News Release

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JANSSEN PRODUCTS, LP MODIFIES PRESCRIBING INFORMATION FOR PROCRIT® (Epoetin alfa) IN CHRONIC KIDNEY DISEASE

Revised prescribing information reflects FDA guidance to update labeling for all drugs within ESA class

Horsham, Pa., June 24, 2011 – Janssen Products, LP, formerly Centocor Ortho Biotech Products, L.P., today announced updated prescribing information for PROCRIT® (Epoetin alfa) when used to treat anemia associated with chronic kidney disease (CKD) as part of a U.S. Food and Drug Administration (FDA)-approved class-wide update for erythropoiesis-stimulating agents (ESAs).

The updates include modifications to the Boxed Warning, Warnings and Precautions, Indications and Usage, and Dosage and Administration sections for CKD, which have been revised to clarify important new information based on the totality of clinical data when ESAs are used to increase hemoglobin (Hb) levels beyond labeled guidance.

The updates to the Boxed Warning include language noting the increased risk for death, serious adverse cardiovascular reactions, and stroke when ESAs are administered to target an Hb level of greater than 11 grams per deciliter (g/dL), and that the lowest dose should be used to reduce the need for red blood cell (RBC) transfusions. Additionally, the Dosage and Administration section for patients with CKD-associated anemia who are not on dialysis has been updated to provide indication-specific guidance to prescribers considering ESA treatment.

The updated label states that for patients with CKD who are not on dialysis, physicians should consider initiating treatment with PROCRIT only when the patient's Hb level is less than 10 g/dL, the rate of Hb decline indicates the likelihood of the patient requiring an RBC transfusion, and the goal is reducing the risk of an immune response to donor antigens or other RBC transfusion-related risks. Additional guidance has been

provided to reduce or interrupt the PROCRIT dose if the patient's Hb level exceeds 10 g/dL and to individualize dosing, using the lowest dose of PROCRIT sufficient to reduce the need for RBC transfusions.

"Anemia is a frequent complication of CKD in patients not yet on dialysis as well as in patients on dialysis, and untreated may lead to the requirement for blood transfusions. As CKD severity progresses in patients not on dialysis, anemia becomes more frequent and severe, and is almost universal among patients requiring dialysis," said Thomas Schaible, Ph.D., Vice President, Medical Affairs, Janssen Products, LP. "PROCRIT is an important treatment option for patients with CKD-associated anemia who are not on dialysis and are likely to require transfusion. The revised label provides additional clarification to prescribers on how to use PROCRIT in this patient segment."

Additional modifications have been made to the label to conform to the guidance of the Physician's Labeling Rule (PLR) and to the Medication Guide, which is part of the full prescribing information. The Medication Guide is a component of the ESA Risk Evaluation and Mitigation Strategy (REMS).

As part of the class-wide update for ESAs, the company is notifying health care providers about the updated prescribing information through a joint Dear Health Care Provider letter with Amgen, and will post the letter along with the updated prescribing information on the PROCRIT website, www.PROCRIT.com.

Additional Label Update Details

The CKD section of the updated Boxed Warning of the PROCRIT label now reads:

Chronic Kidney Disease:

- In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL.
- No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.
- Use the lowest PROCRIT dose sufficient to reduce the need for red blood cell (RBC) transfusions *[see Warnings and Precautions (5.1)]*.

The Warnings and Precautions section highlights state that "Using ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular reactions and has not been shown to provide additional benefit." The section advises prescribers to use caution in patients with coexistent cardiovascular disease and stroke.

The Dosage and Administration section has been revised to include additional guidance to prescribers, as follows:

In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL. No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks. Individualize dosing and use the lowest dose of PROCRIT sufficient to reduce the need for RBC transfusions *[see Warnings and Precautions (5.1)]*. Physicians and patients should weigh the possible benefits of decreasing transfusions against the increased risks of death and other serious cardiovascular adverse events *[see Boxed Warning and Clinical Studies (14)].*

For **all** patients with CKD:

When initiating or adjusting therapy, monitor hemoglobin levels at least weekly until stable, then monitor at least monthly. When adjusting therapy consider hemoglobin rate of rise, rate of decline, ESA responsiveness and hemoglobin variability. A single hemoglobin excursion may not require a dosing change.

