BioCryst Announces FDA Approval of Supplemental New Drug Application for RAPIVAB® Expanding Patient Population to Include Children Six Months and Older

February 3, 2021

RESEARCH TRIANGLE PARK, N.C., Feb. 03, 2021 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental new drug application for RAPIVAB® (peramivir injection) expanding the patient population of RAPIVAB for the treatment of acute uncomplicated influenza to include patients six months and older who have been symptomatic for no more than two days. Prior to this approval, RAPIVAB had been indicated for patients two years and older.

"Influenza can have serious and deadly consequences and we are very pleased that the FDA has extended the approved indication for RAPIVAB to include patients as young as six months. These patients can be among those at greatest risk for severe outcomes and RAPIVAB is an important antiviral with proven benefits," said Dr. William Sheridan, chief medical officer of BioCryst.

About RAPIVAB® (peramivir injection)
RAPIVAB (peramivir injection) is approved in the United States for the treatment of acute uncomplicated influenza in patients six months and older who have been symptomatic for no more than two days. It is administered via an intravenous infusion for a minimum of 15 minutes at recommended doses of 600 mg/kg for adults and adolescents and 12 mg/kg for pediatric patients ages six months to 12 years. 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.

U.S. Indication and Important Safety Information

Indication

RAPIVAB is indicated for the treatment of acute uncomplicated influenza in patients 6 months and older who have been symptomatic for no more than 2 days.

Limitations of Use

- Efficacy of RAPIVAB is based on clinical trials of naturally occurring influenza in which the predominant influenza infections were influenza A virus; a limited number of subjects infected with influenza B virus were enrolled.
- Influenza viruses change over time. Emergence of resistance substitutions could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use RAPIVAB.
- The efficacy of RAPIVAB could not be established in patients with serious influenza requiring hospitalization.

Contraindications

RAPIVAB is contraindicated in patients with known serious hypersensitivity or anaphylaxis to peramivir or any component of the product. Severe allergic reactions have included anaphylaxis, erythema multiforme and Stevens-Johnson Syndrome.

Warnings and Precautions

- Cases of anaphylaxis and serious skin/hypersensitivity reactions such as Stevens-Johnson syndrome and erythema multiforme have occurred with RAPIVAB. Discontinue RAPIVAB and initiate appropriate treatment if anaphylaxis or serious skin reaction occurs or is suspected.
- Neuropsychiatric events: Patients with influenza may be at an increased risk of hallucinations, delirium and abnormal behavior early in their illness. Monitor for signs of abnormal behavior.
- 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 in adults (18 years of age and older) was diarrhea (8% RAPIVAB vs 7% placebo). Lab abnormalities (incidence ≥2%) occurring more commonly with RAPIVAB than placebo were elevated ALT > 2.5 times the upper limit of normal (3% vs 2%), elevated serum glucose >160 mg/dL (5% vs 3%), elevated CPK at least 6 times the upper limit of normal (4% vs 2%), and neutrophils <1.0 x 10^9/L (8% vs 6%). In a subset of subjects with serious influenza requiring hospitalization treated with RAPIVAB 600 mg as monotherapy (N=101), the following adverse reactions were also reported more frequently with RAPIVAB as compared to placebo: constipation (4% versus 2%), insomnia (3% versus 0%), AST increased (3% versus 2%), and hypertension (2% versus 0%).

The safety profile of RAPIVAB in subjects 6 months to 17 years of age was generally similar to that observed in adults. The only adverse reaction

reported in pediatric subjects treated with RAPIVAB (occurring in ≥2% of subjects) and not reported in adults was vomiting (3% versus 9% for oseltamivir). The only clinically significant laboratory abnormality (DAIDS Grade 2) occurring in ≥2% of pediatric subjects treated with RAPIVAB (and not previously reported in adults) was proteinuria by dipstick analysis (3% versus 0% for oseltamivir).

Concurrent Use With Live Attenuated Influenza Vaccine

Antiviral drugs may inhibit viral replication of a live attenuated influenza vaccine (LAIV) and thus may reduce vaccine efficacy. The concurrent use of RAPIVAB with LAIV intranasal has not been evaluated. Avoid use of LAIV within 2 weeks before or 48 hours after administration of RAPIVAB, unless medically indicated.

Please see full prescribing information for RAPIVAB.

You are encouraged to report negative side effects of prescription drugs to the FDA. To report suspected adverse reactions, contact BioCryst Pharmaceuticals at 1-833-633-2279 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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. Oral, once-daily ORLADEYO™ (berotralstat) is approved in the United States and Japan for the prevention of HAE attacks in adults and pediatric patients 12 years and older, and under regulatory review for approval in the European Union. BioCryst has several ongoing development programs including BCX9930, an oral Factor D inhibitor for the treatment of complement-mediated diseases, BCX9250, an ALK-2 inhibitor for the treatment of fibrodysplasia ossificans progressiva, and galidesivir, a potential treatment for Marburg virus disease and Yellow Fever. RAPIVAB® (peramivir injection), a viral neuraminidase inhibitor for the treatment of influenza, has received regulatory approval in the U.S., Canada, Australia, Japan, Taiwan and Korea. Post-marketing commitments for RAPIVAB are ongoing. 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 BioCryst's expectations for RAPIVAB. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to be materially different from those 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: the ongoing COVID-19 pandemic, which could create challenges in all aspects of BioCryst's business, including without limitation delays, stoppages, difficulties and increased expenses with respect to BioCryst's and its partners' development, regulatory processes and supply chains, negatively impact BioCryst's ability to access the capital or credit markets to finance its operations, or have the effect of heightening many of the risks described below or in the documents BioCryst files periodically with the Securities and Exchange Commission; risks related to the commercial success of RAPIVAB, including for the new indication; the FDA or other applicable regulatory agency may require additional studies beyond the studies planned for product candidates, including to support the continued commercialization of approved products, may not provide regulatory clearances which may result in delay of planned clinical trials, may impose certain restrictions, warnings, or other requirements on products and product candidates, may impose a clinical hold with respect to such products and product candidates, or may withhold or withdraw market approval for such products and product candidates; BioCryst's ability to successfully manage its growth and compete effectively; risks related to the international expansion of BioCryst's business; and actual financial results may not be consistent with expectations, including that 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 forward-looking statements.

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