

# **Abbott Laboratories**

December 23, 2003

Abbott Laboratories 100 Abbott Park Rd. Abbott Park, IL 60064-3500

## Dear HIV Treating Clinician:

I want to take this opportunity to respond to your inquiry regarding the recent re-pricing of Norvir® (ritonavir). We hear and understand your issues and share your ultimate concern – ensuring that patients continue to have access to effective HIV therapies.

### **Ensuring Patient Access:**

We did not make this pricing decision lightly, and when doing so, carefully considered patients' ability to access this drug. We took several key steps to ensure that patients are not adversely impacted. As you may know, patients fall into one of three coverage categories: 1) those without prescription drug coverage who pay out of pocket (approximately 5 percent); 2) those who receive public assistance through AIDS Drug Assistance Programs (ADAPs) or Medicaid (approximately 55 percent); and 3) those who are covered by private medical insurance (approximately 40 percent).

For patients without prescription drug coverage or public assistance, we expanded our Patient Assistance Program (PAP) for Norvir to ensure that all patients without drug coverage can receive this drug for free from Abbott, regardless of their financial status. In fact, our PAP for Norvir is the only program in the industry that does not include a financial means requirement. Since implementing the new price on December 4, we have approved all Norvir PAP applications within 24 hours. If you have patients in need of assistance, they can receive an application by calling 1-800-222-6885 (select option 2), Monday through Friday 8:00 a.m. – 5:00 p.m. CST or by visiting <a href="https://www.Abbottvirology.com">www.Abbottvirology.com</a>.

More than half of all patients with HIV receive their drugs through public assistance programs such as ADAPs or Medicaid. Abbott has ensured that these patients will not be impacted by this re-pricing. Specifically, we met with state ADAPs directors over the past three weeks, and have issued a new Memo of Commitment honoring the former Norvir price for all ADAP programs through June 2005. We have also contacted every state Medicaid program to affirm that the cost of Norvir will be held at the former price. We are committed to ongoing collaboration with public assistance programs to ensure patient access in the future.

Patients covered through private insurance should not be adversely impacted either. Within the past week, we have contacted many top private insurance providers, including PacifiCare and HealthNet, to address issues regarding access and co-pays/premiums. None of these providers currently restrict access to HIV medications through a formulary. In addition, none of these plans intend to increase co-pays or premiums based on this pricing action. It is important to note that less than 10 percent of privately insured patients pay a percentage of the prescription cost versus a flat co-pay. It is expected that

these patients are protected and will not pay more annually due to out of pocket maximums.

#### **Balancing New Programs with Economic Realities:**

Ultimately, access to more and better HIV therapies is in the best interest of patients. This new price is necessary to support our ability to continue research to bring a next generation HIV medication to market, to develop improved formulations of our existing products, and to continue our commitment to the developing world. In fact, we are currently investing in new HIV and Hepatitis C compounds as well as new formulations of both of our HIV products. One of Abbott's goals is to develop products that can be stored at room temperature, improving their value and convenience to patients both here and in the developing world.

#### **The Changing Role of Norvir:**

Since Norvir was originally launched, the role and value of Norvir in the treatment of patients with HIV/AIDS has changed dramatically. In 1996, Norvir was prescribed as a stand-alone protease inhibitor at a recommended daily dose of 1200 mg and a daily price of \$20.52. Today, Norvir is primarily used at low doses of 100 mg to 200 mg in combination with other protease inhibitors, with 100 mg being the most commonly prescribed daily dose. At the new price of \$8.57 per 100 mg, Norvir is most often the lowest cost component of a protease inhibitor-based regimen. For example, when you combine Norvir with a regimen based on newly approved therapies such as Reyataz<sup>TM</sup> (atazanavir) at \$22.08 per day<sup>1</sup>, Norvir continues to represent a fraction, typically one-fifth, of the daily cost of therapy.

If you have additional questions or concerns please feel free to call me directly at 847-935-4100.

Regards,

John Leonard, M.D.

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Vice President, Global Pharmaceutical Development

Please see enclosed important safety and full prescribing information.

<sup>1</sup> PriceProbe, December 2003

NORVIR is indicated in combination with other antiretroviral agents for the treatment of HIV infection. This indication is based on the results from a study in patients with advanced HIV disease that showed a reduction in both mortality and AIDS-defining clinical events for patients who received NORVIR either alone or in combination with nucleoside analogues. Median duration of follow-up in this study was 13.5 months.

#### **Safety Information**

NORVIR may not be right for everyone, including people with liver disease, hepatitis, or hemophilia.

Redistribution/accumulation of body fat has been observed in patients receiving protease inhibitors.

Elevated blood sugar levels have been reported in patients taking protease inhibitors.

Allergic reactions ranging from mild to severe have been reported.

Pancreatitis has been observed in patients receiving NORVIR therapy, including those who developed high triglycerides.

The risk of muscle pain, including severe muscle disease, may be increased when NORVIR is used in combination with HMG-CoA reductase inhibitors (statin class of lipid-lowering drugs).

Concomitant use of NORVIR with St. John's wort (*Hypericum perforatum*) is not recommended. St. John's wort may reduce NORVIR levels, lead to increased viral load and possible resistance to protease inhibitors.

Common adverse reactions include diarrhea, vomiting, asthenia, taste perversion, abdominal pain, anorexia, headache, peripheral paresthesia, circumoral paresthesia, and dizziness.

Coadministration of NORVIR with certain nonsedating antihistamines, sedative hypnotics, antiarrhythmics, or ergot alkaloid preparations may result in potentially serious and/or life-threatening adverse events.

NORVIR is contraindicated with the drugs listed below:

amiodarone dihydroergotamine propafenone astemizole ergotamine quinidine bepridil flecainide terfenadine cisapride midazolam pimozide