Centocor Ortho Biotech Data to be Presented at American Society of Clinical Oncology (ASCO) Annual Meeting

HORSHAM, Pa., May 28, 2009 /PRNewswire via COMTEX News Network/ -- Centocor Ortho Biotech Products, L.P. today announced that data related to several compounds will be presented at the 45th American Society of Clinical Oncology (ASCO) Annual Meeting in Orlando, Fla., from May 29 to June 2, 2009. The studies were sponsored by Centocor Ortho Biotech Products, L.P. or its research partner, Ortho Biotech Oncology Research and Development, a unit of Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

"We are pleased that ASCO has accepted these data for presentation at their annual meeting," said Thomas Schaible, Vice President, Medical Affairs, Centocor Ortho Biotech. "Through our ongoing investigation of key clinical compounds, Centocor Ortho Biotech is committed to advancing the understanding of the therapeutic options it offers to patients fighting cancer."

Data from the following studies have been selected for presentation and posters:

-- Relationship of rapid M protein reduction to outcomes in a trial of pegylated liposomal doxorubicin (PLD) plus bortezomib (B) versus B alone in previously treated multiple myeloma (MM) (Abstract 8591) General Poster Session, Saturday May 30, 8:00 am to 12:00 pm, Level 2, West Hall C

Authors: J. J. Shah, A. Londhe, K. C. Lantz, C. Lowery, R. Z. Orlowski; University of Texas M. D. Anderson Cancer Center, Houston, TX; Centocor Ortho Biotech Services LLC, Horsham, PA

-- Correlation of CA-125 and RECIST evaluation in recurrent ovarian cancer (ROC): Results from a randomized phase III study of trabectedin (T) with pegylated liposomal doxorubicin (PLD) versus PLD alone (Abstract 5550)

General Poster Session, Sunday May 31, 2:00 pm to 6:00 pm, Level 2, West Hall C

Authors: T. J. Herzog, J. B. Vermorken, E. Pujade-Lauraine, J. Li, E. Bayever, J. Gomez, A. Yovine, B. J. Monk; Columbia University Medical Center, New York, NY; University Hospital Antwerp, Antwerp, Belgium; Hopital Hotel-Dieu, Paris, France; Johnson & Johnson PRD, USA, Raritan, NJ; PharmaMar SAU, Colmenar Viejo, Madrid, Spain; University of California Irvine Medical Center, Orange, CA

-- Circulating tumor cells (CTC) in a study of relapsed/recurrent advanced ovarian cancer: An exploratory analysis in the OVA-301 phase III study of pegylated liposomal doxorubicin (PLD) compared with trabectedin and PLD (Abstract 5551)

General Poster Session, Sunday May 31, 2:00 pm to 6:00 pm, Level 2, West Hall C

Authors: A. Poveda, S. B. Kaye, R. T. McCormack, S. Wang, D. Ricci, E. Broderick, T. Parekh, C. Lebedinsky, J. C. Tecero, B. J. Monk; Instituto Valenciano de Oncologia, Valencia, Spain; The Royal Marsden Hospital, Sutton, United Kingdom; Ortho Clinical Diagnostics, Raritan, NJ; Ortho Biotech Oncology Research & Development, Raritan, NJ; PharmaMar SAU, Madrid, Spain; University of California Irvine Medical Center, Orange, CA

-- Early hemoglobin decline and survival prognosis in epoetin alfa studies (Abstract 9625)

General Poster Session, Monday June 1, 8:00 am to 12:00 pm, Level 2, West Hall C

Authors: J. A. Berlin, P. J. Bowers, S. Rao, S. Sun, K. Liu, D. H. Henry; Johnson & Johnson PRD, Titusville, NJ; Johnson & Johnson PRD, Raritan, NJ; Pennsylvania Onc Hem Assoc, Philadelphia, PA

- Health-related quality of life/patient-reported outcomes in relapsed ovarian cancer: Results from a randomized phase III study of trabectedin with pegylated liposomal doxorubicin (PLD) versus PLD alone (Abstract 5526)

Poster Discussion, Monday June 1, 2:00 pm to 6:00 pm, Level 3, W340A

Discussion, Monday June 1, 5:00 pm to 6:00 pm, Level 2, West Hall F3

Authors: C. N. Krasner, A. Poveda, T. Herzog, J. Vermorken, B. Monk, P. Zintl, J. Li, Y. Su, R. Dhawan, S. Kaye; Massachusetts General Hospital, Boston, MA; Fundacion Instituto Valenciano de Oncologia, Valencia, Spain; Columbia University Medical Center, New York, NY; Universitair Ziekenhuis Antwerpen, Edegem, Belgium; Chao Family Comprehensive Cancer Center UC, Orange, CA; PharmaMar SAU, Madrid, Spain; Johnson & Johnson, Raritan, NJ; Royal Marsden Hospital, Sutton, United Kingdom

