Pfizer’s Biosimilar RETACRIT® (epoetin alfa-epbx) Approved by U.S. FDA

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RETACRIT, the First U.S. Biosimilar Erythropoiesis-Stimulating Agent (ESA), Now Approved Across All Indications

Pfizer Inc. (NYSE:PFE) today announced the United States (U.S.) Food and Drug Administration (FDA) approved RETACRIT® (epoetin alfa-epbx), a biosimilar to Epogen® and Procrit® (epoetin alfa)1, for all indications of the reference product. RETACRIT is now the first and only biosimilar erythropoiesis-stimulating agent (ESA) to be approved in the U.S.

“As the first approved epoetin alfa biosimilar in the U.S., RETACRIT may provide patients and their physicians with increased access to a high-quality, lower-cost alternative treatment option for anemia and the reduction of allogeneic red blood cell (RBC) transfusions in certain patients,” said Berk Gurdogan, U.S. Institutions President, Pfizer Essential Health. “We are proud of the progress of our biosimilars program to date, which will help address the evolving needs of patients and the broader healthcare community.”

The FDA approval was based on a comprehensive data package submitted by Pfizer demonstrating a high degree of similarity between RETACRIT and its U.S. reference product, Epogen and Procrit.2

In the U.S., RETACRIT is indicated for:3

Treatment of anemia due to: Chronic Kidney Disease (CKD) in patients on dialysis and not on dialysis. Zidovudine in HIV-infected patients. The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy. Reduction of allogeneic red blood cell (RBC)

transfusions in patients undergoing elective, noncardiac, nonvascular surgery. “With the approval of RETACRIT, healthcare providers now have an additional option to choose from when prescribing an ESA,” said George M. Rodgers, M.D., Ph.D., Professor of Medicine, Division of Hematology and Hematologic Malignancies, Department of Internal Medicine, University of Utah School of Medicine. “By providing potentially more affordable therapeutic options, biosimilar medicines can allow for the reallocation of resources to other areas of cancer care. This is positive news for the oncology community.”

RETACRIT is expected to be available in the U.S. at a significant discount to the current wholesaler acquisition cost (WAC) of Epogen and Procrit. WAC is not inclusive of discounts to payers, providers, distributors and other purchasing organizations.

Pfizer has entered into an agreement with Vifor Pharma Inc. for the commercialization of RETACRIT in certain channels.

RETACRIT is Pfizer’s third approved biosimilar in the U.S. Pfizer’s biosimilars pipeline consists of 11 distinct biosimilar molecules with six assets in mid-to-late stage clinical development.4

RETACRIT® IMPORTANT SAFETY INFORMATION

What is the most important information I should know about RETACRIT?

RETACRIT may cause serious side effects that can lead to death, including:

For people with cancer:

Your tumor may grow faster and you may die sooner if you choose to take RETACRIT. Your healthcare provider will talk with you about these risks.

For all people who take RETACRIT, including people with cancer or chronic kidney disease:

Serious heart problems, such as heart attack or heart failure and stroke. You may die sooner if you are treated with RETACRIT to increase red blood cells (RBCs) to near the same level found in healthy people. **Blood clots.** Blood clots may happen at any time while taking RETACRIT. If you are receiving RETACRIT for any reason and you are going to have surgery, talk to your healthcare provider about whether or not you need to take a blood thinner to lessen the chance of blood clots during or following surgery. Blood clots can form in blood vessels (veins), especially in your leg (deep venous thrombosis or DVT). Pieces of a blood clot may travel to the lungs and block the blood circulation in the lungs (pulmonary embolus). Call your healthcare provider or get medical help right away

if you have any of these symptoms: Chest pain Trouble breathing or shortness of breath Pain in your legs, with or without swelling A cool or pale arm or leg Sudden confusion, trouble speaking, or trouble understanding others' speech Sudden numbness or weakness in your face, arm, or leg, especially on one side of your body Sudden trouble seeing Sudden trouble walking, dizziness, loss of balance or coordination Loss of consciousness (fainting) Hemodialysis vascular access stops working

See **"What are the possible side effects of RETACRIT?"** below for more information.

