Pfizer Logo

# Pfizer Announces The U.S. Availability Of Biosimilar INFLECTRA® (infliximab-dyyb)

Monday, October 17, 2016 - 12:05pm

Company to Begin Shipping to Wholesalers in Late November, 2016

Pfizer Inc. (NYSE:PFE) announced today that the company will begin shipment of INFLECTRA® (infliximab-dyyb)for injection, a biosimilar of REMICADE®1 (infliximab) to wholesalers in the United States (U.S.) in late November 2016.

INFLECTRA will be the first biosimilar monoclonal antibody (mAb) and only the second biosimilar to be available in the U.S. It is approved for the treatment of:

- adult patients and pediatric patients (ages six years and older) with moderate to severely active Crohn's disease who have had an inadequate response to conventional therapy;
- adult patients with moderate to severely active ulcerative colitis who have had an inadequate response to conventional therapy; and
- moderate to severely active rheumatoid arthritis in combination with methotrexate; active ankylosing spondylitis; active psoriatic arthritis; and chronic severe plaque psoriasis.

"Biologics have revolutionized the treatment of many life-threatening and chronic diseases. By introducing INFLECTRA to the U.S. marketplace, Pfizer is helping customers access an additional high quality treatment option that promises greater savings for the healthcare system," said Diem Nguyen, regional president North America, Pfizer Essential Health Business. "We are proud of our global leadership in biosimilars, and will continue our efforts to advance a sustainable, competitive marketplace for these therapies to deliver a high quality, consistent supply of product and long-term savings and value for patients and physicians."

Pfizer holds exclusive commercialization rights to Celltrion's INFLECTRA in the U.S., and has already successfully introduced INFLECTRA in other markets across the globe.

INFLECTRA will be introduced at a 15% discount to the current wholesaler acquisition cost (WAC) of REMICADE®, its reference product. WAC is not inclusive of discounts to payers, providers, distributors and other purchasing organizations.

**IMPORTANT SAFETY INFORMATION AND INDICATIONS**

Only your doctor can recommend a course of treatment after checking your health condition. INFLECTRA® (infliximab-dyyb) can cause serious side effects such as lowering your ability to fight infections. **Some patients, especially those 65 years and older, have had serious infections caused by viruses, fungi or bacteria that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. Some of these infections have been fatal. Your doctor should monitor you closely for signs and symptoms of TB during treatment**

**with INFLECTRA®.**

**Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines. Hepatosplenic T-cell lymphoma, a rare form of fatal lymphoma, has occurred mostly in teenage or young adult males with Crohn's disease or ulcerative colitis who were taking infliximab products and azathioprine or 6-mercaptopurine.** For children and adults taking TNF blockers, including INFLECTRA®, the chances of getting lymphoma or other cancers may increase.

You should discuss any concerns about your health and medical care with your doctor.

**What should I tell my doctor before I take INFLECTRA®?**

You should let your doctor know if you have or ever had any of the following:

- Tuberculosis (TB) or have been near someone who has TB. Your doctor will check you for TB with a skin test. If you have latent (inactive) TB, you will begin TB treatment before you start INFLECTRA®.
- Lived in a region where certain fungal infections like histoplasmosis or coccidioidomycosis are common.
- Infections that keep coming back, diabetes, or an immune system problem.
- Any type of cancer or a risk factor for developing cancer, for example, chronic obstructive pulmonary disease (COPD) or had phototherapy for psoriasis.
- Heart failure or any heart condition. Many people with heart failure should not take INFLECTRA®.
- Hepatitis B virus (HBV) infection or think you may be a carrier of HBV. Your doctor will test you for HBV.
- Nervous system disorders (like multiple sclerosis or Guillain-Barré syndrome).

Also tell your doctor if you:

- Use the medicines Kineret (anakinra), Orencia (abatacept), or Actemra (tocilizumab) or other medicines called biologics used to treat the same problems as INFLECTRA®.
- Are pregnant, plan to become pregnant, are breast-feeding, or have a baby and were using INFLECTRA® during your pregnancy. Tell your baby's doctor about your INFLECTRA® use. If your baby receives a live vaccine within 6 months after birth, your baby may develop infections with serious complications that can lead to death.
- Recently received or are scheduled to receive a vaccine. Adults and children taking INFLECTRA® should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer) while taking INFLECTRA®.

