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GlaxoSmithKline and Vertex Receive European Approval for Telzir(R), a New Protease Inhibitor for the Treatment of HIV

London, UK, July 16, 2004 -- GlaxoSmithKline (GSK) and Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) announced today that they have received marketing approval from the European Commission for Telzir(R) (fosamprenavir) for the treatment of HIV infection in adults in combination with other anti-HIV medications. Protease inhibitors, like Telzir, act by inhibiting the HIV-1 protease enzyme leading to the formation of immature virus and preventing the infection of new cells. Telzir was co-discovered by GSK and Vertex Pharmaceuticals.

When combined with other antiretroviral drugs, Telzir has demonstrated its ability to reduce the concentrations of HIV in plasma in both antiretroviral treatment-naive and experienced patients. Telzir with low-dose ritonavir offers a low pill burden (4 tablets per day), good tolerability, and may be dosed with or without food and water, which may facilitate HIV-infected patients' long-term adherence to therapy.

"The European approval of Telzir is good news as it gives clinicians and HIV-infected patients a simpler and well-tolerated treatment option," commented Lynn Marks, M.D., Senior Vice President of Infectious Diseases at GSK. "Today's approval is supported by an extensive clinical trial programme. Recent interim 96-week data for Telzir demonstrated sustained viral suppression, improved immunological status and a lack of protease resistance mutations in previously treatment-naive patients receiving Telzir boosted with ritonavir."

"Telzir's potency, tolerability, and convenience profile make it an excellent choice for protease inhibitor-based combination therapy," said Tony Coles, M.D., Senior Vice President of Commercial Operations at Vertex. "The approval of Telzir in the European Union marks an important step in bringing HIV patients new, state-of-the art treatment options. Our eleven-year collaboration with GlaxoSmithKline in the area of HIV protease inhibitors has been highly productive, and we look forward to continuing to deliver innovation to HIV patients and their physicians."

Indication for Telzir

The indication for Telzir in the European Union is: Telzir in combination with low dose ritonavir is indicated for the treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infected adults in combination with other antiretroviral medicinal products. In moderately antiretroviral-experienced patients, Telzir in combination with low dose ritonavir has not been shown to be as effective as lopinavir/ritonavir. In heavily pretreated patients the use of Telzir in combination with low dose ritonavir has not been sufficiently studied. In protease inhibitor (PI)-experienced patients the choice of Telzir should be based on individual viral resistance testing and treatment history.

Clinical Data

More than 1,200 people - both treatment-naive and PI-experienced patients - participated in clinical studies to test the safety and efficacy of Telzir with and without ritonavir. In all trials, study drugs were taken as part of combination therapy that included two nucleoside reverse transcriptase inhibitors. In these clinical trials(1), Telzir with ritonavir demonstrated:

Durable anti-viral responses through 48 weeks of therapy in treatment-naive patients (<400 copies HIV-1 RNA/mL of blood in 69 percent of patients) and treatment-experienced patients (<400 copies HIV-1 RNA/mL of blood in 58 percent of patients)

Each grade 2-4 drug-related adverse event was reported by <10 percent of treatment-naive patients, with less drug-related diarrhoea than nelfinavir

No treatment-naive patients with wild type virus receiving Telzir with ritonavir developed any PI resistance mutations

Each grade 2-4 drug-related adverse event was reported by <12 percent of PI-experienced patients

Improved immunological status

Durable virological suppression with boosted Telzir up to 96 weeks in treatment-naive subjects (interim observed analysis)

In the EU, the recommended dose of Telzir is one 700mg tablet twice-daily with one 100mg capsule of ritonavir twice-daily (BID)

in combination with other antiretroviral medications in both antiretroviral treatment-naive and experienced patients.

GSK and Vertex will co-promote Telzir in key markets in Europe. Telzir is currently marketed in the United States under the brand name Lexiva(R).

About GlaxoSmithKline

GlaxoSmithKline is one of the world's leading pharmaceutical and healthcare companies and is committed to improving the quality of human life by enabling people to do more, feel better and live longer. GSK is a leader in bringing HIV/AIDS treatments to patients and provides its anti-retrovirals to 63 of the least developed countries and Sub-Saharan Africa at not-for-profit prices. For more information, visit GlaxoSmithKline on the World Wide Web at www.gsk.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 partners. Vertex's product pipeline is principally focused on viral diseases, inflammation, autoimmune diseases and cancer. Vertex co-promotes the HIV protease inhibitor Lexiva(R) with GlaxoSmithKline.

Vertex Safe Harbor Statement

This press release may contain forward-looking statements. 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 Vertex's actual results to vary materially. These risks and uncertainties include those risks listed under Risk Factors in Vertex's form 10-K filed with the Securities and Exchange Commission on March 15, 2004.

Telzir and Lexiva are registered trademarks of the GlaxoSmithKline group of companies.

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References

¹ *The 48-week safety and efficacy data from the SOLO study were presented in November 2002 at the 6th International Congress on Drug Therapy in HIV Infection in Glasgow, UK. The study was also published in the journal AIDS. Gathe J, et al. SOLO: 48-week efficacy and safety comparison of once-daily fosamprenavir/ritonavir vs twice-daily nelfinavir in naive HIV-1-infected patients. AIDS. 2004; 18(11):1529-1537.*

The 96-week interim data from the SOLO study were presented in July 2004 at the XV International AIDS Conference in Bangkok, Thailand. Gathe J, et al. Long-term follow-up on GW433908 (908)/ritonavir (r) QD: Sustained virologic and immunologic response in antiretroviral treatment (ART)-naive subjects over 96 weeks. XV International AIDS Conference, Bangkok, Thailand, 2004; Abstract TuPeB4507.

The 48-week clinical data from the CONTEXT study were presented in July 2004 at the XV International AIDS Conference in Bangkok, Thailand. Elston R C, et al. GW433908 (908)/ritonavir (r): 48-week results in PI-experienced subjects: A retrospective analysis of virological response based on baseline genotype and phenotype. XV International AIDS Conference, Bangkok, Thailand, 2004; Abstract MoOrB1055.