If you decide to take RETACRIT, your healthcare provider should prescribe the smallest dose of RETACRIT that is necessary to reduce your chance of needing RBC transfusions.

What is RETACRIT?

RETACRIT is a prescription medicine used to treat anemia. People with anemia have a lower-than normal number of RBCs. RETACRIT works like the human protein called erythropoietin to help your body make more RBCs. RETACRIT is used to reduce or avoid the need for RBC transfusions.

RETACRIT may be used to treat anemia if it is caused by:

Chronic kidney disease (you may or may not be on dialysis). Chemotherapy that will be used for at least two months after starting RETACRIT. A medicine called zidovudine (AZT) used to treat HIV infection. RETACRIT may also be used to reduce the chance you will need RBC transfusions if you are scheduled for certain surgeries where a lot of blood loss is expected.

If your hemoglobin level stays too high or if your hemoglobin goes up too quickly, this may lead to serious health problems which may result in death. These serious health problems may happen if you take RETACRIT, even if you do not have an increase in your hemoglobin level.

RETACRIT has not been proven to improve quality of life, fatigue, or well-being.

RETACRIT **should not be used** for treatment of anemia:

If you have cancer and you will not be receiving chemotherapy that may cause anemia. If you have a cancer that has a high chance of being cured. Talk with your healthcare provider about the kind of cancer you have. If your anemia caused by chemotherapy treatment can be managed by RBC transfusion. In place of emergency treatment for anemia (RBC transfusions). RETACRIT should not be used to reduce the chance of RBC

transfusions if:

You are scheduled for surgery on your heart or blood vessels. You are able and willing to donate blood prior to surgery. It is not known if RETACRIT is safe and effective in treating anemia in children less than 1 month old who have chronic kidney disease and in children less than 5 years old who have anemia caused by chemotherapy.

Who should not take RETACRIT?

Do not take RETACRIT if you:

Have cancer and have not been counseled by your healthcare provider about treatment with RETACRIT. Have high blood pressure that is not controlled (uncontrolled hypertension). Have been told by your healthcare provider that you have or have ever had a type of anemia called Pure Red Cell Aplasia (PRCA) that starts after treatment with RETACRIT or other erythropoietin protein medicines. Have had a serious allergic reaction to RETACRIT or other epoetin alfa products.

Before taking RETACRIT, tell your healthcare provider about all of your medical conditions, including if you:

Have heart disease. Have high blood pressure. Have had a seizure (convulsion) or stroke. Have phenylketonuria. RETACRIT contains phenylalanine (a component of aspartame). Receive dialysis treatment Are pregnant or plan to become pregnant. It is not known if RETACRIT may harm your unborn baby. Talk to your healthcare provider about possible pregnancy and birth control choices that are right for you. Are breastfeeding or plan to breastfeed. It is not known if RETACRIT passes into breast milk. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take RETACRIT?

If you or your caregiver has been trained to give RETACRIT shots (injections) at home: Be sure that you read, understand, and follow the “Instructions for Use” that come with RETACRIT. Take RETACRIT exactly as your healthcare provider tells you to. Do not change the dose of RETACRIT unless told to do so by your healthcare provider. Your healthcare provider will show you how much RETACRIT to use, how to inject it, how often it should be injected, and how to safely throw away the used vials, syringes, and needles. If you miss a dose of RETACRIT, call your healthcare provider right away and ask what to do. If you take more than the prescribed dose of RETACRIT, call your healthcare provider right away.

During treatment with RETACRIT, continue to follow your healthcare provider’s instructions for diet and medicines. Have your blood pressure checked as instructed by your healthcare provider.

What are the possible side effects of RETACRIT?