**What should I watch for and talk to my doctor about before or while taking INFLECTRA®?**

The following serious (sometimes fatal) side effects have been reported in people taking INFLECTRA®.

You should tell your doctor right away if you have any of the signs listed below:

- Infections (like TB, blood infections, pneumonia)—fever, tiredness, cough, flu, or warm, red, or painful skin or any open sores. INFLECTRA® can make you more likely to get an infection or make any infection that you have worse.
- Lymphoma or any other cancers in adults and children.
- Skin cancer—any changes in or growths on your skin.
- Heart failure—new or worsening symptoms, such as shortness of breath, swelling of your ankles or feet, or sudden weight gain.

- Reactivation of HBV—feeling unwell, poor appetite, tiredness, fever, skin rash, and/or joint pain.
- Liver injury—jaundice (yellow skin and eyes), dark brown urine, right-sided abdominal pain, fever, or severe tiredness.
- Blood disorders—fever that doesn’t go away, bruising, bleeding, or severe paleness.
- Nervous system disorders—numbness, weakness, tingling, changes in your vision, or seizures.
- Allergic reactions during or after the infusion—hives, difficulty breathing, chest pain, high or low blood pressure, swelling of face and hands, and fever or chills.
- Lupus-like syndrome—chest discomfort or pain that does not go away, shortness of breath, joint pain, rash on the cheeks or arms that gets worse in the sun.
- Psoriasis—new or worsening psoriasis such as red scaly patches or raised bumps on the skin that are filled with pus.

The more common side effects with infliximab products are respiratory infections (that may include sinus infections and sore throat), headache, rash, coughing, and stomach pain.

INFLECTRA® is a prescription medication used to treat:

**Crohn's Disease**

- Can reduce signs and symptoms and induce and maintain remission in adult patients with moderately to severely active Crohn’s disease who haven't responded well to other therapies

**Pediatric Crohn's Disease**

- Can reduce signs and symptoms and induce and maintain remission in children (ages 6-17) with moderately to severely active Crohn's disease who haven't responded well to other therapies

**Ulcerative Colitis**

- Can reduce signs and symptoms, induce and maintain remission, promote intestinal healing, and reduce or stop the need for steroids in adult patients with moderately to severely active ulcerative colitis who haven't responded well to other therapies

**Rheumatoid Arthritis**

- Can reduce signs and symptoms, help stop further joint damage, and improve physical function in patients with moderately to severely active rheumatoid arthritis, in combination with methotrexate

**Ankylosing Spondylitis**

- Can reduce signs and symptoms in patients with active ankylosing spondylitis

**Psoriatic Arthritis**

- Can reduce signs and symptoms of active arthritis, help stop further joint damage, and improve physical function in patients with psoriatic arthritis

**Plaque Psoriasis**

- Approved for the treatment of adult patients with chronic severe (extensive and/or disabling) plaque psoriasis under the care of a physician who will determine if INFLECTRA® is appropriate considering

other available therapies

Please see ***full Prescribing Information*** **for INFLECTRA® (infliximab-dyyb)**.

**About Pfizer: Working together for a healthier world®**

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. For more information, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at @Pfizer and@Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

*DISCLOSURE NOTICE: The information contained in this release is as of October 17, 2016. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information about INFLECTRA (infliximab-dyyb), the timing of Pfizer's planned shipment of INFLECTRA to wholesalers in the United States and Pfizer's plans with respect to biosimilars, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, risks related to the ability to meet anticipated shipment dates; uncertainties regarding the commercial success of INFLECTRA; the uncertainties inherent in research and development; intellectual property and/or litigation implications; relationship with the application sponsor; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of INFLECTRA; and competitive developments.*

*A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 10-Q and Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at* www.sec.govand *www.pfizer.com*.

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1 REMICADE® is a U.S. registered trademark of Janssen Biotech, Inc.

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