



March 3, 2009

## **Vertex Pharmaceuticals Strengthens HCV Drug Development Portfolio, Adds Novel Polymerase Inhibitors to Shape New Combinations with Telaprevir**

***- Vertex to acquire privately-held ViroChem Pharma in cash and stock transaction -- Two HCV polymerase inhibitors, VCH-222 and VCH-759, have demonstrated significant antiviral activity in early clinical trials -- First STAT-C combination trial with telaprevir planned for 2H 2009 start -***

CAMBRIDGE, Mass. & LAVAL, Quebec, Mar 03, 2009 (BUSINESS WIRE) -- [Vertex Pharmaceuticals Incorporated](#) (Nasdaq: VRTX), which is developing the hepatitis C virus (HCV) protease inhibitor telaprevir, will add two polymerase inhibitors to its HCV drug development portfolio through a definitive agreement to acquire privately-held ViroChem Pharma Inc. in a stock and cash transaction. With the addition of these compounds, Vertex will advance its strategy to pursue novel combinations of Specifically Targeted Antiviral Therapies for hepatitis C (STAT-Cs) for the treatment of HCV infection. Following completion of the transaction, Vertex will own worldwide rights to ViroChem's HCV drug development portfolio, including VCH-222 and VCH-759, which have demonstrated substantial reductions in plasma HCV RNA when dosed as single agents and have been well-tolerated in clinical studies to date. In particular, VCH-222 dosed as 750 mg twice daily resulted in a median 3.7 log<sub>10</sub> decrease in HCV RNA at the end of dosing in a three-day viral kinetic study, representing the most substantial reduction in viral load reported to date with an investigational HCV polymerase inhibitor dosed as a single agent. Vertex expects to begin clinical evaluation of novel combination regimens of its HCV protease inhibitor telaprevir, currently in Phase 3 clinical development, in the second half of 2009. The transaction is subject to customary pre-closing conditions.

"This acquisition significantly strengthens our pipeline in hepatitis C by bringing together Vertex's telaprevir, our HCV protease inhibitor in registration studies, with the HCV non-nucleoside polymerase inhibitors being developed by ViroChem," said Joshua Boger, Ph.D., Chief Executive Officer of Vertex. "Through this acquisition, we're well positioned as a leader in the development of HCV therapies. Our goal is to further advance HCV care for patients through the creation of novel and highly potent STAT-C combination regimens."

"This move expands Vertex's global presence in HCV and has the potential to enhance the profile and lifecycle of our telaprevir-based combination regimens. We believe it strengthens our ability to compete and stay at the forefront in developing novel STAT-C combination regimens," added Kurt C. Graves, Executive Vice President, Chief Commercial Officer and Head, Strategic Development at Vertex. "We selected ViroChem's compounds following careful evaluation of the STAT-C landscape for more than a year. Key data has emerged that suggest that these compounds could uniquely complement telaprevir and provide a foundation for shaping a potentially new treatment paradigm."

### **ViroChem HCV Drug Development Portfolio**

Two ViroChem HCV polymerase inhibitors, VCH-222 and VCH-759, are currently in clinical development. ViroChem also has a preclinical program directed at the discovery of novel HCV NS5a inhibitors. The status and profile of each clinical compound is detailed below.

**VCH-222:** VCH-222 is an oral non-nucleoside inhibitor of the HCV NS5B polymerase that recently completed a viral kinetic study in HCV patients. In this study involving five treatment-naïve genotype 1a and 1b HCV infected patients, VCH-222 dosed as 750 mg twice daily resulted in a median 3.7 log<sub>10</sub> decrease in HCV RNA - equivalent to a 5,000-fold reduction in virus in the blood - at the end of three days of dosing. The results were consistent from patient to patient, and across HCV genotype 1 subtypes, and represent the most substantial reduction in viral load reported to date with an investigational HCV polymerase inhibitor dosed as a single agent. In clinical evaluations to date, VCH-222 has been well-tolerated, with no serious adverse events observed. VCH-222 has completed 28-day non-clinical toxicology studies in two species.

