



October 4, 2017

## BioCryst Announces RAPIVAB® (peramivir injection) and Galidesivir Presentations at IDWeek 2017™

RESEARCH TRIANGLE PARK, N.C., Oct. 04, 2017 (GLOBE NEWSWIRE) -- [BioCryst Pharmaceuticals, Inc.](http://www.biocryst.com) (NASDAQ:BCRX) announced today that interim results from a clinical trial of a single IV dose of RAPIVAB® (peramivir injection) for the treatment of pediatric influenza and results from preclinical studies of galidesivir (BCX4430) in Rhesus macaques models of Zika virus (ZIKV) infection and Ebola virus (EBOV) infection will be presented at **IDWeek 2017™**, taking place in San Diego, October 4-8, 2017.

Results from a pediatric clinical trial of RAPIVAB® (peramivir injection) (BCX1812-305) will be presented in two poster sessions. This open label trial evaluated the safety and effectiveness of a single dose administration of IV RAPIVAB® (peramivir injection) versus oral oseltamivir for 5 days in a U.S. population of pediatric subjects with acute uncomplicated influenza. To date, the trial enrolled 122 subjects between the ages of 0 to 18 years with acute uncomplicated influenza and symptom onset within 48 hours. Subjects were randomized in a 4:1 ratio peramivir: oseltamivir, stratified by age group. Peramivir was dosed by age group, with 600 mg for age 13 years and older, 12 mg/kg for ages 6 months through < 13 years, and 8 mg/kg for birth through < 6 months. Of the 92 peramivir treated subjects, no serious adverse events or adverse events leading to discontinuation of study drug were reported. Treatment-emergent adverse events possibly, probably or definitely related to study drug were reported in 9% of peramivir treated subjects vs 17% of oseltamivir treated subjects. Peramivir drug levels were consistent with those seen in adults at the approved 600 mg adult dose, as was the time to alleviation of influenza symptoms. A trend was observed suggesting more rapid reduction in virus shedding for peramivir treated subjects compared to oseltamivir with 50% of the peramivir treated subjects vs 77% oseltamivir treated subjects with positive viral titers at Day 3. Treatment with a single dose of IV peramivir was not associated with development of resistance to the drug in this population. The trial is continuing to enroll additional subjects below the age of 2 years.

Results from four nonclinical studies of galidesivir in Zika virus disease models in Rhesus macaques will be presented in an oral abstract session. A total of 74 Rhesus macaques infected with a Puerto Rican ZIKV isolate by various routes were studied, 55 treated with galidesivir and 19 with vehicle. Galidesivir intramuscular (I.M.) was started at different times relative to virus challenge in different treatment groups - from 90 minutes to 72 hours after subcutaneous (SC) ZIKV challenge, and up to 5 days after intravaginal (IVAG) challenge. Efficacy of galidesivir was evaluated over a range of loading and maintenance doses; the highest consisted of a one-day loading dose of 100mg/kg twice a day (BID) followed by a maintenance dose of 25mg/kg BID for nine days. Outcome measures included virology - ZIKV RNA levels in plasma, urine, saliva, and cerebrospinal fluid (CSF) - galidesivir pharmacokinetics, cellular and humoral immunologic markers, complete blood counts, and clinical chemistries.

All vehicle-treated control, animals developed high levels of Zika virus in the blood plasma (viremia), and had readily detectable ZIKV RNA in CSF, saliva and urine post-infection. In contrast, all animals treated with galidesivir in the first 24 hours after SC ZIKV challenge did not develop viremia, and were either negative for or had significantly reduced ZIKV RNA in bodily fluids. Animals treated with galidesivir later (up to 72 hours post infection) were partially protected - they had detectable plasma ZIKV RNA, but the onset of viremia was delayed, and its magnitude was significantly reduced compared to controls. Animals infected via the IVAG route were protected by galidesivir treatment when dosing was delayed as late as 5 days after infection, with no viremia and significant reductions in ZIKV RNA in the CSF compared with controls. Galidesivir was well-tolerated and offered significant protection against ZIKV challenge. These results warrant further study.

