Serious and Fatal Skin Reactions to Incivek

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Vertex Announces Update to U.S. Prescribing Information for INCIVEK® (telaprevir)

- Revised label includes Boxed Warning detailing risk of serious skin reactions observed in the post-marketing setting that require treatment discontinuation –

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that the INCIVEK® (telaprevir) label in the United States has been updated to include a Boxed Warning stating that fatal and non-fatal serious skin reactions have been reported in patients taking INCIVEK combination treatment. Fatal cases of serious skin reactions have been reported in patients with progressive rash and systemic symptoms who continued to receive INCIVEK combination treatment after a serious skin reaction was identified. Rash and serious skin reactions are known adverse events associated with INCIVEK combination treatment and were previously included in the warnings and precautions section of the label. Given the severity of the events reported in the post-marketing setting, and the importance of discontinuing INCIVEK combination treatment in the event of one of these reactions, the information has been given greater prominence through a boxed warning. "The safety of people taking our medicines is our first priority, and we are committed to ensuring that patients and physicians are aware of the label update to help them use INCIVEK properly," said Robert Kauffman, M.D., Ph.D., Senior Vice President and Chief Medical Officer at Vertex. "We will continue to educate physicians to follow the rash management plan developed while INCIVEK was in clinical trials and the information contained in the updated label."

In Phase 3 clinical trials, less than 1 percent of people who received INCIVEK combination treatment experienced a serious skin reaction. These serious skin reactions required hospitalization and all patients recovered. For serious skin reactions, INCIVEK combination treatment must be discontinued immediately, and patients should be promptly referred for urgent medical care. The INCIVEK label was also updated to include additional information on the time to onset and management of anemia.

About INCIVEK INCIVEK® (telaprevir) tablets is an oral medicine that acts directly on the hepatitis C virus protease, an enzyme essential for viral replication. INCIVEK has been prescribed to more than 50,000 patients in the United States. Approximately three out of four U.S. patients who are prescribed a direct-acting antiviral for the treatment of genotype 1 chronic hepatitis C (HCV) receive INCIVEK combination therapy.

In Phase 3 clinical studies, 79 percent of people who had not previously been treated for HCV achieved a viral cure following treatment with INCIVEK combination therapy, compared with 46 percent of those who received pegylated-interferon and ribavirin (P/R) alone. Among people

who were treated previously but did not achieve a viral cure, in the Phase 3 studies: 86 percent of relapsers achieved a viral cure with INCIVEK combination therapy compared to 22 percent with P/R alone; 59 percent of partial responders achieved a viral cure compared with 15 percent with P/R alone; and 32 percent of null responders achieved a viral cure compared with 5 percent with P/R alone. In addition, many people are eligible to complete treatment with INCIVEK combination therapy in 24 weeks — half the time required for treatment with P/R alone.

INCIVEK was approved by the U.S. Food and Drug Administration (FDA) in May 2011 and by Health Canada in August 2011 for use in combination with pegylated interferon and ribavirin for adults with genotype 1 chronic hepatitis C with compensated liver disease (some level of damage to the liver but the liver still functions), including cirrhosis (scarring of the liver). INCIVEK is approved for people who are new to treatment, and for people who were treated previously with interferon-based treatment but who did not achieve a sustained viral response, or viral cure (relapsers, partial responders and null responders).

Vertex developed telaprevir in collaboration with Janssen and Mitsubishi Tanabe Pharma. Vertex has rights to commercialize telaprevir in North America where it is being marketed under the brand name INCIVEK (in-SEE-veck). Janssen has rights to commercialize telaprevir in Europe, South America, Australia, the Middle East and certain other countries. In September 2011, telaprevir was approved in the European Union and Switzerland. Telaprevir is known as INCIVO® in Europe. Mitsubishi Tanabe Pharma has rights to commercialize telaprevir in Japan and certain Far East countries. In September 2011, telaprevir was approved in Japan and is known as Telavic®.

IMPORTANT SAFETY INFORMATION

Indication

INCIVEK® (telaprevir) is a prescription medicine used with the medicines peginterferon alfa and ribavirin to treat chronic (lasting a long time) hepatitis C genotype 1 infection in adults with stable liver problems, who have not been treated before or who have failed previous treatment. It is not known if INCIVEK is safe and effective in children under 18 years of age.

Important Safety Information

INCIVEK® (telaprevir) should always be used in combination with peginterferon alfa and ribavirin. INCIVEK combination treatment may cause serious side effects including skin rash and serious skin reactions, anemia (low red blood cell count) that can be severe, and birth defects or death of an unborn baby.

Skin rashes are common with INCIVEK combination treatment. Sometimes these skin rashes and other skin reactions can become serious, require treatment in a hospital, and may lead to death. Patients should call their healthcare provider right away if they develop any skin changes

during treatment with INCIVEK. Their healthcare provider will decide if they need treatment or if they need to stop INCIVEK or any of their other medicines. Patients should not stop taking INCIVEK combination treatment without talking with their healthcare provider first.

Patients' healthcare providers will do blood tests regularly to check for anemia. If anemia is severe, the healthcare providers may tell them to stop taking INCIVEK.

INCIVEK combined with peginterferon alfa and ribavirin may cause birth defects or death of an unborn baby. Therefore, a patient should not take INCIVEK combination treatment if she is pregnant or may become pregnant, or if he is a man with a sexual partner who is pregnant. Females who can become pregnant and females whose male partner takes these medicines must have a negative pregnancy test before starting treatment, every month during treatment, and for 6 months after treatment ends. Patients must use two forms of effective birth control during treatment and for 6 months after all treatment has ended. These two forms of birth control should not contain hormones, as these may not work during treatment with INCIVEK.

INCIVEK and other medicines can affect each other and can also cause side effects that can be serious or life-threatening. There are certain medicines patients cannot take with INCIVEK combination treatment. Patients should tell their healthcare providers about all the medicines they take, including prescription and non-prescription medicines, vitamins and herbal supplements.

The most common side effects of INCIVEK combination treatment include itching, nausea, diarrhea, vomiting, anal or rectal problems (including hemorrhoids, discomfort , burning or itching around or near the anus), taste changes and tiredness. There are other possible side effects of INCIVEK, and side effects associated with peginterferon alfa and ribavirin also apply to INCIVEK combination treatment. Patients should tell their healthcare provider about any side effect that bothers them or doesn't go away.

Please see full Prescribing Information including Boxed Warning, and the Medication Guide for INCIVEK available at www.INCIVEK.com.