

June 5, 2017

# **BioCryst Announces RAPIVAB® Pediatric sNDA Acceptance**

RESEARCH TRIANGLE PARK, N.C., June 05, 2017 (GLOBE NEWSWIRE) -- <u>BioCryst Pharmaceuticals</u>, <u>Inc.</u> (NASDAQ:BCRX) announced today that the U.S. Food and Drug Administration (FDA) has accepted for review the supplemental New Drug Application (sNDA) for a pediatric indication of RAPIVAB<sup>®</sup> (peramivir injection), which was submitted in March 2017. The sNDA has been classified by the FDA as a priority review and has a Prescription Drug User Fee Act (PDUFA) goal date for a decision by the end of September 2017.

"The acceptance of the pediatric sNDA by the FDA represents another important milestone for BioCryst and our partner, Seqirus," said Jon P. Stonehouse, President & Chief Executive Officer. "We are excited the FDA has granted a priority review with the possibility of making RAPIVAB available to treat pediatric patients in the next flu season."

RAPIVAB is being commercialized by Seqirus globally, excluding Japan, Taiwan, Korea and Israel. Seqirus is a leader in influenza prevention through the global supply of seasonal and pandemic influenza vaccines.

### About RAPIVAB (peramivir injection)

Approved by FDA in December 2014, RAPIVAB (peramivir injection) is an intravenous viral neuraminidase inhibitor for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days. Efficacy of RAPIVAB is based on clinical trials of naturally occurring influenza in which the predominant influenza infections were influenza A virus and a limited number of patients infected with influenza B virus. Visit <a href="http://www.rapivab.com">http://www.rapivab.com</a> to learn more.

#### **About BioCryst Pharmaceuticals**

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in rare diseases. BioCryst has several ongoing development programs: BCX7353 and other second generation oral inhibitors of plasma kallikrein for hereditary angioedema, and galidesivir, a broad spectrum viral RNA polymerase inhibitor that is a potential treatment for filoviruses. RAPIVAB<sup>®</sup> (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, Japan, Taiwan and Korea. Post-marketing commitment development activities for RAPIVAB are ongoing, as well as activities to support regulatory approvals in other territories. For more information, please visit the Company's website at <a href="https://www.bioCryst.com">www.bioCryst.com</a>.

#### **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 are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Some of the factors that could affect the forward-looking statements contained herein include: that developing any HAE drug candidate may take longer or may be more expensive than planned; that ongoing and future preclinical and clinical development of HAE second generation drug candidates (including APeX-1 and ZENITH-1) may not have positive results; that BioCryst may not be able to enroll the required number of subjects in planned clinical trials of product candidates; that the Company may not advance human clinical trials with product candidates as expected; that the FDA may require additional studies beyond the studies planned for product candidates, or may not provide regulatory clearances which may result in delay of planned clinical trials, or may impose a clinical hold with respect to such product candidate, or withhold market approval for product candidates (including approval for the pediatric indication of RAPIVAB); that BioCryst may not receive additional government funding to further support the development of galidesivir; that galidesivir development may not be successful; that BARDA and/or NIAID may further condition, reduce or eliminate future funding; that revenue from peramivir injection is unpredictable and may never result in significant revenue for the Company; that the Company may not be able to continue development of ongoing and future development programs; that such development programs may never result in future products; that actual financial results may not be consistent with expectations, including that 2017 operating expenses and cash usage may not be within management's expected ranges. Please refer to the documents BioCryst files periodically with the Securities and

Exchange Commission, specifically BioCryst's 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 BioCryst's projections and forward-looking statements.

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