May 23, 2011

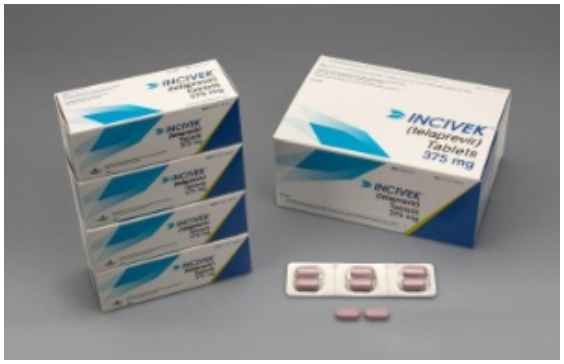
# FDA Approves INCIVEK™ (telaprevir) for People with Hepatitis C

*-79% of people treated for the first time achieved a SVR (viral cure) with INCIVEK combination treatment-*

*-Vertex launches a comprehensive financial assistance and patient support program-*

*-Conference call today at 11:00 a.m. ET to provide more information on the commercialization of INCIVEK-*

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) today announced that the U.S. Food and Drug Administration (FDA) has approved INCIVEK™ (telaprevir) tablets for a broad group of people 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 (in-SEE-veck) is approved for people who are new to treatment, and for people who were treated previously but who did not achieve a viral cure (relapsers, partial responders and null responders). INCIVEK is given for 12 weeks in combination with pegylated-interferon and ribavirin, two other medicines approved to treat hepatitis C. After the first 12 weeks, all patients stop receiving INCIVEK and continue treatment with pegylated-interferon and ribavirin alone for an additional 12 weeks or 36 weeks of treatment. With INCIVEK combination treatment, more than 60 percent of people treated for the first time, as well as those who relapsed after previous therapy, are expected to complete all treatment in 24 weeks — half the time needed if they were to take pegylated-interferon and ribavirin alone. All other patients will receive a total of 48 weeks of treatment. INCIVEK will arrive in pharmacies this week.




INCIVEK (750 mg) is given as two 375-mg tablets three times daily for 12 weeks. It is packaged in weekly boxes that include daily blister strips to help patients keep track of their doses. (Photo: Business Wire)

The approval of INCIVEK was based on data from three Phase 3 studies, which showed that people who received INCIVEK combination treatment achieved significantly higher rates of sustained viral response (SVR, or viral cure) compared to those who received pegylated-interferon and ribavirin alone, regardless of their prior treatment experience:

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| **People new to treatment:** | 79 percent vs. 46 percent |
| **People who were treated previously but did not achieve a viral cure:** | |
| **-- Relapsers:** | 86 percent vs. 22 percent |
| **-- Partial responders:** | 59 percent vs. 15 percent |
| **-- Null responders:** | 32 percent vs. 5 percent |

INCIVEK (750 mg) is given as two 375-mg tablets three times daily. It is packaged in weekly boxes that include daily blister strips to help patients keep track of their doses.

Rash and anemia are the most serious side effects associated with INCIVEK. The most common side effects reported with INCIVEK combination treatment include fatigue, itching, nausea, diarrhea, vomiting, anal or rectal problems, and taste changes.

"Hepatitis C can lead to liver failure, cancer and the need for a transplant, and for the past decade, the best we could offer patients was a year of difficult treatment that resulted in a viral cure for fewer than half of them," said Ira Jacobson, M.D., Chief of the Division of Gastroenterology and Hepatology, Weill Cornell Medical College and principal investigator for a Phase 3 study of INCIVEK. "With INCIVEK, 79 percent of people new to treatment achieved a viral cure."

"Today marks a turning point in the fight against hepatitis C, particularly for people who have been living with this silent disease for decades, hoping for a better chance of a viral cure," said Matthew Emmens, Chairman, President and Chief Executive Officer of Vertex. "The approval of INCIVEK was only possible thanks to more than 4,000 people who volunteered for our clinical studies, the doctors, nurses and coordinators who managed the studies, and our own pioneering scientists who have worked for more than 15 years to bring this new medicine to people with hepatitis C."

Vertex has 200 field-based employees across the United States, including a 115-person sales team, who are ready to support the introduction of INCIVEK. The sales team has an average of more than 14 years of experience bringing medicines to people who need them, including eight years of direct experience with antiviral medicines for diseases such as hepatitis C.

