U.S. Government Exercises Option to Purchase Additional RAPIVAB® (peramivir injection) from BioCryst for Pandemic Influenza Preparedness

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RESEARCH TRIANGLE PARK, N.C., Aug. 25, 2022 (GLOBE NEWSWIRE) -- BioCryst Pharmaceuticals, Inc. (Nasdaq: BCRX) today announced that the U.S. Department of Health and Human Services (HHS) has exercised its option to purchase an additional 10,000 doses of BioCryst's antiviral influenza therapy, RAPIVAB® (peramivir injection), for approximately $7 million.

The RAPIVAB purchase by the HHS Administration for Strategic Preparedness and Response will strengthen the nation's preparedness to respond to a potential pandemic influenza event.

The order is the final of five purchase options from a $34.7 million contract (Contract No. 75D301-18-C-02984) the Centers for Disease Control and Prevention awarded in 2018 for the procurement of up to 50,000 doses of RAPIVAB over a five-year period. With the fulfillment of this new order, BioCryst will have delivered all 50,000 doses to HHS under the contract.

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 multiple global markets. 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) is approved in the U.S. and multiple global markets, with post-marketing commitments 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 sales of RAPIVAB. These statements involve known and unknown risks, uncertainties and other factors which may cause BioCryst's actual results 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: BioCryst relies on third-party manufacturers to manufacture RAPIVAB in a timely manner and in accordance with applicable governmental regulations, and any failure of such third-party manufacturers to perform their obligations could impact BioCryst's ability to supply RAPIVAB pursuant to its government procurement contract; government contracts contain certain terms and conditions that subject BioCryst to additional risks; and 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' supply chains, negatively impact BioCryst's ability to access the capital or credit markets to finance its operations, or have the effect of heightening the other risks described herein or in the documents BioCryst files periodically with the Securities and Exchange Commission. 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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