September 21, 2017

BioCryst's RAPIVAB® (peramivir injection) Receives FDA Approval for a Pediatric Indication

RESEARCH TRIANGLE PARK, N.C., Sept. 21, 2017 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (NASDAQ:BCRX) a biotechnology company focused on the development and commercialization of treatments for rare and infectious diseases, announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental New Drug Application for RAPIVAB (peramivir injection), an intravenous (i.v.) neuraminidase inhibitor, extending its availability for the treatment of acute uncomplicated influenza to pediatric patients 2 years and older who have been symptomatic for no more than two days. The pediatric approval was based on the interim analysis of an ongoing pediatric clinical study. Those results will be presented at the upcoming ID Week 2017 meeting in San Diego.

"This approval represents the first new influenza antiviral for pediatric use in over 10 years," said Jon P. Stonehouse, President & Chief Executive Officer. "RAPIVAB provides another treatment option for pediatric patients with acute, uncomplicated influenza and represents another important milestone for BioCryst."

"RAPIVAB is a great addition to our armamentarium of antiviral agents to combat influenza," said John A. Vanchiere, MD, PhD, Chief, Section of Pediatric Infectious Diseases at LSU Health Sciences Center. "It will be especially helpful for patients who cannot tolerate oral medications. In addition, the long half-life allows for one-time dosing which will improve compliance."

About RAPIVAB (peramivir injection)

Approved by FDA in December 2014, RAPIVAB (peramivir injection) is an intravenous viral neuraminidase inhibitor approved for the treatment of acute uncomplicated influenza in patients 2 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 http://www.rapivab.com 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® (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 www.BioCryst.com.

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 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 or MAA 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; that the Company 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 that 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.

BCRXW

CONTACT: Thomas Staab, BioCryst Pharmaceuticals, +1-919-859-7910


Primary Logo

Source: BioCryst Pharmaceuticals