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One Year Maintenance and Switching Data in Patients with Crohn's Disease Support the Use of INFLECTRA®* (infliximab CT-P13) in IBD1

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Efficacy and safety profiles including immunogenicity were observed to be comparable between patients maintained on INFLECTRA or REMICADE and those switched to INFLECTRA from REMICADE®**1

New data show that switching patients with Crohn's disease (CD) to INFLECTRA (infliximab CT-P13) from REMICADE (infliximab) led to comparable efficacy, safety and tolerability to treatment with REMICADE over a 24 week period.1 The full 54-week results of the randomized controlled trial comparing INFLECTRA and REMICADE in biologic-naïve patients with active CD support the long-term effectiveness of treatment with INFLECTRA.1 The results also show that INFLECTRA was well-tolerated, with a similar safety profile to REMICADE.1 Pfizer Inc. (NYSE:PFE) and Celltrion Healthcare jointly announced the secondary outcomes from the phase III trial of INFLECTRA in CD at the 25th United European Gastroenterology (UEG) Week.

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*INFLECTRA is marketed as INFLECTRA (infliximab-dyyb) in the United States (U.S.) and under other brand names in some countries. In the EU, INFLECTRA is marketed as INFLECTRA (infliximab CT-P13)
**REMICADE is a U.S. registered trademark of Janssen Biotech, Inc.

"The data announced today show that 24 weeks (six months) after switching from REMICADE to the Infliximab biosimilar CT-P13, patients with Crohn's disease continue to experience similar efficacy, safety and tolerability compared to staying on REMICADE," said Stephen B Hanauer, M.D., Professor of Medicine-Gastroenterology and Hepatology, Feinberg School of Medicine, Northwestern University, US. "These data support previous findings which demonstrate the importance of CT-P13 as a treatment option for patients with Crohn's disease, providing healthcare professionals further confidence when stable patients switch to CT-P13 from REMICADE."

"These new data add to the considerable body of evidence, including real-world studies and the NOR-SWITCH trial, for the switching of stable patients to INFLECTRA," said Sam Azoulay, M.D., Senior Vice President, Chief Medical Officer, Pfizer Essential Health. "Today's announcement further highlights Pfizer's commitment to biosimilars and provides additional evidence supporting use of INFLECTRA in Crohn's disease."

The study previously reported its primary endpoint at six weeks, demonstrating non-inferiority of INFLECTRA compared to REMICADE in the treatment of CD.2

More than 50 real-world studies in IBD have been conducted with INFLECTRA, evaluating over 7,500 IBD patients in real-world settings.2,3,4,5,6,7,8,9,10,11,12,13,14 There is an important and growing body of

evidence for the switching of stable REMICADE patients to INFLECTRA. Clinical studies supporting this switch include NOR-SWITCH,15 BIO-SWITCH,16 PROSIT-BIO3 and now CT-P13 3.4.1,2,17 For example, the NOR-SWITCH study published earlier this year showed that switching from REMICADE to INFLECTRA was not inferior to continued treatment with REMICADE when measured across all adult indications.15

About the trial

This is a randomized, double-blind, parallel-group, phase III study conducted over 54 weeks in 220 patients with active CD to compare overall safety and efficacy between INFLECTRA and REMICADE as determined by the Crohn's Disease Activity Index (CDAI)-70 response rates†.1 The primary endpoint of the 54 week study was collected at week 6 to demonstrate that INFLECTRA is non-inferior to REMICADE in the treatment of CD.2 From Week 30, patients on REMICADE were randomized to either continue on the same treatment or switch to INFLECTRA while patients on INFLECTRA were randomized to either continue on the same treatment or switch to REMICADE.1 Final study results were collected at 54-weeks.1

The pre-specified secondary endpoints reported today include CDAI-70 response rates after week 6, clinical remission,[1] Short Inflammatory Bowel Disease Questionnaire (SIBDQ)[2] results, and safety endpoints including adverse events and immunogenicity. While not powered to draw definitive conclusions, these new data add to the body of evidence supporting use of INFLECTRA in the Crohn's Disease indication, including switch to INFLECTRA from REMICADE.1 Comparable efficacy, as measured by CDAI-70 response and clinical remission after week 6 was observed, and these response rates were maintained and observed to be similar in all study arms at week 54.1 One-year data including adverse drug reactions, serious adverse events and infections were observed to be similar among all treatment groups.1 There were no clinically meaningful differences in immunogenicity results throughout the study period among treatment groups up to week 54.1

† CDAI: Crohn's Disease Activity Index, a recognised measure for the evaluation of disease activity. A response to treatment is measured as a decrease of 70 points or greater (CDAI-70).
[1] Clinical remission: decrease in CDAI >150 points
[2] Short Inflammatory Bowel Disease Questionnaire, a health-related quality of life tool measuring physical, social, and emotional status, and has been predominantly used in trials for Crohn's disease.

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

Paediatric 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, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and 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 30, 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; uncertainties regarding the outcome and impact of the suit filed against Johnson & Johnson; 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, 2016, 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 and www.pfizer.com.

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