GILEAD
Advancing Therapeutics.
Improving Lives.

May 2016

IMPORTANT PRESCRIBING INFORMATION

Subject: **Important Information regarding the voluntary withdrawal of VITEKTA ® (elvitegravir) tablets**

Dear Healthcare Provider:

Gilead Sciences, Inc. would like to inform you that VITEKTA (elvitegravir 85 mg and 150 mg) tablets will be voluntarily withdrawn from sale globally as of February 2017. This decision is based on low utilization of the product (less than 50 US patients taking VITEKTA) and is not a result of any ongoing or new safety issues with VITEKTA. Gilead believes that there is no current unmet need for VITEKTA because of the availability of other antiretroviral agents with indications broad enough to be inclusive of the VITEKTA indication. Given the alternatives available, this withdrawal will not deprive patients of viable treatment options. Importantly, the withdrawal of VITEKTA as a standalone product will not impact the availability of fixed-dose combinations that contain elvitegravir.

Gilead remains fully committed to the treatment of HIV and to the patients currently using VITEKTA. We recommend that prior to the withdrawal you transition all patients currently being treated with an HIV-1 regimen that includes single agent VITEKTA (85 mg or 150 mg) tablets to another antiretroviral regimen. Additionally, we recommend that no new patients be initiated on VITEKTA.

A copy of the full Prescribing Information for VITEKTA is enclosed with this letter. Please also see the next page for Indication and Important Safety Information for VITEKTA.

Thank you for your attention to this matter. For questions about VITEKTA or more information about Gilead products and services you can contact us at 1-800-GILEAD-5 (1-800-445-3235) [select option 2] or go to Gilead.com.

Sincerely,

Norbert Bischofberger

Norbert Bischofberger, Ph.D.
Executive Vice President, Research and Development and Chief Scientific Officer
Gilead Sciences, Inc.

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA
phone 650 574 3000 *facsimile* 650 578 9264
www.gilead.com

INDICATION

VITEKTA® (elvitegravir 85 mg and 150 mg) tablets, an HIV-1 integrase inhibitor used in combination with a protease inhibitor/ritonavir and with other antiretroviral agents, is indicated for the treatment of HIV-1 infection in antiretroviral treatment-experienced adults.

Limitations of Use:

- There are no comparative pharmacokinetic or clinical data evaluating VITEKTA with cobicistat as single entities compared to STRIBILD® (elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate).
- VITEKTA coadministered with protease inhibitors and cobicistat is not recommended.
- Coadministration of VITEKTA with dosage regimens or HIV-1 protease inhibitors other than those presented (see Dosage and Administration section) is not recommended.

IMPORTANT SAFETY INFORMATION

Contraindications

- **Coadministration:** There are no contraindications to VITEKTA. Due to the need to use VITEKTA with a protease inhibitor/ritonavir, prescribers should consult the complete prescribing information of the coadministered protease inhibitor and ritonavir for a description of contraindications associated with the co-administered agents.

Warnings and precautions

- **Risk of adverse reactions or loss of virologic response due to drug interactions:** VITEKTA is metabolized by CYP3A. Drugs that induce CYP3A activity may result in decreased concentrations of both VITEKTA and the coadministered protease inhibitor/ritonavir, leading to a loss of therapeutic effect and possible resistance; review concomitant medications during VITEKTA therapy; and monitor for the adverse reactions associated with the concomitant drugs.
- **Use with other antiretroviral products:** Do not coadminister VITEKTA with other products containing elvitegravir, including combination products. VITEKTA should only be used in combination with a protease inhibitor/ritonavir. Do not use with a protease inhibitor/cobicistat, as dosing recommendations for such combinations have not been established and may result in suboptimal concentrations of VITEKTA and/or the protease inhibitor, leading to loss of therapeutic effect and development of resistance.
- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable times to onset, has been reported.

Adverse reactions

- **Common adverse drug reactions** (incidence ≥2%; all grades) in clinical studies with other antiretroviral agents were diarrhea (7%), nausea (4%), and headache (3%).

Drug interactions

- **CYP3A inducers:** Drugs that induce CYP3A can decrease the concentration of VITEKTA. Do not use with drugs that induce CYP3A as this may lead to a loss of therapeutic effect and possible resistance (see Warnings and Precautions).
- **CYP3A substrates:** Protease inhibitors with ritonavir that are coadministered with VITEKTA may increase the concentration of drugs metabolized by CYP3A. For drug interactions related to the coadministered protease inhibitor and ritonavir, consult the full prescribing information for the coadministered agents.
- **Antiretroviral agents:** Atazanavir and lopinavir have been shown to significantly increase concentrations of VITEKTA; dose VITEKTA at 85 mg once daily when coadminstered with atazanavir or lopinavir (see Dosage and Administration section). Efavirenz and nevirapine are expected to decrease concentrations of VITEKTA which may result in loss of therapeutic effect and possible resistance; coadministration with efavirenz or nevirapine is not recommended.
- **Antacids**: Separate VITEKTA and antacid administration by at least 2 hours.

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA
phone 650 574 3000 *facsimile* 650 578 9264
www.gilead.com

- **Prescribing information:** Consult the full prescribing information for VITEKTA for more information on potentially significant drug interactions, including clinical comments.

Dosage and administration

- **Adult dosage:** One 85 or 150 mg tablet taken orally once daily with food in combination with a protease inhibitor coadministered with ritonavir and another antiretroviral drug.
- **Recommended dosing regimens:** VITEKTA 85 mg once daily in combination with atazanavir/ritonavir at 300/100 mg once daily, or lopinavir/ritonavir at 400/100 mg twice daily. VITEKTA 150 mg once daily in combination with darunavir/ritonavir at 600/100 mg twice daily; fosamprenavir/ritonavir at 700/100 mg twice daily; or tipranavir/ritonavir at 500/200 mg twice daily. All regimens should be used in combination with other HIV-1 antiretroviral agents.
- **Treatment history:** Treatment history and, when available, resistance testing should guide the use of VITEKTA containing regimens.

Pregnancy and breastfeeding

- **Pregnancy Category B:** There are no adequate and well-controlled studies in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk.
- **Breastfeeding:** It is not known if VITEKTA is secreted in human milk. Because of both the potential for HIV transmission and the potential for serious adverse reactions in nursing infants, mothers should be instructed not to breastfeed.

For more information, please see the enclosed full Prescribing Information for VITEKTA.

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA
phone 650 574 3000 *facsimile* 650 578 9264
www.gilead.com