- Do not increase the dose more frequently than once every 4 weeks. Decreases in dose can occur more frequently. Avoid frequent dose adjustments.
- If the hemoglobin rises rapidly (e.g., more than 1 g/dL in any 2-week period), reduce the dose of PROCRIT by 25% or more as needed to reduce rapid responses.
- For patients who do not respond adequately, if the hemoglobin has not increased by more than 1 g/dL after 4 weeks of therapy, increase the dose by 25%.
- For patients who do not respond adequately over a 12-week escalation period, increasing the PROCRIT dose further is unlikely to improve response and may increase risks. Use the lowest dose that will maintain a hemoglobin level sufficient to reduce the need for RBC transfusions. Evaluate other causes of anemia. Discontinue PROCRIT if responsiveness does not improve.

For patients with CKD **on dialysis**:

- Initiate PROCRIT treatment when the hemoglobin level is less than 10 g/dL.
- If the hemoglobin level approaches or exceeds 11 g/dL, reduce or interrupt the dose of PROCRIT.
- The recommended starting dose for adult patients is 50 to 100 Units/kg 3 times weekly intravenously or subcutaneously. For pediatric patients, a starting dose of 50 Units/kg 3 times weekly intravenously or subcutaneously is recommended. The intravenous route is recommended for patients on hemodialysis.

For patients with CKD **not on dialysis**:

- Consider initiating PROCRIT treatment only when the hemoglobin level is less than 10 g/dL and the following considerations apply:
    - The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion and,
    - reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal.
- If the hemoglobin level exceeds 10 g/dL, reduce or interrupt the dose of PROCRIT, and use the lowest dose of PROCRIT sufficient to reduce the need for RBC transfusions.
- The recommended starting dose for adult patients is 50 to 100 Units/kg 3 times weekly intravenously or subcutaneously.

When treating patients who have chronic kidney disease and cancer, physicians should refer to

Warnings and Precautions (5.1 and 5.3).

Refer patients who self-administer PROCRIT to the Instructions for Use *[see Patient Counseling Information (17)]*.

About PROCRIT® (Epoetin alfa)

PROCRIT is indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion. PROCRIT is indicated for the treatment of anemia due to zidovudine administered at ≤ 4200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL. PROCRIT is indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy. PROCRIT is indicated to reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin > 10 to ≤ 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. PROCRIT is not indicated for patients who are willing to donate autologous blood pre-operatively. PROCRIT has not been shown to improve quality of life, fatigue, or patient well-being.

PROCRIT is not indicated for use:

- In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
- In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- In patients scheduled for surgery who are willing to donate autologous blood.
- In patients undergoing cardiac or vascular surgery.
- As a substitute for RBC transfusions in patients who require immediate correction of anemia.

IMPORTANT SAFETY INFORMATION

WARNINGS: ESAs INCREASE THE RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE

Chronic Kidney Disease:

- **In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL.**
- **No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.**
- **Use the lowest PROCRIT dose sufficient to reduce the need for red blood cell (RBC) transfusions.**

Cancer:

- **ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers.**
- **Because of these risks, prescribers and hospitals must enroll in and comply with the ESA APPRISE Oncology program to prescribe and/or dispense PROCRIT to patients with cancer. To enroll in the ESA APPRISE Oncology Program, visit www.esa-apprise.com or call 1-866-284-8089 for further assistance.**

- **To decrease these risks, as well as the risk of serious cardiovascular and thromboembolic reactions, use the lowest dose needed to avoid red blood cell (RBC) transfusions.**
- **Use ESAs only for anemia from myelosuppressive chemotherapy.**
- **ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure.**
- **Discontinue following the completion of a chemotherapy course.**

Perisurgery:
- **Due to increased risk of deep venous thrombosis (DVT), DVT prophylaxis is recommended.**

(See WARNINGS AND PRECAUTIONS: Increased Mortality, Myocardial Infarction, Stroke, and Thromboembolism, WARNINGS AND PRECAUTIONS: Increased Mortality and/or Increased Risk of Tumor Progression or Recurrence in Patients With Cancer, INDICATIONS AND USAGE, and DOSAGE AND ADMINISTRATION.)

Contraindications
PROCRIT is contraindicated in patients with:
- Uncontrolled hypertension
- Pure red cell aplasia (PRCA) that begins after treatment with PROCRIT or other erythropoietin protein drugs
- Serious allergic reactions to PROCRIT

PROCRIT from multidose vials contains benzyl alcohol and is contraindicated in:
- Neonates, infants, pregnant women, and nursing mothers. When therapy with PROCRIT is needed in neonates and infants, use single-dose vials; do not admix with bacteriostatic saline containing benzyl alcohol.