**Helping People with Hepatitis C Get INCIVEK**

The people who work at Vertex understand that medicines can only help patients who can get them. With that in mind, the company today introduced a comprehensive financial assistance and patient support program to help people get INCIVEK who might not otherwise be able to afford it. The program will help people with hepatitis C learn about insurance benefits for their medicines, give INCIVEK for free to eligible patients who do not have insurance and provide coverage for co-pay or co-insurance costs associated with INCIVEK for people who meet certain program criteria. Additionally, patients will have access to nurses through a 24-7 hotline by which they can receive support, guidance and educational materials about hepatitis C and its treatment. Vertex will also provide nurses and doctors with educational tools and resources so they can offer support and care to people with hepatitis C before, during and after the treatment process.

For eligible patients, the program includes the following:

- Insurance Benefits Research and Support: Vertex case managers will research patients' insurance benefits for INCIVEK combination treatment, assist people with insurance appeals and help guide them to other forms of financial support, including Vertex's free medicine and co-pay programs;
- Free Medicine Program: Vertex will give INCIVEK for free to people who do not have insurance and have an annual household income of $100,000 or less; and
- Co-Pay Support: Vertex will cover co-pay or co-insurance costs up to 20 percent of the total cost of INCIVEK for people who have private insurance plans that cover INCIVEK, regardless of their household income. For people covered by government insurance, Vertex will also make donations to the independent, non-profit Patient Access Network Foundation, which has a fund to provide co-pay support to people taking hepatitis C medicines.

More information about this program is available by calling 1-855-837-8394 or visiting www.INCIVEK.com.

**About INCIVEK**

INCIVEK is an oral medicine that acts directly on the hepatitis C virus protease, an enzyme essential for viral replication. The Phase 3 registration studies evaluated INCIVEK in combination with Pegasys® (pegylated-interferon alfa-2a) and Copegus® (ribavirin) in people with hepatitis C who were new to treatment as well as those who were treated previously with pegylated-interferon and ribavirin but who did not achieve a viral cure, including:

- Prior Relapsers: Defined as people whose hepatitis C virus was undetectable after a full course of previous treatment, but whose virus became detectable during the follow-up period;
- Prior Partial Responders: Defined as people who achieved at least a 2 $\log_{10}$ reduction in hepatitis C virus at week 12, but whose hepatitis C virus never became undetectable by week 24 of a prior course of therapy; and
- Prior Null Responders: Defined as people who achieved a less than 2 $\log_{10}$ reduction in hepatitis C virus at week 12 of a prior course of therapy.

Vertex developed telaprevir in collaboration with Tibotec BVBA and Mitsubishi Tanabe Pharma. Vertex has rights to commercialize telaprevir in North America. Through its affiliate, Janssen, Tibotec has rights to commercialize telaprevir in Europe, South America, Australia, the Middle East and certain other countries. Mitsubishi Tanabe Pharma has rights to commercialize telaprevir in Japan and certain Far East countries. In the United States, telaprevir will be marketed with the brand name INCIVEK.

**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**

**Who should not take INCIVEK?**

Do not take INCIVEK if you are pregnant or may become pregnant, or if you are a man with a sexual partner who is pregnant.

Do not take INCIVEK if you are taking certain medicines as there could be serious side effects. If these drugs are taken together, this can cause you to have too much or not enough INCIVEK or your other medicines in your body. It can also cause side effects that can be serious or life-threatening. These medicines include: alfuzosin hydrochloride (Uroxatral®), atorvastatin (Lipitor®, Caduet®), ergot containing medicines such as methylergonovine (Methergine®), lovastatin (Advicor®, Altoprev®, Mevacor®), pimozide (Orap®), rifampin (Rifadin®, Rifamate®, Rifater®), sildenafil citrate (Revatio®) or tadalafil (Adcirca®) for the lung problem pulmonary artery hypertension (PAH), simvastatin (Zocor®, Vytorin®, Simcor®), St. John's wort (*Hypericum perforatum*), or triazolam (Halcion®).

Talk to your healthcare provider before taking INCIVEK if any of the above applies to you. Your healthcare provider may need to change the amount of medicines you take.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. INCIVEK and other medicines can affect each other.

