

# BioCryst Announces Partnership With Torii Pharmaceutical to Commercialize BCX7353 in Japan for the Prevention of HAE Attacks

November 5, 2019

-Agreement includes up to \$42 million of upfront and potential milestone payments plus royalties on net sales-

#### -JNDA submission to PMDA on track for Q1 2020-

#### -Deal leverages Torii's proven track record to deliver innovative therapies to Japanese patients-

RESEARCH TRIANGLE PARK, N.C., Nov. 05, 2019 (GLOBE NEWSWIRE) -- <u>BioCryst Pharmaceuticals. Inc.</u> (Nasdaq:BCRX) today announced that it has licensed commercialization rights in Japan to Torii Pharmaceutical, Co. for BCX7353, an oral, once-daily treatment for the prevention of hereditary angioedema (HAE) attacks.

BioCryst will receive a \$22 million upfront payment and is eligible to receive up to an additional \$20 million upon achievement of certain milestones. In addition, BioCryst will receive tiered royalties ranging from the mid-teens to potentially 40 percent of Japanese net sales of BCX7353.

"We are excited to partner with Torii to accelerate access for Japanese patients to BCX7353," said Jon Stonehouse, president and chief executive officer of BioCryst. "Torii has a strong and recent history of significant commercial success as a Japanese partner, and the breadth of experience and infrastructure to build the prophylactic HAE market with BCX7353."

BioCryst received Orphan Drug and Sakigake designation for BCX7353 and plans to submit a Japanese New Drug application (JNDA) to the Pharmaceuticals and Medical Devices Agency (PMDA) in the first quarter of 2020.

"Given its clinical profile and the tremendous unmet need of HAE patients here in Japan, we are honored to add BCX7353 to our portfolio," said Goichi Matsuda, president of Torii. "We are well positioned to use our experience in building disease awareness, in driving patient identification, and our broad reach across the base of treaters, including dermatologists, allergists, and other specialists, to bring this important treatment to HAE patients."

"With no approved treatments in Japan for the prevention of HAE attacks, there is a significant unmet need today," said professor Beverley Yamamoto, president of the Japanese Hereditary Angioedema Patient Association. "A safe, effective oral prophylactic therapy would offer tremendous benefit to Japanese HAE patients and their families."

## About BioCryst Pharmaceuticals

BioCryst Pharmaceuticals discovers novel, oral small-molecule medicines that treat rare diseases in which significant unmet medical needs exist and an enzyme plays a key role in the biological pathway of the disease. BioCryst has several ongoing development programs including BCX7353, an oral treatment for hereditary angioedema, BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases, galidesivir, a potential treatment for Marburg virus disease and Yellow Fever, and BCX9250, an oral ALK-2 inhibitor for the treatment of fibrodysplasia ossificans progressiva. RAPIVAB® (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, is BioCryst's first approved product and has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan, Korea and the European Union. Post-marketing commitments for RAPIVAB are ongoing. For more information, please visit the Company's website at www.BioCryst.com.

### About Torii Pharmaceutical Co., Ltd.

The corporate mission of Torii Pharmaceutical Co., Ltd. is to contribute to the improvement of human health and to fulfill its responsibilities to customers, shareholders, society and employees, by supplying world-class pharmaceutical products. Torii Pharma focuses on Renal diseases, Hemodialysis, Allergy and Skin diseases as its therapeutic areas of importance. Torii is a member of Japan Tobacco Inc. (JT) group. Collaboration with JT takes the form of functional focus, with JT undertaking R&D on new compounds and Torii integrating manufacture and marketing. In addition to Torii's independent activities, Torii's partnership with JT includes in-licensing of high-quality pharmaceuticals. More details can be found on the corporate website https://www.torii.co.jp/ en/

# **Forward-Looking Statements**

This Press Release contains forward-looking statements, including statements regarding future results, performance or achievements. These statements involve known and unknown risks, uncertainties and other factors which may cause BioCryst's actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Factors that could cause actual results to differ materially from the forward-looking statements contained herein include, without limitation, the following: the results of our partnership with Torii may not meet our current expectations (including with respect to the receipt or amounts of potential milestone or royalty payments); competitor products may limit the commercial potential of BCX7353 in Japan and the amount of any related royalties we would be entitled to receive; there are risks related to our relying on the performance of our partner, particularly with respect to the conduct of commercialization activities in line with our current expectations; there are risks related to government actions, including that decisions and other actions relating to approval, pricing, and exclusivity of BCX7353 in Japan may not be taken when expected or at all, or that the outcomes of such decisions and other actions may not be in line with our current expectations; we rely on third-party contract manufacturing organizations to manufacture BCX7353 and any failure of such parties to meet their obligations may impair our ability to supply the required amounts of BCX7353 to our partner; there are inherent risks related to

commercializing drugs, including regulatory, manufacturing and supply risks; development activities for any indication may take longer or may be more expensive than planned; ongoing and future preclinical and clinical development of our HAE drug candidates (including for APeX-2, APeX-S and APeX-J) may not have positive results; we may not be able to enroll the required number of subjects in planned clinical trials; we may not advance human clinical trials as expected (including those for BCX7353); the FDA, EMA, PMDA or other applicable regulatory agency may require additional studies beyond the studies planned for product candidates (including BCX7353), or may not provide regulatory clearances, which could result in delays of planned clinical trials; and applicable regulatory bodies may impose a clinical hold with respect to, or withhold market approval for, product candidates (including BCX7353). Please refer to the documents the Company files periodically with the Securities and Exchange Commission, specifically our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, all of which identify important factors that could cause the actual results to differ materially from those contained in our projections and forward-looking statements.

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