



## Lonza and BlueJay Therapeutics Announce Manufacturing Agreement for its Antibody BJT-778 Targeting Chronic HBV Infection

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- Lonza to provide a program tailored to BlueJay's needs to enable manufacturing of BJT-778
  - Collaboration to provide BlueJay access to cell line construction, process development, drug substance manufacturing, and drug product development and manufacturing
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**Basel, Switzerland, 17 November 2021** – BlueJay, a developer of innovative therapeutics for functional cures of chronic hepatitis B virus (HBV) infection, and Lonza, a global development and manufacturing partner to the pharma, biotech and nutrition industries, have entered a manufacturing agreement for BJT-778, one of BlueJay's lead candidates. This monoclonal antibody (mAb), targeting the HBV surface antigen (HBsAg), is currently under preclinical development for the restoration of patient's adaptive immunity and functional cure for chronic HBV infection.

Under the terms of the agreement, Lonza has tailored its Ibex® Design offering to manufacture cGMP material for BJT-778 for preclinical and clinical testing. The agreement will cover the early stages from gene to IND and provide cell line development, process and analytical development, and drug product (DP) manufacturing at Lonza's Visp, Basel and Stein (CH) sites. The expression of BJT-778 will be performed using a robust cell line constructed with the GS Xceed® Expression System and will utilize well-optimized process development and logistics workflows.

DP development of BJT-778 requires a highly concentrated protein formulation to allow for optimal potency, epitope, dosing frequency and safety of the final product while ensuring low injection volume. Lonza's experience in developing high-concentration formulations, together with a comprehensive analytical toolbox assessing the quality and safety of drug products, will allow BlueJay to bring their innovative treatment closer to the patient.

**Keting Chu, CEO, BlueJay Therapeutics, commented:** "Chronic HBV infection (CHBV) is a significant global healthcare issue. More than 850,000 people die a year from CHBV related liver diseases. The current standard of care (SOC) has a low cure rate, and innovative therapeutics are much needed. We believe BJT-778 has significant potential to achieve a high rate of functional cures in CHBV patients in combination with SOC. We were impressed by the professionalism, deep knowledge and experience of the Lonza team, particularly the timeline to enable IND submission at the end of 2022. We look forward to working with the Lonza team to develop BJT-778."



**Jeetendra Vaghjiani, Executive Director, Clinical Development & Strategic Marketing, Lonza, added:** "This collaboration signifies our commitment and flexibility in accommodating the specific and unique needs of emerging biotechs taking their lead candidate to clinic. Our team has extensive expertise to set up a customized formulation platform, proactively anticipate risks and suggest mitigation measures that will help move BlueJay's candidate from preclinical stages into the clinic."

### **About Lonza**

Lonza is the preferred global partner to the pharmaceutical, biotech and nutrition markets. We work to enable a healthier world by supporting our customers to deliver new and innovative medicines that help treat a wide range of diseases. We achieve this by combining technological insight with world-class manufacturing, scientific expertise and process excellence. Our unparalleled breadth of offerings enables our customers to commercialize their discoveries and innovations in the healthcare sector.

Founded in 1897 in the Swiss Alps, today, Lonza operates across five continents. With approximately 15,000 employees, we comprise high-performing teams and individual talent that make a meaningful difference to our own business, as well as to the communities in which we operate. The company generated sales of CHF 2.5 billion with a CORE EBITDA of CHF 847 million in H1 2021. Find out more at [www.lonza.com](http://www.lonza.com)

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### **About BlueJay Therapeutics**

Bluejay Therapeutics, Inc. is a Delaware company headquartered in the San Francisco Bay Area California. The mission of Bluejay is to develop innovative cures for infectious diseases with the first target indication for chronic HBV infections (CHBV). Bluejay licensed exclusively the global rights to three assets that target three different mechanisms of action for functional cures of CHBV. The strategy of Bluejay is to focus on the reduction of HBsAg in CHBV patients and to restore patient's adaptive immunity to achieve high rate of functional cures.

One lead assets, BJT-778, is a best-in-class anti-HBsAg monoclonal antibody with strong preclinical efficacy data in the clearance of HBsAg in the blood. The second lead asset, BJT-574, an oral small molecule HBV inhibitor, is also at IND-enabling stage with favorable pharmaceutical properties and compelling preclinical efficacy data in the clearance of HBsAg in HBV infected liver cells. For more information: [www.bluejaytx.com](http://www.bluejaytx.com)



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Certain matters discussed in this news release may constitute forward-looking statements. These statements are based on current expectations and estimates of Lonza Group Ltd, although Lonza Group Ltd can give no assurance that these expectations and estimates will be achieved. Investors are cautioned that all forward-looking statements involve risks and uncertainty and are qualified in their entirety. The actual results may differ materially in the future from the forward-looking statements included in this news release due to various factors. Furthermore, except as otherwise required by law, Lonza Group Ltd disclaims any intention or obligation to update the statements contained in this news release.