



ViroPharma Announces Presentation of Data from Non-Toxigenic *Clostridium difficile* (VP20621) Phase 1 Study

New Data Validating VP20621 Clinical Proof of Concept Presented at the 50th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) -

EXTON, Pa., Sept 15, 2010 /PRNewswire via COMTEX/ -- ViroPharma Incorporated (Nasdaq: VPHM) today announced the presentation of data from its Phase 1 study of VP20621 (non-toxigenic *Clostridium difficile*), a novel treatment approach for preventing recurrent *Clostridium difficile* infections (CDI), a common and dangerous gastrointestinal infection typically occurring in older adults after use of antibiotic medications. VP20621 contains the spores of a naturally occurring non-toxin producing strain of *C. difficile*.

The poster entitled 'Phase 1 Evaluation of an Oral Suspension of VP 20621, Spores of a Non-Toxigenic *C. difficile* Strain (NTCD), in Healthy Older Subjects Pretreated With Oral Vancomycin' is being presented today at the 50th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in poster session F1-2127b by Stephen Villano, M.D., ViroPharma's vice president of clinical research and development.

The Phase 1 study was designed to determine the safety and tolerability of VP20621 dosed orally as single and repeat escalating doses in healthy young (18 to 45 years of age) and older (60 years of age and older) adults. Because VP20621 was shown to be well tolerated following single and repeat doses in younger and older healthy subjects, the company also performed repeat dosing in older adults following exposure to oral antibiotic. The new data presented today was from healthy subjects above 60 years of age who were pre-dosed with oral vancomycin to disrupt their gastrointestinal flora and render them potentially susceptible to *C. difficile* colonization. Subjects were subsequently given either placebo or VP20621 doses of 10 (4), 10(6), or 10(8) spores (once daily for 14 days). Conclusions from the study include:

- Multiple doses of VP20621 were generally well tolerated at all dose levels; there were no serious or severe adverse events, and no discontinuations from study drug due to adverse events.
- All 27 volunteers (100 percent) who were given VP20621 had positive non-toxigenic *C. difficile* stool cultures by day 6, suggesting that VP20621 rapidly colonizes the susceptible GI tract.
- No patient dosed with VP20621 tested positive for toxin-producing strains of *C. difficile* during the 28-day study period.
- By comparison, 5 of 9 subjects (56 percent) who received placebo (i.e. did not receive VP20621) tested positive for either toxin-negative or toxin-positive *C. difficile* during the study period.

"I am highly encouraged by the data from this Phase 1 study of VP20621, which for the first time support the tolerability and colonization effectiveness of non-toxigenic *C. difficile*, mimicking what we have inferred from observing colonization of patients with these organisms," commented Dale Gerding, M.D., Associate Chief of Staff for Research at the Hines VA Hospital. "Colonization protection of VP20621 awaits demonstration in a Phase 2 clinical trial in CDI patients to confirm pre-clinical data and observational studies of natural colonization in humans that have demonstrated high levels of protection against CDI that approach 100%."

"Previous animal and clinical observational studies have described the prevention of symptomatic CDI by colonization of the large bowel with non-toxin producing strains of *C. difficile*," commented Dr. Colin Broom, ViroPharma's chief scientific officer. "We now know that VP20621 appears to behave similarly, rapidly colonizing the large bowel and potentially protecting it from colonization with dangerous toxin-producing strains of *C. difficile*. We are excited by these positive data and expect to move rapidly into Phase 2 studies with VP20621 in the coming months. Our goal with VP20621 is to provide a novel, non antibiotic therapy to protect patients from colonization by virulent toxin producing bacteria until their normal, protective GI flora returns, thereby significantly reducing the incidence of recurrent disease for patients with CDI."

About VP20621

Antibiotics including those used to treat acute *C. difficile* infection (CDI) disrupt the normal gastrointestinal flora which renders individuals susceptible to *C. difficile* colonization. Orally-dosed liquid VP20621 utilizes non-toxigenic spore-based technology as a potential means of recolonization and protection. The goal of VP20621 dosing following antibiotic exposure is to colonize with this non-toxigenic strain of *C. difficile* and to prevent colonization by toxigenic strains, thereby preventing disease. VP20621 may have therapeutic utility in the prevention of recurrence following treatment of acute CDI and in the primary prevention of

CDI. The most common side effects observed following multiple doses of VP20621 were mild loose or watery stools on a single study day that resolved despite continued dosing, mild burning sensation on the tongue, and mild dyspepsia.