About DOXIL(R) (doxorubicin HCl liposome injection)

DOXIL is indicated for the treatment of patients with ovarian cancer whose disease has progressed or recurred after prior platinum based therapy. DOXIL in combination with VELCADE(R) (bortezomib) is indicated for the treatment of patients with multiple myeloma who have not previously received VELCADE and have received at least one prior therapy. DOXIL is also indicated for the treatment of AIDS-related Kaposi's sarcoma in patients after failure of prior systemic chemotherapy or intolerance to such therapy.

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS:

Cardiotoxicity, infusion reaction, myelosuppression, liver impairment, substitution

- The use of DOXIL may lead to cardiac toxicity. Myocardial damage may lead to congestive heart failure and may occur as the total cumulative dose of doxorubicin HCl approaches 550 mg/m2
  - Prior use of other anthracyclines or anthracenediones should be included in calculations of total cumulative dose
  - Cardiac toxicity may also occur at lower cumulative doses (400 mg/m2) in patients with prior mediastinal irradiation or who are receiving concurrent cyclophosphamide therapy
- Acute infusion-related reactions including, but not limited to, flushing, shortness of breath, facial swelling, headache, chills, back pain, tightness in the chest or throat, and/or hypotension have occurred in up to 10% of patients treated with DOXIL. In most patients, these reactions have resolved within several hours to a day once the infusion is terminated. In some patients, reactions resolved with slowing of the infusion rate
  - Serious and sometimes life-threatening or fatal allergic/anaphylactoid-like infusion reactions have occurred. Medications to treat such reactions, as well as emergency equipment, should be available for immediate use
  - The initial rate of infusion should be 1 mg/min to minimize the risk of infusion reactions
- Severe myelosuppression may occur
- DOXIL dosage should be reduced in patients with impaired hepatic function

- Accidental substitution has resulted in severe side effects. Do not substitute for doxorubicin HCl on a mg per mg basis

Contraindications

- Patients with a history of hypersensitivity reactions to a conventional doxorubicin formulation or the components of DOXIL
- Nursing mothers

Additional Safety Information

- Cardiac function should be carefully monitored
  - Congestive heart failure or cardiomyopathy may occur after discontinuation of anthracycline therapy
  - For patients with a history of cardiovascular disease, or if the results of cardiac monitoring indicate possible cardiac injury, the benefit of therapy must be weighed against the risk of myocardial injury
  - In the randomized multiple myeloma study, 25 patients (8%) in the VELCADE for Injection arm and 42 patients (13%) in the VELCADE plus DOXIL arm experienced left ventricular ejection fraction decrease (defined as absolute decrease greater than or equal to 15% over baseline or a greater than or equal to 5% decrease below institutional lower limit of normal)
- Myelosuppression may occur; frequently monitor complete blood count (including platelet count), at least prior to each dose of DOXIL
  - In patients with recurrent ovarian cancer or AIDS-related Kaposi's sarcoma, hematologic toxicity (based on platelet count or absolute neutrophil count) may require dose reduction or delay in administration of DOXIL
  - In patients with multiple myeloma, hematologic toxicity (based on platelet count, absolute neutrophil count, hemoglobin level, or neutropenia with fever) may require dose reduction, delay in administration, or suspension of DOXIL and/or VELCADE
  - Persistent severe myelosuppression may result in superinfection, neutropenic fever, or hemorrhage
  - Sepsis occurring during neutropenia has resulted in discontinuation of treatment and in rare cases of death
- DOXIL may potentiate the toxicity of other anticancer therapies, especially hematologic toxicities, when used in combination with other therapies that suppress bone marrow
- Hand-foot syndrome (HFS) may occur during therapy with DOXIL
  - Based on HFS toxicity grade, dose reduction, or delay in administration, or discontinuation of DOXIL may be required
  - HFS was generally observed after 2 to 3 cycles of treatment, but may occur earlier
  - The reaction was mild in most patients, resolving in 1 to 2 weeks
  - The reaction can be severe and debilitating in some patients, resulting in discontinuation of therapy
- DOXIL is an irritant, not a vesicant; use precautions to avoid extravasation
- DOXIL can cause fetal harm when used during pregnancy
- Recall reaction has occurred with DOXIL administration after radiotherapy
- DOXIL may interact with drugs known to interact with the conventional formulation of doxorubicin HCl
- In patients with recurrent ovarian cancer, the most common all-grade adverse reactions (ARs) >20% (DOXIL vs topotecan, respectively) included: asthenia (40% vs 51%), fever (21% vs 31%), nausea (46% vs 63%), stomatitis (41% vs 15%), vomiting (33% vs 44%), diarrhea (21% vs 35%), anorexia (20% vs 22%), dyspnea (15% vs 23%), HFS (51% vs 1%), and rash (29% vs 12%)