**VCH-759:** VCH-759 is an oral non-nucleoside inhibitor of the HCV NS5B polymerase that has completed Phase 1b clinical development. In a Phase 1b trial reported at a medical conference in 2007, VCH-759 dosed as 800 mg three times daily showed a mean maximal 2.5 log<sub>10</sub> reduction in HCV RNA and a median 1.7 log<sub>10</sub> reduction in HCV RNA at the end of 10 days. VCH-759 was also well-tolerated with no serious adverse events observed in clinical studies to date. VCH-759 has completed 28-day non-clinical toxicology studies.

**Future clinical plans:** Vertex plans to conduct additional dose-ranging studies of VCH-222 as a single agent and in combination with pegylated interferon and ribavirin. Vertex plans to initiate a first clinical study combining telaprevir with a ViroChem HCV polymerase inhibitor in the second half of 2009. Data from *in vitro* HCV replicon studies suggest that VCH-222 and VCH-759 may provide synergistic or additive antiviral activity to the HCV protease inhibitor telaprevir, thus creating the potential for a non-cross resistant, complementary profile in exploratory clinical studies.

## Terms of the Transaction

Under the terms of the agreement, which have been approved by the Boards of Directors of both companies, ViroChem shareholders will receive \$100 million in cash and 9.9 million shares of Vertex common stock. The stock portion of the consideration is subject to a collar, and the actual number of shares of Vertex stock to be issued will be based on an average Vertex share price prior to the acquisition closing, but per the agreement will not exceed 11.0 million shares. Vertex expects the shares issued in this transaction will be immediately tradeable under a resale registration statement which Vertex plans to file at the time of closing. Goldman, Sachs & Co. is acting as exclusive financial advisor to Vertex.

## Vertex HCV Portfolio

Vertex is developing telaprevir, one of the most advanced investigational agents in development that specifically targets HCV. Telaprevir is being evaluated in a broad Phase 3 registration program, which has enrolled more than 2,200 genotype 1 HCV patients, including patients who have both failed prior treatment with pegylated interferon and ribavirin, as well as patients who are naive to treatment. Vertex plans to file an NDA for telaprevir in the second half of 2010 assuming successful completion of its ongoing Phase 3 program. In addition, Vertex is developing two other novel HCV protease inhibitors, VX-813 and VX-985, currently in Phase 1 and preclinical development respectively.

Vertex retains commercial rights to telaprevir in North America. Vertex and Tibotec are collaborating to develop and commercialize telaprevir in Europe, South America, Australia, the Middle East, and other countries. Vertex is collaborating with Mitsubishi Tanabe Pharma Corporation to develop and commercialize telaprevir in Japan and certain Far East countries. Vertex retains worldwide rights to VX-813 and VX-985.

## HCV Protease and Polymerase as Targets for New Drug Development

Since the identification and sequencing of the hepatitis C virus in 1989, efforts to discover new drugs for HCV infection have focused on specific antiviral targets, including the HCV NS3 protease and the HCV NS5B polymerase. Several specifically targeted antiviral therapies for HCV (known as STAT-Cs) have demonstrated promising clinical results, with the potential for a significant advancement in HCV treatment and disease outcomes when dosed in combination with the currently available treatment of pegylated interferon and ribavirin. As investigational compounds targeting HCV protease and polymerase have advanced in development, clinicians have expressed interest in combining these investigational approaches, with the goal of further optimizing HCV treatment regimens, including treatment of certain hard to treat populations, by potentially increasing SVR rates, decreasing the duration of HCV therapy and increasing the tolerability of HCV treatment regimens.

## About Vertex

Vertex Pharmaceuticals Incorporated is a global biotechnology company committed to the discovery and development of breakthrough small molecule drugs for serious diseases. The Company's strategy is to commercialize its products both independently and in collaboration with major pharmaceutical companies. Vertex's product pipeline is focused on viral diseases, cystic fibrosis, inflammation, autoimmune diseases, cancer, and pain. Vertex co-discovered the HIV protease inhibitor, Lexiva, with GlaxoSmithKline.