**Serious Side Effects**

INCIVEK can cause serious side effects, including:

- Birth defects or death of an unborn baby
  INCIVEK combined with peginterferon alfa and ribavirin may cause birth defects or death of your unborn baby. If you or your sexual partner is pregnant or plan to become pregnant, do not take these medicines. You or your partner should not become pregnant while taking INCIVEK with peginterferon alfa and ribavirin and for 6 months after treatment is over.

  You must have a negative pregnancy test before starting treatment, every month during treatment, and for 6 months after your treatment ends. You must use 2 effective methods of birth control during treatment and for 6 months after all treatment has ended. These 2 forms of birth control should not contain hormones, as these may not work as well during treatment with INCIVEK. Talk to your healthcare provider about the forms of birth control you should use during this time.

  Two weeks after stopping INCIVEK, you can use a hormonal form of birth control as one of your two forms of birth control.

  If you or your partner becomes pregnant during treatment or within 6 months after stopping these medicines, tell your healthcare provider right away. Contact the Ribavirin Pregnancy Registry right away by calling 1-800-593-2214. The Registry collects information about what happens to mothers and their babies if the mother takes ribavirin while pregnant.

- Skin reactions: Mild skin rashes are common with INCIVEK combination treatment. Sometimes these skin rashes and other skin reactions can become severe and require treatment in a hospital.

  Call your healthcare provider right away if you develop any skin changes with these symptoms: rash with or without itching, blisters or skin lesions, mouth sores or ulcers, red or inflamed eyes like "pink eye" (conjunctivitis), swelling of your face, or fever.

  Your healthcare provider will decide if these changes may be a sign of a serious skin reaction. Your healthcare provider will also decide if you need treatment for your rash or to stop INCIVEK or your other medicines. Never stop taking INCIVEK combination treatment without talking to your healthcare provider first.

- Do not take INCIVEK alone to treat chronic hepatitis C infection. It must be used with peginterferon alfa and ribavirin to treat chronic hepatitis C infection.
- Low red blood cell count (anemia) that can be severe. Tell your healthcare provider if you have any of these symptoms of anemia: dizziness, shortness of breath, tiredness, or weakness.

  Your healthcare provider will do blood tests regularly to check your red blood cell count during treatment. If your anemia is severe your healthcare provider may tell you to stop taking INCIVEK. If this happens, do not start taking it again.

**What should I tell my healthcare provider before taking INCIVEK?**

Tell your healthcare provider if you:

- have certain blood problems such as anemia
- have liver problems other than hepatitis C infection
- have hepatitis B, HIV infection, or any problems with your immune system
- have a history of gout or high uric acid levels in your blood
- have had an organ transplant
- plan to have surgery
- have any other medical condition
- are breastfeeding

**How should I take INCIVEK?**

Take INCIVEK exactly as your healthcare provider tells you. Take 2 INCIVEK pills 3 times a day, 7 to 9 hours apart, with food. Eat a meal or snack containing about 20 grams of fat within 30 minutes before you take each dose. Talk to your healthcare provider about examples of food you can eat.

If you miss a dose within 4 hours of when you usually take it, take your dose with food as soon as possible. If you miss a dose and it is more than 4 hours after the time you usually take it, skip that dose only and take the next dose at your normal time. Do not stop taking INCIVEK unless your healthcare provider tells you to. If your healthcare provider tells you to stop, you should not start taking it again, even if the reason for stopping goes away. If you take too much INCIVEK, call your healthcare provider or local Poison Control Center, or go to the nearest emergency room right away.

**Common Side Effects of INCIVEK Combination Treatment**

The most common side effects include itching, nausea, diarrhea, vomiting, anal or rectal problems (including hemorrhoids, discomfort or burning around or near the anus, itching around or near the anus), taste changes, and tiredness. Tell your healthcare provider about any side effect that bothers you or doesn't go away.

These are not all the possible side effects of INCIVEK. For more information, ask your healthcare provider or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA at 1-800-FDA-1088 or 1-800-332-1088 or www.fda.gov/medwatch.

You may also report side effects to Vertex Pharmaceuticals Incorporated at 1-877-824-4281.

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

For healthcare providers who are interested in information about INCIVEK, you can also call 1-877-824-4281.