Additional Important Safety Information

Increased Mortality, Myocardial Infarction, Stroke, and Thromboembolism
- In controlled clinical trials of patients with CKD comparing higher hemoglobin targets (13 - 14 g/dL) to lower targets (9 - 11.3 g/dL), PROCRIT and other ESAs increased the risk of death, myocardial infarction, stroke, congestive heart failure, thrombosis of hemodialysis vascular access, and other thromboembolic events in the higher target groups.
- Using ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular reactions and has not been shown to provide additional benefit. Use caution in patients with coexistent cardiovascular disease and stroke. Patients with CKD and an insufficient hemoglobin response to ESA therapy may be at even greater risk for cardiovascular reactions and mortality than other patients. A rate of hemoglobin rise of greater than 1 g/dL over 2 weeks may contribute to these risks.
- In controlled clinical trials of patients with cancer, PROCRIT and other ESAs increased the risks for death and serious adverse cardiovascular reactions. These adverse reactions included myocardial infarction and stroke.
- In controlled clinical trials, ESAs increased the risk of death in patients undergoing coronary artery bypass graft surgery (CABG) and the risk of deep venous thrombosis (DVT) in patients undergoing orthopedic procedures.

Increased Mortality and/or Increased Risk of Tumor Progression or Recurrence in Patients With Cancer

- ESAs resulted in decreased locoregional control/progression-free survival and/or overall survival. These findings were observed in studies of patients with advanced head and neck cancer receiving radiation therapy, in patients receiving chemotherapy for metastatic breast cancer or lymphoid malignancy, and in patients with non-small cell lung cancer or various malignancies who were not receiving chemotherapy or radiotherapy.

Hypertension

- PROCRIT is contraindicated in patients with uncontrolled hypertension. Following initiation and titration of PROCRIT, approximately 25% of patients on dialysis required initiation of or increases in antihypertensive therapy; hypertensive encephalopathy and seizures have been reported in patients with CKD receiving PROCRIT.
- Appropriately control hypertension prior to initiation of and during treatment with PROCRIT. Reduce or withhold PROCRIT if blood pressure becomes difficult to control. Advise patients of the importance of compliance with antihypertensive therapy and dietary restrictions.

Seizures

- PROCRIT increases the risk of seizures in patients with CKD. During the first several months following initiation of PROCRIT, monitor patients closely for premonitory neurologic symptoms. Advise patients to contact their healthcare practitioner for new-onset seizures, premonitory symptoms or change in seizure frequency.

Lack or Loss of Hemoglobin Response to PROCRIT

- For lack or loss of hemoglobin response to PROCRIT, initiate a search for causative factors (e.g., iron deficiency, infection, inflammation, bleeding). If typical causes of lack or loss of hemoglobin response are excluded, evaluate for PRCA. In the absence of PRCA, follow dosing recommendations for management of patients with an insufficient hemoglobin response to PROCRIT therapy.

Pure Red Cell Aplasia

- Cases of PRCA and of severe anemia, with or without other cytopenias that arise following the development of neutralizing antibodies to erythropoietin have been reported in patients treated with PROCRIT. This has been reported predominantly in patients with CKD receiving ESAs by subcutaneous administration. PRCA has also been reported in patients receiving ESAs for anemia related to hepatitis C treatment (an indication for which PROCRIT is not approved).
- If severe anemia and low reticulocyte count develop during treatment with PROCRIT, withhold PROCRIT and evaluate patients for neutralizing antibodies to erythropoietin. Contact Janssen Products, LP at 1-800-JANSSEN (1-800-526-7736) to perform assays for binding and neutralizing antibodies. Permanently discontinue PROCRIT in patients who develop PRCA following treatment with PROCRIT or other erythropoietin protein drugs. Do not switch patients to other ESAs.

Serious Allergic Reactions

- Serious allergic reactions, including anaphylactic reactions, angioedema, bronchospasm, skin rash, and urticaria may occur with PROCRIT. Immediately and permanently discontinue PROCRIT and administer appropriate therapy if a serious allergic or anaphylactic reaction occurs.

Laboratory Monitoring

- Evaluate transferrin saturation and serum ferritin prior to and during PROCRIT treatment. Administer supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation

is less than 20%. The majority of patients with CKD will require supplemental iron during the course of ESA therapy. Following initiation of therapy and after each dose adjustment, monitor hemoglobin weekly until the hemoglobin level is stable and sufficient to minimize the need for RBC transfusion.