About Vancocin® (vancomycin hydrochloride capsules, USP)

Vancocin® Capsules (vancomycin hydrochloride capsules, USP) is the only antibiotic approved to treat two significant bacterial infections of the lower digestive tract. It may be administered orally for treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains) and antibiotic-associated pseudomembranous colitis caused by [Clostridium difficile](#). Vancocin Capsules are contraindicated in patients with known hypersensitivity to vancomycin.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Vancocin Capsules and other antibacterial drugs, Vancocin Capsules should only be used to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Adverse events include nephrotoxicity, ototoxicity, reversible neutropenia and "Red Man's Syndrome." Infrequently, allergic reactions have been reported. Clinically significant serum concentrations have been reported in some patients treated with Vancocin Capsules for pseudomembranous colitis caused by *C. difficile*. It is noteworthy that total systemic and renal clearance of vancomycin are reduced in the elderly. Monitoring of serum concentrations may be appropriate in patients with renal insufficiency and/or colitis.

About Clostridium difficile

One of the most serious problems facing the U.S. healthcare system today is hospital-acquired infections (HAIs) and *Clostridium difficile* infection is one of the most common and devastating HAIs. The incidence of *C. difficile* observed in U.S. healthcare facilities more than doubled approximately every five years since 1999 and the reported mortality rates from *C. difficile* in the U.S. have more than quadrupled in the last decade to 23.7 per million. Elderly patients exposed to antibiotics, long-term care patients, or those who have a serious underlying illness are at greatest risk to contract the disease. Patients with this disease have GI tract conditions that are significantly different from those of a healthy individual due to infection. Typical symptoms include diarrhea (which can be severe), fever, nausea, abdominal pain, and dehydration, though cases can lead to life-threatening complications such as megacolon, peritonitis and perforation of the colon.

About ViroPharma Incorporated

ViroPharma Incorporated is a biopharmaceutical company dedicated to the development and commercialization of products that address serious diseases treated by physician specialists and in hospital settings. ViroPharma commercializes Vancocin®, approved for oral administration for treatment of antibiotic-associated pseudomembranous colitis caused by *Clostridium difficile* and enterocolitis caused by *Staphylococcus aureus*, including methicillin-resistant strains. ViroPharma commercializes Cinryze™ (C1 esterase inhibitor [human]) for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema (HAE), also known as C1 inhibitor deficiency (for prescribing information on ViroPharma's commercial products, please download the package inserts at <http://www.viopharma.com/Products.aspx>). ViroPharma currently focuses its drug development activities in diseases including cytomegalovirus (CMV), HAE, and *C. difficile*.

ViroPharma routinely posts information, including press releases, which may be important to investors in the investor relations and media sections of our company's web site, <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 the Company's current expectations or forecasts of future events. Forward-looking statements in this press release include statements regarding the timing and nature of ViroPharma's clinical development programs, including statements that VP20621 may potentially protect a patient from colonization with toxin-producing strains of *C. difficile* and VP20621 may significantly reduce the incidence of recurrent disease for patients with CDI. Our actual results could differ materially from those results expressed in, or implied by, these forward-looking statements. The development and commercialization of pharmaceutical products is subject to risks and uncertainties. The studies described in this press release represent the initial human studies with VP20621 and the results of the Phase 1 study may not be predictive of how VP20621 will perform in future studies. There can be no assurance that that we will conduct additional studies with VP20621 in the timeframes we expect or at all, or that VP20621 can significantly reduce the incidence of recurrent disease for patients with CDI. The FDA or EMA may view the data regarding VP20621 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, or deny the approval of VP20621. These factors, and other factors, including, but not limited to those described in ViroPharma's annual report on Form 10-K and quarterly reports on Form 10-Q filed with the Securities and Exchange Commission during 2010, could cause future results to differ materially from the expectations expressed in this press release. The forward-looking statements contained in this press release may become outdated over time. ViroPharma does not assume any responsibility for updating any forward-looking statements.

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