SystImmune and Bristol Myers Squibb announce a global strategic collaboration agreement for the development and commercialization of BL-B01D1.

**SystImmune and Bristol Myers Squibb to co-develop and co-commercialize BL-B01D1 in the United States; SystImmune to retain exclusive rights in Mainland China and Bristol Myers Squibb to gain an exclusive license in the rest of the world.**

**BL-B01D1 is a potentially first-in-class bispecific EGFRxHER3 ADC with potential to treat patients with lung and breast cancer, with opportunities to expand into additional tumor types.**

This collaboration combines SystImmune’s ADC expertise with Bristol Myers Squibb’s clinical development and oncology leadership to further advance the potential of BL-B01D1, and further diversifies Bristol Myers Squibb’s oncology portfolio and enhances the company’s presence in the ADC space.

REDMOND, WA & PRINCETON, N.J. – December 11, 2023—SystImmune, a clinical-stage biopharmaceutical company, and Bristol Myers Squibb (NYSE: BMY) today announced an exclusive license and collaboration agreement for SystImmune’s BL-B01D1, a potentially first-in-class EGFRxHER3 bispecific antibody-drug conjugate (ADC). Under the terms of the agreement, the companies will jointly develop and commercialize BL-B01D1 in the United States. Through its affiliates, SystImmune will be solely responsible for development, commercialization, and manufacturing in Mainland China and will be responsible for manufacturing certain drug supplies for use outside of Mainland China. Bristol Myers Squibb will assume sole responsibility for development and commercialization in the rest of the world.

BL-B01D1, a bispecific topoisomerase inhibitor-based ADC which targets both epidermal growth factor receptor and human epidermal growth factor receptor 3 (EGFRxHER3), is currently being evaluated in a global multi-center Phase 1 study (BL-B01D1-LUNG101) for safety and efficacy in individuals with metastatic or unresectable non-small cell lung cancer (NSCLC). Data from earlier clinical studies of BL-B01D1 were presented in 2023 at ASCO, ESMO and the San Antonio Breast Cancer Symposium; these data demonstrate promising anti-tumor activity in patients with a range of solid tumors that had progressed after standard of care treatments, including NSCLC and breast cancer.

“Recent BL-B01D1 trials have shown broad potential across different solid tumors as well as a manageable safety profile,” said Dr. Yi Zhu, Chief Executive Officer at SystImmune. “We have long admired Bristol Myers Squibb’s global clinical development and commercialization capabilities in oncology, and this strategic collaboration is an exciting step forward in delivering potential antitumor medicines to patients worldwide. We look forward to a productive partnership.”

“Our collaboration with SystImmune allows us to strengthen our leadership in oncology and is consistent with our strategy to diversify beyond immuno-oncology to transform patient care,” said Samit Hirawat, MD, Executive Vice President, Chief Medical Officer, Global Drug Development at Bristol Myers Squibb. “SystImmune’s BL-B01D1 adds yet another ADC to our diverse pipeline and helps strengthen our approach of matching the most appropriate therapeutic modality to areas of unmet medical need across solid tumor oncology. We look forward to working with SystImmune to advance BL-B01D1 in hopes of offering a differentiated treatment option for patients in need.”

Financial Highlights
Bristol Myers Squibb will pay SystImmune $800 million in an upfront payment and up to $500 million in contingent near-term payments. SystImmune is eligible to receive additional payments of up to $7.1 billion contingent upon the achievement of certain development, regulatory and sales performance milestones for a total potential consideration of up to $8.4 billion. The companies will share certain global development expenses and profits and losses in the United States. Through its affiliates, SystImmune will retain exclusive development and commercialization rights in Mainland China, where Bristol Myers Squibb will receive a royalty on net sales. Outside the United States and Mainland China, SystImmune will receive a tiered royalty on net sales. The agreement is subject to customary clearance by antitrust regulators.

About SystImmune’s BL-B01D1

BL-B01D1 is a potentially first-in-class bispecific ADC developed by SystImmune, targeting both EGFR and HER3, which are highly expressed in most epithelial tumors. BL-B01D1 is comprised of SystImmune’s proprietary bispecific antibody and linker-payload which contains a stable, cleavable linker and a topoisomerase inhibitor.

About SystImmune

SystImmune is a clinical-stage biopharmaceutical company located in Redmond, WA. SystImmune specializes in developing innovative cancer treatments using its established drug development platforms, focusing on bispecific, multi-specific antibodies, and ADCs. For more information visit systimmune.com.

About Bristol Myers Squibb

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol Myers Squibb, visit us at BMS.com or follow us on LinkedIn, Twitter, YouTube, Facebook and Instagram.

SystImmune Forward-Looking Statements

This press release contains forward looking statements regarding future events and our future results within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, and the Private Securities Litigation Reform Act of 1995, which reflects the expectations regarding the company’s goals, strategies, results of operations, performance, business prospects, and opportunities, including but not limited to any statements on the outcome, benefits and synergies of the collaboration, the performance of BL-B01D1. Terms such as “anticipates,” “believes,” “expects,” “estimates,” “could,” “intends,” “may,” “plans,” “potential,” “projects,” “will,” “would” and other similar expressions, or the negative of these terms, are generally indicative of forward-looking statements.

While SystImmune, Inc. believes that expectations expressed in the forward-looking statements are based on the company’s reasonable assumptions and beliefs in light of the information available to the company at the time such statements are made, it cannot give assurance that such forward-looking statements will prove to have been correct. Such forward-looking statements are not fact and are subject to significant uncertainties and other factors that could cause actual results to differ materially from such statements. Unless otherwise expressly noted herein, we undertake no obligation to update any forward-looking statements contained in this press release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.
Bristol Myers Squibb Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of pharmaceutical products described herein and the collaboration with SystImmune. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, that the expected benefits of, and opportunities related to, the collaboration with SystImmune may not be realized by Bristol Myers Squibb or may take longer to realize than anticipated, that the therapeutic potential of BL-B01D1 may change, that Bristol Myers Squibb may fail to discover and develop any commercially successful product candidates through the collaboration with SystImmune, that such product candidates may not receive regulatory approval for the indications described in this release and, if approved, whether such product candidates will be commercially successful.

No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Bristol Myers Squibb’s business and market, particularly those identified in the cautionary statement and risk factors discussion in Bristol Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2022, as updated by our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, Bristol Myers Squibb undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

Bristol Myers Squibb

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