Results from a recent nonclinical study of galidesivir in an Ebola virus disease model in Rhesus macaques will be presented in a poster session. The goals of this 28-day study were to assess the effect of different dosing regimens of galidesivir I.M. on survival in the setting of established Ebola virus disease. The study included three treatment groups (n=6 each) treated with different galidesivir dosing schedules and one vehicle control group of six animals. Following inoculation of virus on Day 0, six of 6 (100%) animals survived after receiving 100 mg/kg BCX4430 twice on day 2, followed by 25 mg/kg twice daily for an additional nine days, compared to none of 6 controls ( $p < 0.001$ ). Animals treated with the same loading and maintenance dose regimen of BCX4430, but starting on day 3, also showed improved survival (4 of 6, 67%,  $p = 0.005$ ), as did animals treated with 25 mg/kg of galidesivir twice daily for 14 days starting on day 2 (4 of 6, 67%,  $p = 0.005$ ).

Presentation schedule:

**Title:** Single Dose IV Peramivir is Safe and Effective in the Treatment of Pediatric Influenza

**Session Title:** Pediatric Virology

**Poster Number:** 2335

**Session Date:** Saturday, October 7, 2017

**Session Time:** 12:30 PM - 2:00 p.m. Pacific Time

**Presenting author:** John Vanchiere MD, PhD, LSU Health Sciences Center, Shreveport, LA

**Title:** Single Dose IV Peramivir Treatment in Pediatric Influenza: Lack of Development of Influenza Virus Variants with Reduced Susceptibility to Peramivir

**Session Title:** Viral Treatment and Prevention

**Poster Number:** 1657

**Session Date:** Friday, October 6, 2017

**Session Time:** 12:30 PM - 2:00 p.m. Pacific Time

**Presenting author:** Marie-Ève Hamelin PhD, Centre de Recherche en Infectiologie du CHUL, Laval University, Québec, Canada

**Title:** Galidesivir, a direct-acting antiviral drug, abrogates viremia in Rhesus macaques challenged with Zika virus

**Session Title:** Zika A- Z

**Oral Abstract Session:** 1781

**Session Date:** Saturday, October 7, 2017

**Session Time:** 8:30 a.m. Pacific Time

**Presenting author:** James B. Whitney, PhD, Assistant Professor of Medicine, Harvard Medical School, Principal Investigator in the Center for Virology and Vaccine Research at Beth Israel Deaconess Medical Center in Boston, and an Associate Member of The Ragon Institute of MGH, MIT and Harvard.

**Title:** Efficacy of Galidesivir against Ebola Virus Disease in Rhesus Monkeys

**Session Title:** Zika Virus

**Poster Number:** 843

**Session Date:** Thursday, October 5, 2017

**Session Time:** 12:30 PM - 2:00 p.m. Pacific Time

**Presenting Author:** Travis Warren, PhD, USAMRID, Fort Detrick, MD

#### **About IDWeek 2017™**

IDWeek 2017™ is an annual meeting of the Infectious Diseases Society of America (IDSA), the Society for Healthcare Epidemiology of America (SHEA), the HIV Medicine Association (HIVMA) and the Pediatric Infectious Diseases Society (PIDS). With the theme "Advancing Science, Improving Care," IDWeek features the latest science and bench-to-bedside approaches in prevention, diagnosis, treatment, and epidemiology of infectious diseases, including HIV, across the lifespan. IDWeek 2017 takes place October 4-8 at the San Diego Convention Center in San Diego. For more information, visit [www.idweek.org](http://www.idweek.org).

#### **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 [www.rapivab.com](http://www.rapivab.com) to learn more

#### **About Galidesivir (BCX4430)**

Galidesivir is a broad spectrum antiviral in advanced development under the Animal Rule for the treatment of Ebola virus disease. A Phase 1 clinical safety and pharmacokinetics study in healthy subjects has been completed, and in animal studies, galidesivir has demonstrated survival benefits against a variety of serious pathogens, including Ebola, Marburg, Yellow Fever and Zika viruses. Galidesivir has also demonstrated broad-spectrum activity in vitro against more than 20 RNA viruses in nine different families, including filoviruses, togaviruses, bunyaviruses, arenaviruses, paramyxoviruses, coronaviruses and flaviviruses. BioCryst is developing galidesivir in collaboration with U.S. Government Agencies and other institutions.

#### **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](http://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.

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