GlaxoSmithKline
PO Box 13398
Five Moore Drive
Research Triangle Park
North Carolina 27709

Tel. 919 483 2100
www.gsk.com

IMPORTANT PRESCRIBING INFORMATION

September 2004

Dear Health Care Professional:

This letter is intended to inform you that GlaxoSmithKline will be discontinuing the sale and distribution of AGENERASE® (amprenavir) 150 mg Capsules by the end of 2004. This action is not the result of any safety or efficacy issues regarding the product.

AGENERASE 50 mg Capsules and 15 mg/mL Oral Solution will continue to be available.

GlaxoSmithKline has taken this action because the clinical demand for AGENERASE 150 mg capsules has diminished significantly. Additionally, in the recent treatment recommendations by the Department for Health and Human Services (DHHS), AGENERASE is no longer recommended as a component of a preferred or alternative initial regimen.

Because of this discontinuation, you should consider not initiating treatment with AGENERASE 150 mg Capsules in your patients with HIV infection. If you are aware of a patient receiving AGENERASE 150 mg Capsules, please notify the prescribing health care provider (if someone other than yourself) and the patient regarding this announcement. We encourage you or the prescribing health care provider to discuss appropriate alternative treatment regimens with your patients currently receiving AGENERASE 150 mg Capsules.

AGENERASE is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. The following points should be considered when initiating therapy with AGENERASE: in a study of NRTI-experienced, protease inhibitor-naive patients, AGENERASE was found to be signficantly less effective than indinavir. Mild to moderate gastrointestinal adverse events led to discontinuation of AGENERASE primarily during the first 12 weeks of therapy. There are no data on response to therapy with AGENERASE primarily during the first 12 weeks of therapy. There are limited data on response to therapy with AGENERASE in protease inhibitor-experienced patients.

Because of the potential risk of toxicity from the large amount of the excipient propylene glycol contained in AGENERASE Oral Solution, that formulation is contraindicated in infants and children below the age of 4 years, pregnant women, patients with hepatic or renal failure, and patients treated with disulfiram or metronidazole. AGENERASE Oral Solution should be used only when other protease inhibitor formulations are not therapeutic options. Amprenavir is a sulfonamide, and patients with a known sulfonamide allergy should be treated with caution. Caution should be exercised when administering

AGENERASE to patients with hepatic impairment. In patients receiving protease inhibitors (including amprenavir), hyperglycemia, diabetes mellitus, acute hemolytic anemia and spontaneous bleeding in hemophiliacs have been reported. Severe and life-threatening drug interactions could occur, and skin reactions including Stevens-Johnson syndrome have occurred with amprenavir. Redistribution/accumulation of body fat has been observed in patients receiving antiretroviral therapy. The causal relationship, mechanism, and long-term consequences of these events are currently unknown. Please consult the enclosed full prescribing information for AGENERASE Capsules and AGENERASE Oral Solution.

GlaxoSmithKline is committed to providing you with current product information for the management of your patients with HIV infection. The medical community can assist us in monitoring the safety of our products by reporting adverse events to GlaxoSmithKline's Customer Response Center at 1-888-825-5249 or to the FDA MEDWATCH program by telephone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by modem at 1-800-FDA-7737, via www.FDA.gov/medwatch, or by mail to:

MEDWATCH HF-2
FDA
5600 Fisher's Lane
Rockville, MD 20857

If you have any questions or want additional medical information, please contact our Customer Response Center at 1-888-825-5249.

Sincerely,

Douglas J. Manion, M.D.
Vice President, Clinical Development and Medical Affairs