Lexiva is a registered trademark of the GlaxoSmithKline group of companies.

Vertex's press releases are available at [www.vrtx.com](http://www.vrtx.com).

## Conference Call

Vertex Pharmaceuticals will host a conference call and webcast on Tuesday, March 3, 2009 at 5:15 p.m. EST to review recent developments. This call and webcast will be broadcast via the Internet at [www.vrtx.com](http://www.vrtx.com). It is suggested that webcast participants go to the web site at least 10 minutes in advance of the call to ensure that they can access the slides. The link to the webcast is available on the Events and Presentations button on the home page.

To listen to the call on the telephone, dial (800) 374-0296 (U.S. and Canada) or (702) 696-4937 (International) and the conference ID number is 88366180. Vertex is also providing a podcast MP3 file available for download on the Vertex website at [www.vrtx.com](http://www.vrtx.com).

The call will be available for replay via telephone commencing March 3, 2009 at 8:00 p.m. EST running through 5:00 p.m. EST on March 9, 2009. The replay phone number for the U.S. and Canada is (800) 642-1687. The international replay number is (706) 645-9291 and the conference ID number is 88366180. Following the live webcast, an archived version will be available on Vertex's website until 5:00 p.m. EST on March 16, 2009.

## Safe Harbor Statement

This press release contains forward-looking statements, including the statements regarding the Company's (i) expectation that the acquisition will strengthen the Company's HCV drug development portfolio by adding two polymerase inhibitors that the Company can bring together with telaprevir; (ii) expectation that the customary pre-closing conditions will be satisfied and the acquisition of ViroChem Pharma will be completed; (iii) plan for a STAT-C combination trial to begin in the second half of 2009; (iv) expectation that these compounds will allow the Company to advance its strategy to pursue STAT-C combinations; (v) belief that this acquisition positions the Company to be a leader in the development of HCV therapies; (vi) goal to further advance HCV care for patients through the creation of novel and highly potent STAT-C combination regimens; (vii) expectation that the transaction has the potential to enhance the profile and lifecycle of our telaprevir-based combination regimens and to strengthen the Company's ability to compete and stay at the forefront in developing novel STAT-C combination regimens; (viii) belief that key data suggest that VCH-222 and VCH-759 could uniquely complement telaprevir and provide a foundation for shaping a potential new treatment paradigm; (ix) statements regarding clinical results for VCH-222 and VCH-759; (x) plan to conduct additional dose-ranging studies of VCH-222; (xi) statements regarding *in vitro* studies and these studies suggesting that VCH-222 and VCH-759 may provide synergistic or additive antiviral activity to telaprevir creating the potential for a complementary profile in exploratory clinical studies; (xii) expectations regarding the consideration to be issued and that the shares will be immediately tradable; and (xiii) plan to file an NDA for telaprevir in the second half of 2010 assuming successful completion of its ongoing Phase 3 program. While the Company believes the forward-looking statements contained in this press release are accurate, there are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements. Those risks and uncertainties include, among other things, that the outcomes for our planned telaprevir clinical trials and studies may not be favorable, that there may be varying interpretations of data produced by one or more of our clinical trials, that the transaction contemplated by this press release might not be completed, that the Company may not obtain the benefits it expects to obtain from this transaction for a variety of reasons including the possibilities that the Company may not be able to successfully develop combination therapies involving telaprevir and the drug candidates that the Company is acquiring in this transaction and that early clinical trials and *in vitro* data regarding VCH-222 and VCH-759 may not be predictive of results that may be obtained from large clinical trials involving VCH-222 and/or VCH-759, and the other risks listed under Risk Factors in Vertex's annual report and quarterly reports filed with the Securities and Exchange Commission and available through the Company's website at [www.vrtx.com](http://www.vrtx.com). We disclaim any obligation to update the information contained in this press release as new information becomes available.

(VRTX-GEN)

SOURCE: Vertex Pharmaceuticals Incorporated

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