- In addition, 19% vs 52.3% reported alopecia (all grades)
- Grade 3/4 hematologic ARs reported in >5% (DOXIL vs topotecan, respectively) were neutropenia (12% vs 76%) and anemia (6% vs 29%)

- In patients with multiple myeloma, the most common all-grade ARs >20% (VELCADE plus DOXIL vs VELCADE, respectively) included: neutropenia (36% vs 22%), thrombocytopenia (33% vs 28%), anemia (25% vs 21%), fatigue (36% vs 28%), pyrexia (31% vs 22%), asthenia (22% vs 18%), nausea (48% vs 40%), diarrhea (46% vs 39%), vomiting (32% vs 22%), constipation (31% vs 31%), mucositis/stomatitis (20% vs 5%), peripheral neuropathy (42% vs 45%), neuralgia (17% vs 20%), and rash (22% vs 18%)
  - In addition, 19% vs <1% reported HFS

- In patients with AIDS related Kaposi's sarcoma, ARs reported in greater than or equal to 5% of DOXIL-treated patients were: neutropenia (ANC <1000/mm3, 46%; <500/mm3, 11%), anemia (Hb <10 g/dL, 58%; <8 g/dL, 16%), thrombocytopenia (<150,000 platelets/mm3, 61%), nausea (18%), asthenia (7%), fever (8%), alopecia (9%), vomiting (8%), diarrhea (5%), and stomatitis (5%)

Please see accompanying full Prescribing Information, including Boxed WARNINGS.

DOXIL is marketed in the United States by Centocor Ortho Biotech Products, L.P., and in Israel by Janssen-Cilag. Schering-Plough Corporation, under a licensing agreement, has exclusive rights to market the medication as CAELYX throughout the rest of the world, excluding Japan and Israel. For more information about DOXIL, please visit www.DOXIL.com.

About PROCRIT (Epoetin alfa)

PROCRIT is used for the treatment of anemia in patients with most types of cancer receiving chemotherapy, with chronic renal failure who are on dialysis and those who are not on dialysis, who are being treated with zidovudine for HIV infection, and to reduce the need for transfusion in anemic patients who are scheduled for elective noncardiac, nonvascular surgery. Depending on the country in which Epoetin alfa is marketed, these indications may differ.

Important Safety Information

WARNINGS: Increased Mortality, Serious Cardiovascular and Thromboembolic Events, and increased risk of tumor progression OR recurrence

Renal failure: Patients experienced greater risks for death and serious cardiovascular events when administered erythropoiesis-stimulating agents (ESAs) to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies. Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.

Cancer:

- ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in some clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers (see WARNINGS: Table 1).
- To decrease these risks, as well as the risk of serious cardio- and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusion.
- Use ESAs only for treatment of anemia due to concomitant myelosuppressive chemotherapy.
- ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure.

- Discontinue following the completion of a chemotherapy course.

Perisurgery: PROCRIT (Epoetin alfa) increased the rate of deep venous thromboses in patients not receiving prophylactic anticoagulation. Consider deep venous thrombosis prophylaxis.

Contraindications

- PROCRIT is contraindicated in patients with uncontrolled hypertension or with known hypersensitivity to albumin (human) or mammalian cell-derived products.

