# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

## **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 17, 2005

# VERTEX PHARMACEUTICALS INCORPORATED

(Exact name of registrant as specified in its charter)

MASSACHUSETTS

(State or other jurisdiction of incorporation)

**000-19319** (Commission File Number) 04-3039129 (IRS Employer Identification No.)

130 Waverly Street

Cambridge, Massachusetts 02139 (Address of principal executive offices) (Zip Code)

(617) 444-6100

Registrant's telephone number, including area code:

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

## Item 8.01. Other Events.

On June 17, 2005, Vertex Pharmaceuticals Incorporated and Merck & Co., Inc. issued a joint press release that announced the initiation of an additional Phase I study with VX-680, a small molecule inhibitor of Aurora kinases. A copy of that press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

## Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

Exhibit

**Description of Document** 

99.1 Joint Press Release of Vertex Pharmaceuticals Incorporated and Merck & Co., Inc., dated June 17, 2005, titled "Vertex and Merck Initiate Clinical Study in Hematologic Cancers with Aurora Kinase Inhibitor VX-680".

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

## VERTEX PHARMACEUTICALS INCORPORATED

(Registrant)

/s/ IAN F. SMITH

IAN F. SMITH Chief Financial Officer and Senior Vice President

Date: June 17, 2005



#### Vertex and Merck Initiate Clinical Study in Hematologic Cancers with Aurora Kinase Inhibitor VX-680

Whitehouse Station, NJ and Cambridge, MA, June 17 2005 – Merck & Co., Inc. (NYSE: MRK) and Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced the initiation of an additional Phase I clinical study with VX-680, a small molecule inhibitor of Aurora kinases. The two-part, openlabel, dose escalation study is designed to evaluate the safety and tolerability of VX-680 when administered over a five-day treatment cycle in patients with hematologic cancers. The study will evaluate VX-680 in patients with relapsed or refractory acute myelogenous leukemia (AML), myelodysplastic syndrome (MDS), acute lymphocytic leukemia (ALL) or chronic myelogenous leukemia (CML) in blast crisis. With the start of this clinical study, Merck and Vertex now have three clinical studies underway with VX-680 in cancer.

The initiation of this clinical study is supported by VX-680's activity against hematologic cancers in both *in vitro* and *in vivo* studies. VX-680 is a potent inhibitor of Aurora kinases and of Flt-3 kinase, which have been implicated in the onset and progression of human leukemias. VX-680 has demonstrated prolonged survival and induced sustained remission in a model of human AML, and has also shown profound effects in a number of other preclinical cancer models.

"The biologic profile and preclinical studies of VX-680 indicate that this compound has the potential for treating a broad range of human leukemias by inducing apoptosis in the cells that drive disease," said Stephen H. Friend, M.D., Ph.D., Executive Vice President, Advanced Technology and Oncology at Merck Research Laboratories. "The clinical study announced today is designed to promote rapid clinical assessment of VX-680 in patients with a variety of leukemic and pre-leukemic disease states. In addition, access to the leukemic cells in the blood provides a unique opportunity for understanding the biologic effects and anti-cancer activity of Aurora kinase inhibition on a molecular level."

– more –

## VX-680 Clinical Studies

In addition to this Phase I study in hematologic cancers announced today, Merck is presently conducting two clinical studies of VX-680 in patients with recurrent or non-responsive solid tumors, or cancers for which standard therapy does not currently exist.

### Background: Aurora Kinases and the VX-680 Collaboration

Cancer cells typically contain mutations in a number of genes, which ultimately result in uncontrolled cell growth and tumor metastasis. As enzymes specific for and essential to cell growth and division, Aurora kinases hold the potential to be important control points for slowing the growth and spread of tumors. Aurora kinases (also known as BTAK and STK15) are a family of serine-threonine kinases that are believed to play multiple roles in the development and progression of cancer by acting as regulators of cell proliferation, by transforming normal cells into cancer cells and by down-regulating p53, one of the body's natural tumor suppressors. Aurora kinases are known to be over-expressed in many tumor types, including colon cancer, breast cancer and leukemia. Amplification of Aurora genes is associated with progression of colorectal cancer and poor prognosis in certain types of breast cancer.

In June 2004, Vertex and Merck entered into a global collaboration to develop and commercialize VX-680. Along with clinical development, Vertex and Merck are conducting a joint research program to characterize VX-680's activity across a broad range of cancer types and will seek to identify additional drug candidates targeting the Aurora kinases.

## **About Merck**

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines in more than 20 therapeutic categories. The company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit www.merck.com.



#### **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 principally focused on viral diseases, inflammation, autoimmune diseases and cancer. Vertex co-promotes the HIV protease inhibitor, Lexiva<sup>®</sup>, with GlaxoSmithKline.

Lexiva<sup>®</sup> is a registered trademark of the GlaxoSmithKline group of companies.

Vertex's press releases are available at www.vrtx.com.

#### **Merck Forward-Looking Statement**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the cautionary statements in Item 1 of Merck's Form 10-K for the year ended Dec. 31, 2004, and in its periodic reports on Form 10-Q and Form 8-K, which the company incorporates by reference.

#### **Vertex Forward-Looking Statement**

This press release may contain forward-looking statements, including statements that (i) the biologic profile and preclinical studies of VX-680 indicate that this compound has the potential for treating a broad range of human leukemias by inducing apoptosis in the cells that drive disease and (ii) Vertex and Merck are conducting a joint research program to characterize VX-680's activity across a broad range of cancer types, and will seek to identify additional drug candidates targeting the Aurora kinases. While management makes its best efforts to be accurate in making forward-looking statements, such statements are subject to risks and uncertainties that could cause the actual results of studies to vary materially. Those risks and uncertainties include the risk that non-clinical results targeting Aurora kinases may

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not be predictive of human clinical results in the treatment of cancer, that development of VX-680 may not be pursued due to clinical, technical or financial issues, that the rate of patient enrollment may limit expected study timelines and follow-on studies, that Merck may choose to not develop VX-680 or any other Aurora kinase inhibitor discovered by Vertex for commercial or scientific reasons, and other risks listed under Risk Factors in Vertex's Form 10-K filed with the Securities and Exchange Commission on March 16, 2005.

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