PROCRIT is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

Anemia in Patients with Chronic Kidney Disease Not on Dialysis

- Consider initiating PROCRIT treatment only when the hemoglobin level is less than 10 g/dL and:
  - The patient's rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion and
  - Reducing the risk of alloimmunization and/or other RBC transfusion related risks is a goal.
- If the hemoglobin level exceeds 10 g/dL, reduce or interrupt the dose of PROCRIT, and use the lowest dose of PROCRIT sufficient to reduce the need for RBC transfusions.
- When initiating or adjusting therapy, monitor hemoglobin levels at least weekly until stable then monitor at least monthly. When adjusting therapy consider hemoglobin rate of rise, rate of decline, ESA responsiveness and hemoglobin variability. A single hemoglobin excursion may not require a dosing change.
  - Do not increase the dose more frequently than once every 4 weeks. Decreases in dose can occur more frequently. Avoid frequent dose adjustments.
  - If the hemoglobin rises rapidly (e.g. more than 1 g/dL in any 2-week period), reduce the dose of PROCRIT by 25% or more as needed to reduce rapid responses.
  - For patients who do not respond adequately, if the hemoglobin has not increased by more than 1 g/dL after 4 weeks of therapy, increase the dose by 25%.
  - For patients who do not respond adequately over a 12-week escalation period, increasing the PROCRIT dose further is unlikely to improve response and may increase risks. Use the lowest dose that will maintain a hemoglobin level sufficient to reduce the need for RBC transfusions. Evaluate other causes of anemia. Discontinue PROCRIT if responsiveness does not improve.
- Adverse reactions in ≥ 5% of PROCRIT-treated patients in clinical studies were hypertension and arthralgia.

Chemotherapy-Induced Anemia

- PROCRIT is not indicated for use in patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy.
- PROCRIT is not indicated for use in patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure.
- Initiate PROCRIT in patients on cancer chemotherapy only if the hemoglobin is less than 10 g/dL, and if there is a minimum of two additional months of planned chemotherapy.
- Use the lowest dose of PROCRIT necessary to avoid RBC transfusions.
- Reduce dose by 25% if:
  - Hemoglobin increases greater than 1 g/dL in any 2-week period or
  - Hemoglobin reaches a level needed to avoid RBC transfusion.
- Withhold dose if hemoglobin exceeds a level needed to avoid RBC transfusion. Reinitiate at a dose 25% below the previous dose when hemoglobin approaches a level where RBC transfusions may be required.
- Adverse reactions in ≥ 5% of PROCRIT-treated patients in clinical studies were nausea, vomiting, myalgia, arthralgia, stomatitis, cough, weight decrease, leukopenia, bone pain, rash, hyperglycemia, insomnia, headache, depression, dysphagia, hypokalemia, and thrombosis.

Surgery/Perisurgery

- PROCRIT is not indicated for use in patients scheduled for surgery who are willing to donate autologous blood.
- PROCRIT is not indicated for use in patients undergoing cardiac or vascular surgery.
- Deep venous thrombosis prophylaxis is recommended during PROCRIT therapy.
- Adverse reactions in ≥ 5% of PROCRIT-treated patients in clinical studies were nausea, vomiting, pruritus, headache, injection site pain, chills, deep vein thrombosis, cough, and hypertension.

Anemia in Zidovudine-treated HIV-infected Patients

- Withhold PROCRIT if hemoglobin exceeds 12 g/dL. Resume therapy at a dose 25% below the previous dose when hemoglobin declines to less than 11 g/dL.
- Discontinue PROCRIT if an increase in hemoglobin is not achieved at a dose of 300 Units/kg for 8 weeks.
- Adverse reactions in ≥ 5% of PROCRIT-treated patients in clinical studies were pyrexia, cough, rash, and injection site irritation.

The full PROCRIT prescribing information, including Boxed WARNINGS, will be available at www.PROCRIT.com.

About Janssen Products, LP

Janssen Products, LP redefines the standard of care in immunology, oncology, urology and nephrology. Built upon a pioneering history, Janssen Products harnesses innovations in large-molecule and small-molecule research to create important new therapeutic options. Beyond its innovative medicines, Janssen Products is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates, and health care professionals have access to the latest treatment information, support services, and quality care. Janssen Products, LP is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Products, LP and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; trends toward health care cost containment; and increased scrutiny of the healthcare industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 2, 2011. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Janssen Products, LP nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

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