**Conference Call Information**

Vertex will host a conference call and webcast today, May, 23, 2011 at 11:00 a.m. ET to provide more information about today's approval, the price of INCIVEK and Vertex's new financial assistance and patient support program. The conference call will be webcast live and a link to the webcast may be accessed from the 'Events & Presentations' page of Vertex's website at www.vrtx.com. To listen to the call on the telephone, dial 1-866-501-1537 (United States and Canada) or 1-720-545-0001 (International). Vertex is also providing a podcast MP3 file available for download on the Vertex website at www.vrtx.com. The conference ID number for the live call and replay is 68267164. The call will be available for replay via telephone commencing May 23, 2011 at 5:00 p.m. ET running through 5:00 p.m. ET on May 30, 2011. The replay phone number for the United States and Canada is 1-800-642-1687. The international replay number is 1-706-645-9291. Following the live webcast, an archived version will be available on Vertex's website until 5:00 p.m. ET on June 6, 2011. To ensure a timely connection, it is recommended that users register at least 15 minutes prior to the scheduled webcast.



**About Hepatitis C**

Hepatitis C is a serious liver disease caused by the hepatitis C virus, which is spread through direct contact with the blood of infected people and ultimately affects the liver.[1] Chronic hepatitis C can lead to serious and life-threatening liver problems, including liver damage, cirrhosis, liver failure or liver cancer.[1] Though many people with hepatitis C may not experience symptoms, others may have symptoms such as fatigue, fever, jaundice and abdominal pain.[1]

Unlike HIV and hepatitis B virus, chronic hepatitis C is curable.[2] However, approximately 60 percent of people do not achieve SVR,[3,4,5] or viral cure,[6] after treatment with 48 weeks of pegylated-interferon and ribavirin alone. If treatment is not successful and a person does not achieve a viral cure, they remain at an increased risk for progressive liver disease.[7,8]

More than 170 million people worldwide are chronically infected with hepatitis C.[6] In the United States, nearly 4 million people have chronic hepatitis C and 75 percent of them are unaware of their infection.[9] Hepatitis C is four times more prevalent in the United States compared to HIV.[9] The majority of people with hepatitis C in the United States were born between 1946 and 1964, accounting for two of every three people with chronic hepatitis C.[10] Hepatitis C is the leading cause of liver transplantations in the United States and is reported to contribute to 4,600 to 12,000 deaths annually.[11,12] By 2029, total annual medical costs in the United States for people with hepatitis C are expected to more than double, from $30 billion in 2009 to approximately $85 billion.[9]

**About Vertex**

Vertex creates new possibilities in medicine. Our team discovers, develops and commercializes innovative therapies so people with serious diseases can lead better lives. Vertex scientists and our collaborators are working on new medicines to cure or significantly advance the treatment of hepatitis C, cystic fibrosis, epilepsy and other life-threatening diseases.

Founded more than 20 years ago in Cambridge, MA, we now have ongoing worldwide research programs and sites in the U.S., U.K. and Canada.

**Special Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding (i) Vertex's sales team being ready to support the introduction of INCIVEK, (ii) Vertex's financial assistance and patient support programs and its commitment to help people who might not otherwise be able to afford INCIVEK receive it and (iii) the use of INCIVEK as a treatment for people with genotype 1 chronic hepatitis C virus infection. While the company believes the forward-looking statements contained in this press release are accurate, there are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements. Those risks and uncertainties include, among other things, risks related to the commercialization of INCIVEK and the other risks listed under Risk Factors in Vertex's annual report and quarterly reports filed with the Securities and Exchange Commission and available through Vertex's website at www.vrtx.com. Vertex disclaims any obligation to update the information contained in this press release as new information becomes available.

For more information and to view Vertex's press releases, please visit www.vrtx.com.

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Photos/Multimedia Gallery Available: http://www.businesswire.com/cgi-bin/mmg.cgi?eid=6733469&lang=en

**Vertex::**
**Media:**
Dawn Kalmar
Amy Pasqua
Zachry Barber
617-444-6992 or mediainfo@vrtx.com
or
**Investors:**
Michael Partridge, 617-444-6108
Lora Pike, 617-444-6755
Matthew Osborne, 617-444-6057

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