



ViroPharma Announces Positive CHMP Opinion for Buccolam® (Midazolam, Oromucosal Solution) in the European Union

EXTON, Pa., June 24, 2011 /PRNewswire/ -- ViroPharma Incorporated (Nasdaq: VPHM) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending approval of a Pediatric Use Marketing Authorization (PUMA) for Buccolam® (midazolam, oromucosal solution), for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from 3 months to less than 18 years. If approved by the European Commission, Buccolam would be the first product approved through the centralized PUMA procedure.

Buccolam is oral midazolam provided in a pre-measured, age-specific dose formulation for convenient buccal (i.e. via the cavity between the cheek and gum line) delivery. Buccal midazolam has been shown in four clinical studies to be either comparable or superior in both its effectiveness and speed of onset of action to the current standard treatment, rectally-administered diazepam, for terminating pediatric convulsive epileptic seizures.

"The potential approval of Buccolam would address a major challenge for physicians currently prescribing rectally-administered diazepam for acute seizures, namely that it can be difficult to use and may be socially unacceptable in the community," said Professor Ian Wong, Director of the Centre for Paediatric Pharmacy Research at the School of Pharmacy, University of London. "Midazolam is recommended for treating prolonged acute convulsive seizures according to published treatment guidelines in European countries, and the availability of Buccolam — an oromucosal formulation of midazolam — would be an important, convenient and welcomed alternative to treat seizures in pediatric and adolescent patients."

The CHMP is responsible for issuing the EMA's scientific evaluation and opinions on all Marketing Authorization Applications (MAAs) for medicines for human use. Their positive opinion forms the scientific basis for the European Commission to issue a binding decision for an MAA or a PUMA, a centralized marketing authorization which is valid throughout all the Member States of the European Union (EU) as well as in the European Economic Area (EEA), namely Norway, Iceland and Liechtenstein. The anticipated timeframe for the European Commission decision is by the fourth quarter of 2011. A summary of the CHMP opinion will be available here: <http://tinyurl.com/2am4ubc>. Please select "B" to access the Buccolam summary opinion.

"This positive CHMP opinion - the first for a product seeking centralized authorization through a PUMA - is a great step towards the European marketing authorization for Buccolam, a product that addresses significant unmet need for families and caregivers — namely the quick and effective termination of prolonged, acute convulsive seizures in children and adolescents," commented Thierry Darcis, M.D., ViroPharma's vice president, general manager, Europe. "We will work closely with physicians across Europe on improving the seizure treatment paradigm, and bringing this much-needed emergency medication to market as soon as possible this year."

A Pediatric Use Marketing Authorization (PUMA) is a new type of centralized marketing authorization procedure for medicines that are developed specifically for children and may already be authorized for other indications or routes of administration in adults but are not patented. These medicines benefit from 10 years of market protection as an incentive. In August 2010, the EMA's Pediatric Committee (PDCO) confirmed that the required Pediatric Investigation Plan (PIP) for Buccolam had been fully completed.

About Buccolam® (Midazolam, Oromucosal Solution)

Buccolam is oral midazolam provided in a unique individual dose formulation for buccal delivery. It is provided as a convenient, portable, ready to use, pre-filled, age-specific dose to treat prolonged acute convulsive epileptic seizures in children, for use in the community. Buccolam is fixed-dose, banded by age, to provide approximately 0.25 to 0.5 mg/kg, based upon the pivotal clinical studies and recommended by the British National Formulary for Children (BNFC). The company is seeking approval through a PUMA which was submitted to the EMA in 2010. ViroPharma is pursuing marketing authorization in the EU for Buccolam for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents, from three months to less than 18 years.

The CHMP is also recommending that Buccolam should only be used in by patients/carers where the patient has been diagnosed to have epilepsy. For infants between 3-6 months of age, treatment should be in a hospital setting where monitoring is possible and resuscitation equipment is available.

About Non-Epileptic and Epileptic Seizures

Seizures occur because of sudden and abnormal electrical activity in the brain. There are many causes of seizures affecting pediatric patients other than epilepsy, including medicines, head injuries, certain diseases, and high fevers (called 'febrile seizures'). Febrile seizures are the most common type of seizure in children; approximately one in every 25 children will have at least one febrile seizure, and more than one-third of these children will have additional febrile seizures before they outgrow the tendency to have them. Epilepsy is among the most common childhood neurological disorders in developed countries, affecting nearly one percent of the population. There are over four million people affected by epilepsy in Europe; and nearly one million European children and adolescents have active epilepsy. Epilepsy commonly causes physical manifestations including muscle destruction and degradation of renal function, and numerous negative cognitive, behavioral and neurological effects. Seizures can last from a few seconds to several minutes or longer in some cases and can have many symptoms that are not always recognized as seizures by the person experiencing them or by health care professionals: blank staring, lip smacking, or jerking movements of arms and legs.

About ViroPharma Incorporated

ViroPharma Incorporated is an international biopharmaceutical company committed to developing and commercializing novel solutions for physician specialists to address unmet medical needs of patients living with diseases that have few if any clinical therapeutic options, including C1 esterase inhibitor deficiency, pediatric epilepsy and *C. difficile* infection (CDI). Our goal is to provide rewarding careers to employees, to create new standards of care in the way serious diseases are treated, and to build international partnerships with the patients, advocates, and health care professionals we serve. ViroPharma's commercial products address diseases including hereditary angioedema (HAE) and CDI; for full U.S. prescribing information on our products, please download the package inserts at <http://www.viopharma.com/Products.aspx>; the prescribing information for other countries can be found at www.viopharma.com.

ViroPharma routinely posts information, including press releases, which may be important to investors in the investor relations and media sections of our company's website, <http://www.viopharma.com/>. The company encourages investors to consult these sections for more information on ViroPharma and our business.

Forward Looking Statements

Certain statements in this press release contain forward-looking statements that involve a number of risks and uncertainties. Forward-looking statements provide our current expectations or forecasts of future events, including our regulatory filings in Europe related to Buccolam, including without limitation statements related to potential regulatory timelines, the likelihood of regulatory success and the scope of indications for which Buccolam may be approved. The EC may view the data regarding the use of Buccolam for treatment of prolonged, acute, convulsive seizures in infants, toddlers, children and adolescents (from 3 months to less than 18 years) submitted in the PUMA as insufficient or inconclusive, request additional data, require additional clinical studies, delay any decision past the time frames anticipated by us, limit any approved indications, deny the approval of Buccolam. These factors, and other factors, including, but not limited to those described in our annual report on Form 10-K for the year ended December 31, 2010 and 10-Q for the quarter ended March 31, 2011 filed with the Securities and Exchange Commission, could cause future results to differ materially from the expectations expressed in this press release. The forward-looking statements contained in this press release are made as of the date hereof and may become outdated over time. ViroPharma does not assume any responsibility for updating any forward-looking statements. These forward looking statements should not be relied upon as representing our assessments as of any date subsequent to the date of this press release.

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