



# New Data in Crohn's Disease Patients Shows Similar Efficacy and Safety Profiles for INFLECTRA® and REMICADE® a

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Pfizer in partnership with Celltrion Healthcare presents new data for INFLECTRA in Crohn's disease

Data announced jointly today by Pfizer Inc. (NYSE:PFE) and Celltrion Healthcare, at the 12th Congress of the European Crohn's and Colitis Organisation (ECCO), showed that for patients with moderate-to-severe Crohn's disease (CD), treatment with INFLECTRA (infliximab CT-P13) has similar efficacy and safety to treatment with REMICADE (infliximab).<sup>1</sup> The randomized 54 week clinical trial (RCT)<sup>2</sup> in 214 patients met its primary end point demonstrating that, at six weeks, INFLECTRA was similar to REMICADE in the treatment of CD thereby meeting the criterion for non-inferiority. The trial evaluated the number of patients experiencing a fall of 70 points or greater in the Crohn's Disease Activity Index (CDAI-70), a well-established assessment of treatment response in CD. The response rates, 71.4% for INFLECTRA and 75.2% for REMICADE,<sup>1</sup> were not statistically significantly different. INFLECTRA is marketed as INFLECTRA (infliximab-dyyb) in the United States (U.S.) and under other brand names in some countries.

"Today's presentation of randomized control trial data in patients with Crohn's disease further supports the existing clinical profile of CT-P13 in inflammatory bowel disease. In addition to existing data from the registration studies, real-world experience and the NOR-SWITCH trial, this data adds to the body of evidence supporting use of CT-P13 across its approved indications," said Sam Azoulay, M.D., Senior Vice President, Chief Medical Officer, Pfizer Essential Health, Pfizer. Pfizer Essential Health, Pfizer.

Additional disease activity measures used in the trial, clinical remission and CDAI-100 response rates, demonstrated similar and consistent efficacy between the two treatments. Six-week data also showed that INFLECTRA had a similar safety and tolerability profile as REMICADE. The number of patients experiencing at least one adverse event, serious adverse events, and adverse events of special interest (such as infusion reaction and infection) were similar between the two treatment arms.<sup>1</sup> No new safety signals were identified.

Further results on the longer-term safety and efficacy of INFLECTRA from this ongoing 54-week study in CD are expected later this year. The study is also examining the treatment response and safety profile in patients when switched from REMICADE to INFLECTRA, and from INFLECTRA to REMICADE.<sup>2</sup>

### About the trial

This is a randomized, double-blind, parallel-group, phase III study being conducted in patients with moderately-to-severe Crohn's disease to compare overall safety and efficacy between INFLECTRA and REMICADE in terms of Crohn's Disease Activity Index (CDAI)-70 response rates. The primary endpoint of the 54-week study was collected at week six to demonstrate that INFLECTRA is similar to REMICADE in the treatment of CD. The study used the standard assessment of CDAI-70 as primary endpoint. From Week 30, patients on REMICADE will be randomized to either continue on the same treatment or switch to INFLECTRA while patients on INFLECTRA will be randomized to either continue on the same treatment or switch to the REMICADE. Further results will be collected and reported at 54-weeks.<sup>2</sup>

### ABOUT INFLECTRA:

#### IMPORTANT SAFETY INFORMATION AND INDICATIONS FROM THE U.S. PRESCRIBING INFORMATION

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](http://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](https://www.facebook.com/Pfizer).

DISCLOSURE NOTICE: The information contained in this release is as of February 17, 2017. 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), including its 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, uncertainties regarding the commercial success of INFLECTRA; the uncertainties inherent in research and development, including, without limitation, the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; 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.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com). a REMICADE® is a U.S. registered trademark of Janssen Biotech, Inc. 1 Kim YH., et al., Phase III Randomised, Double-blind, Controlled Trial to Compare Biosimilar Infliximab (CT-P13) with Innovator Infliximab (INX) in Patients with Active Crohn's Disease: Early Efficacy and Safety Results. DOP061, presented at ECCO 2017 2 [ClinicalTrials.gov](http://ClinicalTrials.gov). Demonstrate Noninferiority in Efficacy and to Assess Safety of CT-P13 in Patients With Active Crohn's Disease. Available at: <https://www.clinicaltrials.gov/ct2/show/NCT02096861?term=ct-p13+crohns&rank=1>. Last accessed February 2017

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