Comisión Nacional del Mercado de Valores
Att. Director del Área de Mercados
Paseo de la Castellana nº 19
28046 Madrid

Madrid, a 20 de noviembre de 2008

En relación con el Hecho Relevante publicado en el día de hoy bajo el número 100535, y en el que se informa de la presentación por Ortho Biotech Products, L.P. a la FDA (U.S. Food and Drug Administration) de una solicitud de autorización de comercialización (New Drug Application (NDA)) para Yondelis® en combinación con DOXIL® para el tratamiento del cáncer de ovario refractario, se adjunta nota de prensa que dicha Compañía ha distribuido a los medios de comunicación.

Atentamente,

Sebastián Cuenca
Secretario del Consejo de Administración
Zeltia, S.A.

NEWS

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ORTHO BIOTECH ANNOUNCES NDA SUBMISSION FOR TRABECTEDIN FOR THE TREATMENT OF RELAPSED OVARIAN CANCER

Bridgewater, N.J. (November 20, 2008) – Ortho Biotech Products, L.P. today announced the submission of a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for trabectedin when administered in combination with DOXIL® (pegylated liposomal doxorubicin) for the treatment of women with relapsed ovarian cancer (ROC). If approved, trabectedin combined with DOXIL will provide a new, non-platinum treatment option for these patients in the United States.

The application follows the completion of a multicenter, randomized Phase III study, ET743-OVA-301, one of the largest studies conducted in ROC, comparing the combination of trabectedin and DOXIL to DOXIL alone in 672 patients. The study showed that patients treated with the combination treatment had a statistically significant improvement in the primary endpoint of progression-free survival (PFS, or the length of time during and after treatment in which the disease does not progress) compared to patients treated with DOXIL alone.

"This is a significant milestone in the development of trabectedin, an agent with a novel mechanism of action that holds promise for patients with relapsed ovarian cancer," said Craig Tendler, M.D., vice president, Medical Affairs, Oncology/ Nephrology, Ortho Biotech Products,

L.P. "We are confident in the strength of the data supporting the application and look forward to working with the FDA throughout the regulatory review process."

Relapsed ovarian cancer refers to epithelial carcinoma of the ovary that recurs after treatment. According to the National Cancer Institute (NCI), it is estimated that 21,650 women will be diagnosed with, and 15,520 women will die from ovarian cancer in the U.S. in 2008.

Trabectedin is being developed under a license from PharmaMar, and DOXIL is marketed by Ortho Biotech Products, L.P. in the U.S.

About the ET743-OVA-301 Study

Patients were enrolled at 124 centers in 21 countries. Per the study protocol, the data was evaluated by a blinded, independent radiology review and a blinded, independent oncology review. The trabectedin/DOXIL combination demonstrated a statistically significant improvement in PFS compared to DOXIL alone (median PFS 7.3 versus 5.8 months, respectively) and a statistically significant reduction of 21% in the risk of progression or death during the observation period in the independent review of patients with radiologically measurable disease (HR=0.79, 95% CI (0.65;0.96), p=0.0190). This result is consistent with the results of the independent oncology review that takes into account clinical as well as imaging data in the assessment of progression. In this review, there was a 28% risk reduction for disease progression or death with the trabectedin/DOXIL combination (HR = 0.72, 95% CI (0.60; 0.88), p = 0.0008).

Secondary endpoints included response rate, overall survival, and safety. A statistically significant increase in response rate was seen with the trabectedin and DOXIL combination (28%) compared to DOXIL alone (19%), as measured by the independent radiology review. A final protocol-specified survival analysis is planned after the occurrence of 520 events. The safety profile in the study was consistent with previous experience with trabectedin and DOXIL.

The most common adverse reactions (≥20%) for the trabectedin/DOXIL combination compared to DOXIL alone, respectively were:

- Hematological reactions including neutropenia (77% versus 38%, with febrile neutropenia occurring in 8% of the cases and sepsis in 1% of the cases), leucopenia (48% versus 26%), anemia (48% versus 25%) and thrombocytopenia (36% versus 8%);
- Gastrointestinal reactions including nausea (74% versus 42%), vomiting (56% versus 30%) and diarrhea (26% versus 19%);
- Liver enzyme (transaminase) elevations were more common in the combination arm, but were generally reversible and not associated with evidence of chronic liver damage or

other clinical consequences. These included increased alanine aminotransferase (55% versus 9%) and increased aspartate aminotransferase (40% versus 10%); and

- Fatigue (46% versus 36%).

Additionally, commonly associated DOXIL adverse events, such as hand-foot syndrome (HFS) and stomatitis, occurred in fewer patients receiving the combination compared to DOXIL alone (24% versus 54% and 20% versus 33%, respectively).

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 III development in ovarian cancer and to expand its uses in sarcoma.

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

About Ortho Biotech Products, L.P.

Ortho Biotech Products, L.P. is a leading biopharmaceutical company devoted to helping improve the lives of patients with cancer and with anemia due to multiple causes, including chronic kidney disease. Since it was founded in 1990, Ortho Biotech and its worldwide affiliates have earned a global reputation for researching, manufacturing and marketing innovative products that enhance patients' health. Located in Bridgewater, N.J., Ortho Biotech is an established market leader in anemia management. The company also markets treatments for recurrent ovarian cancer, rejection of transplanted organs and other serious illnesses. For more information, visit www.orthobiotech.com.

Ortho Biotech Products, L.P. is a member of the Johnson & Johnson Family of Companies.

Forward-Looking Statement

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 Company's expectations and

projections. Risks and uncertainties include general industry conditions and competition; economic conditions, 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; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of the Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2007. Copies of this Form 10-K, as well as subsequent filings, are available online at http://www.sec.gov, www.jnj.com or on request from Johnson & Johnson. The Company does not undertake to update any forward-looking statements as a result of new information or future events or developments.

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