma (MCL) in January 2019.

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 rituximab for the treatment of Non-Hodgkin lymphoma, which includes patients with FL, 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.

"The granting of orphan drug status for BI-1206 for follicular lymphoma is another important step forward in the development of our lead drug candidate. The clinical update we presented recently clearly suggests BI-1206 may restore the response to rituximab in patients who have few treatment alternatives, with the results in follicular lymphoma being particularly impressive. We are looking forward to continuing to progress this anti-FcγRIIB antibody through clinical development to meet the needs of this underserved patient population," said **Martin Welschof, CEO of BioInvent**.

## 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 1/2 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](http://www.bioinvent.com)

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**Attachments**

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