RETACRIT may cause serious side effects, including:

See **“What is the most important information I should know about RETACRIT?”** **High blood pressure.** High blood pressure is a common side effect of RETACRIT in people with chronic kidney disease. Your blood pressure may go up or be difficult to control with blood pressure medicine while taking RETACRIT. This can happen even if you have never had high blood pressure before. Your healthcare provider should check your blood pressure often. If your blood pressure does go up, your healthcare provider may prescribe new or more blood pressure medicine. **Seizures.** If you have any seizures while taking RETACRIT, get medical help right away and tell your healthcare provider. **Antibodies to RETACRIT**. Your body may make antibodies to RETACRIT. These antibodies can block or lessen your body’s ability to make RBCs and cause you to have severe anemia. Call your healthcare provider if you have unusual tiredness, lack of energy, dizziness, or fainting. You may need to stop taking RETACRIT. **Serious allergic reactions**. Serious allergic reactions can cause a skin rash, itching, shortness of breath, wheezing, dizziness and fainting because of a drop in blood pressure, swelling around your mouth or eyes, fast pulse, or sweating. If you have a serious allergic reaction, stop using RETACRIT and call your healthcare provider or get medical help right away. **Severe skin reactions**. Signs and symptoms of severe skin reactions with RETACRIT may include: skin rash with itching, blisters, skin sores, peeling, or areas of skin coming off. If you have any signs or symptoms of a severe skin reaction, stop using RETACRIT and call your healthcare provider or get medical help right away.

Common side effects of RETACRIT include:

joint, muscle, or bone pain fever cough dizziness high blood sugar low potassium levels in the blood chills rash nausea vomiting blood vessel blockage low white blood cells trouble sleeping difficulty swallowing soreness of mouth itching headache respiratory infection weight decrease depression muscle spasm redness and pain at the RETACRIT injection site These are not all of the possible side effects of RETACRIT. Your healthcare provider can give you a more complete list. Tell your healthcare provider about any side effects that bother you or that do not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store RETACRIT?

Do not shake RETACRIT. Store RETACRIT vials in the carton it comes in to protect from light. Store RETACRIT in the refrigerator between 36°F to 46°F (2°C to 8°C). **Do not freeze RETACRIT.** Do not use RETACRIT that has been frozen. Single-dose vials of RETACRIT should be used only one time. Throw the vial away after use even if there is medicine left in the vial.

Keep RETACRIT and all medicines out of the reach of children.

General information about RETACRIT.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RETACRIT for a condition for which it was not prescribed. Do not give RETACRIT to other people even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about RETACRIT that is written for healthcare professionals.

What are the ingredients in RETACRIT?

Active Ingredient: epoetin alfa-epbx

Inactive Ingredients:

All vials contain calcium chloride dehydrate, glycine, isoleucine, leucine, L-glutamic acid, phenylalanine, polysorbate 20, sodium chloride, sodium phosphate dibasic anhydrous, sodium phosphate monobasic monohydrate, and threonine, in water for injection.

Please see full Prescribing Information for RETACRIT (epoetin alfa-epbx), including BOXED WARNING and Medication Guide.

Pfizer Inc.: 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 May 15, 2018. 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 RETACRIT (epoetin alfa-epbx), 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 launch timing and commercial success of RETACRIT in the United States; the uncertainties inherent in research and development; whether and when any applications for RETACRIT or label updates for RETACRIT may be filed with regulatory authorities in any other jurisdictions and whether and when regulatory authorities in other jurisdictions may approve any such other applications that are pending or that may be filed for RETACRIT, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; intellectual property and/or litigation implications; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of RETACRIT; 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, 2017 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.

_____ 1 Epogen® is a registered U.S. trademark of Amgen Inc.; Procrit® is a registered U.S. trademark of Johnson & Johnson 2 U.S. Food & Drug Administration, Oncologic Drugs Advisory Committee Meeting. (2017, May 23). ODAC Briefing Document: BLA 125545 for “Epoetin Hospira”, a proposed biosimilar to

Epogen/Procrit. Retrieved from https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Oncol
3 https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125545s000lbl.pdf 4 Pfizer. (2018, January 30). Pfizer pipeline. Retrieved from https://www.pfizer.com/sites/default/files/product-pipeline/01302018_PipelineUpdate.pdf

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