Zeltia

Comisión Nacional del Mercado de Valores
Att. Director del Área de Mercados
C/ Edison nº4
28006 Madrid

Madrid, a 24 de Noviembre de 2014

De conformidad con lo previsto en el artículo 82 de la Ley del Mercado de Valores, por la presente se procede a comunicar el siguiente **HECHO RELEVANTE**:

"Se informa que Janssen Research & Development, LLC ha anunciado la presentación a la FDA (Food and Drug Administration) americana de una solicitud de autorización de comercialización (New Drug Application (NDA)) para Yondelis® para el tratamiento de pacientes con sarcoma de tejidos blandos avanzado que han recibido previamente quimioterapia incluyendo una antraciclina. Se adjunta nota de prensa que dicha Compañía acaba de distribuir a los medios de comunicación".

ZELTIA, S.A.

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Janssen Submits New Drug Application for YONDELIS® (trabectedin) to U.S. FDA for the Treatment of Patients with Advanced Soft Tissue Sarcoma

Additionally, Trabectedin Expanded Access Program Now Allows Entry of Eligible Patients with Previously Treated Advanced Soft Tissue Sarcoma, Including those with Liposarcoma and Leiomyosarcoma

RARITAN, NJ, November 24, 2014 – Janssen Research & Development, LLC (Janssen) has submitted a New Drug Application (NDA) for YONDELIS® (trabectedin) to the U.S. Food and Drug Administration (FDA) for the treatment of patients with advanced soft tissue sarcoma (STS), including liposarcoma and leiomyosarcoma subtypes, who have received prior chemotherapy including an anthracycline.

"We are particularly proud of this filing, as it represents our commitment to YONDELIS and the people it may help," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, Janssen. "The advanced soft tissue sarcoma treatment landscape has been relatively stagnant for decades and it's our hope that YONDELIS will be a new treatment option for people living with this aggressive disease."

Janssen also announced plans to amend the protocol for the Phase 3 randomized, open-label study ET743-SAR-3007, on which the NDA submission is based. The protocol will be revised to offer patients who were randomized to the dacarbazine comparator arm the option of receiving trabectedin treatment at their physician's discretion. This trial is evaluating the safety and efficacy of trabectedin versus dacarbazine for the treatment of advanced liposarcoma and leiomyosarcoma, the most common types of STS in adults, in more than 500 patients previously treated with an anthracycline and ifosfamide, or an anthracycline followed by one additional line of chemotherapy. Results of the study will be presented at a future date.

"Today, we are one step closer to our goal of making another treatment option available for people living with advanced soft tissue sarcoma," said Denise Reinke, President and CEO of Sarcoma Alliance for Research through Collaboration. "People living with this type of cancer are in urgent need of new options to help treat their disease, and we welcome new medicines that may help make a difference in their lives."

In related news, Janssen will be revising the current U.S. trabectedin expanded access program (EAP), ET743-SAR-3002, to allow entry of eligible patients with liposarcoma and leiomyosarcoma. The program was developed to provide trabectedin to eligible patients with previously treated STS who cannot be expected to benefit from limited currently available therapeutic options. Patient enrollment will be extended to those with liposarcoma or leiomyosarcoma as soon as the protocol amendment is implemented at participating sites. Interested patients should discuss the option of accessing trabectedin through the EAP with their physician to understand if this is an appropriate option for them.

Information about the Study ET743-SAR-3007 (NCT01343277) and the EAP treatment protocol (NCT00210665) may be found on www.clinicaltrials.gov. U.S. healthcare professionals may also contact 1-800-JANSSEN.

About Soft Tissue Sarcoma

Soft tissue sarcomas are a type of cancer originating in the soft tissues that connect, support and surround other body structures,[1] such as muscle, fat, blood vessels, nerves, tendons and the lining of joints. More than 12,000 people will be diagnosed[2,3] and approximately 4,700 are expected to die of soft tissue sarcomas in 2014.[3] Leiomyosarcoma is an aggressive type of soft tissue sarcoma[4] that occurs in smooth muscles, such as those in the uterus, gastrointestinal

tract or lining of blood vessels.[1] Liposarcoma originates in fat cells and most commonly occurs in the thigh and abdominal cavity, though it can occur in fat cells in any part of the body.[5,6]

About YONDELIS® (trabectedin)

YONDELIS® (trabectedin) is a novel, multimodal, synthetically produced antitumor agent, originally derived from the sea squirt, Ecteinascidia turbinata. The anti-cancer medicine works by preventing the tumor cells from multiplying and is approved in 76 countries in North America, Europe, South America and Asia for the treatment of advanced soft-tissue sarcomas as a single-agent, and in 69 countries for relapsed ovarian cancer in combination with DOXIL®/CAELYX® (doxorubicin HCl liposome injection).

Under a licensing agreement with PharmaMar, a wholly owned member of the Zeltia Group, Janssen Products, LP has the rights to develop and sell YONDELIS globally except in Europe, where PharmaMar SA holds the rights, and in Japan, where PharmaMar has granted a license to Taiho Pharmaceuticals Co., Ltd. If approved in the U.S., YONDELIS would be commercialized by Janssen Biotech, Inc.

About Janssen Research & Development, LLC

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world. Janssen Research & Development, LLC; Janssen Products, LP; and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit www.janssenrnd.com for more information.

Janssen in Oncology

In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed, and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on hematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualized use of our

therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to laws and regulations, including domestic and foreign health care reforms; and general industry conditions, including trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2013, including in Exhibit 99 thereto, and our subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.)

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[1] Mayo Clinic. Disease Conditions: Soft tissue sarcoma.
Available from: http://www.mayoclinic.org/diseases-conditions/soft-tissue-sarcoma/basics/definition/con-20033386.
Accessed: November 2014.

[2] National Cancer Institute. SEER Cancer Statistics Review 1975-2011. Source SEER 18 areas.

[3] American Cancer Society. What are the Key Statistics About Soft Tissue Sarcomas? Available at: http://www.cancer.org/cancer/sarcoma-adultsofttissuecancer/detailedguide/sarcoma-adult-soft-tissue-cancer-key-statistics. Accessed November 2014.

[4] The Liddy Shriver Sarcoma Initiative. An Introduction to Leiomyosarcoma of the Bone and Soft Tissue.
Available at: http://sarcomahelp.org/leiomyosarcoma.html.
Accessed: November 2014.

[5] The Liddy Shriver Sarcoma Initiative. What is Liposarcoma? Available at:
http://sarcomahelp.org/liposarcoma.html.
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[6] University of Rochester Medical Center. Liposarcoma.
Available at: http://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=134&ContentID=221.
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