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BioCryst's RAPIVAB(TM) (peramivir injection) Receives FDA Approval for the Treatment of Acute Uncomplicated Influenza

RESEARCH TRIANGLE PARK, N.C., Dec. 22, 2014 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](#), (Nasdaq:BCRX) a pharmaceutical company focused on the development and commercialization of treatments for rare and infectious diseases, today announced that the [U.S. Food and Drug Administration](#) (FDA) has approved RAPIVAB (peramivir injection), an intravenous (i.v.) 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.

"RAPIVAB is the first neuraminidase inhibitor that has shown to be safe and effective as a single-dose, i.v. therapy for patients with acute, uncomplicated influenza, and represents the first new antiviral treatment for influenza approved by the FDA in 15 years," said [Richard Whitley, M.D.](#), University of Alabama at Birmingham. "In a blinded, randomized placebo-controlled trial, a single dose of RAPIVAB alleviated flu symptoms, and reduced fever significantly faster than placebo."

"The approval of RAPIVAB provides a new choice to immediately deliver an effective treatment in one dose to adult patients with influenza," said [Jon P. Stonehouse, President & Chief Executive Officer](#) of BioCryst. "This is the first U.S. approval of a BioCryst discovered drug and represents an important milestone for our company. We thank our funding partner [BARDA/HHS](#); the development and approval of RAPIVAB is an excellent example of a successful public/private partnership."

About RAPIVAB (peramivir injection)

RAPIVAB's approval was supported by data from over 2,700 subjects treated with peramivir in 27 clinical trials. In January 2010, Shionogi & Co., Ltd. launched intravenous peramivir in Japan under the name RAPIACTA[®] and in August 2010, Green Cross Corporation announced that it had received marketing and manufacturing authorization for i.v. peramivir in Korea under the name PeramiFlu[®]. It is estimated that more than one million patients have received peramivir treatment to date. The recommended dose of RAPIVAB, in most adult patients 18 years of age or older with acute uncomplicated influenza, is a single 600 mg dose administered via intravenous infusion for 15 to 30 minutes. RAPIVAB was developed under contract number HHSO10020070032C from the Biomedical Advanced Research and Development Authority (BARDA/HHS), a \$234.8 million contract.

INDICATION & IMPORTANT SAFETY INFORMATION

Indication

RAPIVAB is indicated for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than two days.

Contraindications

None

Warnings and Precautions

Rare cases of serious skin reactions, including Stevens-Johnson syndrome and erythema multiforme have occurred with RAPIVAB.

Patients with influenza may be at an increased risk of hallucinations, delirium and abnormal behavior early in their illness. There have been post-marketing reports (from Japan) of delirium and abnormal behavior leading to injury in patients with influenza who were receiving neuraminidase inhibitors, including RAPIVAB. Because these events were reported voluntarily during clinical practice, estimates of frequency cannot be made, but they appear to be uncommon.

Serious bacterial infections may begin with influenza-like symptoms or may coexist with or occur as complications during the course of influenza. RAPIVAB has not been shown to prevent such complications.

Adverse Reactions

The most common adverse reaction (incidence > 2%) is diarrhea (8% RAPIVAB vs. 7% placebo).

Lab abnormalities (incidence > 2%) occurring more commonly than placebo were elevated ALT 2.5 times the upper limit of normal (3% vs. 2%), elevated serum glucose greater than 160 mg/dL (5% vs. 3%), elevated CPK more than 6 times the upper limit of normal (4% vs. 2%) and neutrophils less than $1.0 \times 10^9/L$ (8% vs. 6%).

About BioCryst

BioCryst Pharmaceuticals designs, optimizes and develops novel small molecule drugs that block key enzymes involved in rare diseases. BioCryst currently has several ongoing development programs: oral inhibitors of plasma kallikrein for hereditary angioedema, including [BCX4161](#) and several second generation compounds; and [BCX4430](#), a broad spectrum viral RNA polymerase inhibitor. 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 our 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. Some of the factors that could affect the forward-looking statements contained herein include: that the FDA may not approve peramivir for use in pediatric patients, or that FDA approval for pediatric use may be limited; demand for RAPIVAB in this flu season is unpredictable; the supply of RAPIVAB may be limited; the Company may not be able to successfully commercialize RAPIVAB; and that RAPIVAB may never be purchased by any government entity for stockpiling. 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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