Additional Important Safety Information

- Patients with chronic renal failure experienced greater risks for death and serious cardiovascular events (including myocardial infarction, stroke, congestive heart failure, and hemodialysis vascular access thrombosis) when administered ESAs to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL) in two clinical studies; these risks also increased in controlled clinical trials of patients with cancer. A rate of hemoglobin rise of 1 g/dL over 2 weeks may contribute to these risks.
- Dose of PROCRIT
  - Chronic renal failure patients: The dose of PROCRIT should be titrated for each patient to achieve and maintain hemoglobin levels between 10 to 12 g/dL. If a patient does not attain hemoglobin levels of 10 to 12 g/dL despite 12 weeks of appropriate PROCRIT therapy, see DOSAGE and ADMINISTRATION in the PROCRIT Prescribing Information.
  - Cancer patients: PROCRIT therapy should not be initiated at hemoglobin levels greater than or equal to 10 g/dL. The dose of PROCRIT should be titrated for each patient to achieve and maintain the lowest hemoglobin level sufficient to avoid the need for blood transfusion. Discontinue if after 8 weeks of therapy there is no response as measured by hemoglobin levels or if transfusions are still required (see recommended Dose Modification section in DOSAGE and ADMINISTRATION of the PROCRIT Prescribing Information).
  - HIV patients: The dose of PROCRIT should be titrated for each patient to achieve and maintain the lowest hemoglobin level sufficient to avoid transfusion and not to exceed the upper safety limit of 12 g/dL.
- Monitor hemoglobin regularly during therapy, weekly until hemoglobin becomes stable.
- Cases of pure red cell aplasia (PRCA) and of severe anemia, with or without other cytopenias, associated with neutralizing antibodies to erythropoietin have been reported in patients treated with PROCRIT predominantly in patients with chronic renal failure receiving PROCRIT by subcutaneous administration. PRCA has also been reported in patients receiving ESAs while undergoing treatment for Hepatitis C with interferon and ribavirin. If any patient develops a sudden loss of response to PROCRIT, accompanied by severe anemia and low reticulocyte count, and anti-erythropoietin antibody-associated anemia is suspected, withhold PROCRIT and other erythropoietic proteins. Contact ORTHO BIOTECH (1-888-2ASKOBI or 1-888-227-5624) to perform assays for binding and neutralizing antibodies. If erythropoietin antibody-mediated anemia is confirmed, PROCRIT should be permanently discontinued and patients should not be switched to other erythropoietic proteins.
- The safety and efficacy of PROCRIT therapy have not been established in patients with a known history of a seizure disorder or underlying hematologic disease (e.g., sickle cell anemia, myelodysplastic syndromes, or hypercoagulable disorders).
- In some female patients, menses have resumed following PROCRIT therapy; the possibility of pregnancy should be discussed and the need for contraception evaluated.
- Prior to and regularly during PROCRIT therapy monitor iron status; transferrin saturation should be greater than or equal to 20% and

ferritin should be greater than or equal to 100 ng/mL. During therapy absolute or functional iron deficiency may develop and all patients will eventually require supplemental iron to adequately support erythropoiesis stimulated by PROCRIT.

-- Treatment of patients with grossly elevated serum erythropoietin levels (e.g., >200 mUnits/mL) is not recommended.

-- During PROCRIT therapy, blood pressure should be monitored carefully and aggressively managed, particularly in patients with an underlying history of hypertension or cardiovascular disease.

-- In studies, the most common side effects included fever (pyrexia), diarrhea, nausea, vomiting, swelling of hands or feet (edema), lack or loss of strength or weakness (asthenia, fatigue), shortness of breath, high blood pressure, headache, joint pain (arthralgias), abnormal skin sensations (as tingling or tickling or itching or burning; paresthesia), rash, constipation and upper respiratory infection.

Please visit www.procrit.com for the full Prescribing Information, including the Boxed WARNINGS, and for the Medication Guide and Patient Instructions for Use.

About Trabectedin

Trabectedin is a novel cytotoxic antitumor agent that was originally derived from the Caribbean tunicate, Ecteinascidia turbinate ("sea squirt"). The compound is now produced synthetically. Trabectedin binds to the minor groove of DNA, interfering with cell division and genetic transcription processes and DNA repair machinery. Trabectedin is currently in Phase 3 development in ovarian cancer and to expand its uses in sarcoma.

According to the licensing agreement, PharmaMar SAU has rights to market the compound in Europe and Japan, while Centocor Ortho Biotech Products, L.P. has marketing rights for the product in the rest of the world.

About Centocor Ortho Biotech Products, L.P.

Centocor Ortho Biotech redefines the standard of care in immunology, nephrology, and oncology. The company was formed when Centocor, Inc. and Ortho Biotech Products, L.P. were consolidated in late 2008, and was renamed Centocor Ortho Biotech. Built upon a pioneering history, Centocor Ortho Biotech harnesses innovations in large-molecule and small-molecule research to create important new therapeutic options. Beyond its innovative medicines, Centocor Ortho Biotech is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates, and healthcare professionals have access to the latest treatment information, support services, and quality care.

Note: This release corresponds to ASCO abstracts 5526, 5550, 5551, 8591 and 9625

SOURCE Centocor Ortho Biotech Products, L.P.

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