NEWS RELEASE

U.S. FDA Grants Priority Review for YONDELIS® (trabectedin) for the Treatment of Patients with Advanced Soft Tissue Sarcoma

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RARITAN, N.J., Feb. 3, 2015 /PRNewswire/ -- Janssen Research & Development, LLC (Janssen) announced today that the U.S. Food and Drug Administration (FDA) has granted Priority Review for the New Drug Application (NDA) for YONDELIS® (trabectedin) to treat patients with advanced soft tissue sarcoma (STS), including liposarcoma and leiomyosarcoma subtypes, who have received prior chemotherapy including an anthracycline. Janssen**submitted the NDA** to the FDA on November 24, 2014.

Priority Review is a designation for a drug that treats a serious condition and may offer major advances in treatment when compared to existing options. A priority review designation means the FDA's goal is to take action, following the two month period for the validation and acceptance of the NDA, within six months as compared to 10 months under standard review.

The filing is based on the Phase 3 randomized, open-label study ET743-SAR-3007. This trial is evaluating the safety and efficacy of trabectedin versus dacarbazine for the treatment of patients with 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.

"We are excited the FDA has granted Priority Review for YONDELIS, as it is an important step forward in making this therapy available to physicians and those living with this aggressive disease," said Peter F. Lebowitz, M.D., Ph.D., Global Oncology Head, 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. In the U.S., nearly 12,000 people will be diagnosed and approximately 4,870 are expected to die of soft tissue sarcomas in 2015.[2] Leiomyosarcoma is an aggressive type of soft tissue sarcoma that occurs in smooth muscles, such as those in the uterus, gastrointestinal tract or lining of blood vessels.[3] 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.[4,5]

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 77 countries, within North America, Europe, South America and Asia, for the treatment of advanced soft-tissue sarcomas as a single-agent, and in 70 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.)

[1]Mayo Clinic. Disease Conditions: Soft tissue sarcoma. Available at: **http://www.mayoclinic.org/diseases-conditions/soft-tissue-sarcoma/basics/definition/con-20033386**. Accessed: January 2015.

[2]National Cancer Institute. Adult Soft Tissue Sarcoma Treatment (PDQ®). Available at: **http://www.cancer.gov/cancertopics/pdq/treatment/adult-soft-tissue-sarcoma/HealthProfessional**. Accessed: January 2015.

[3] The Liddy Shriver Sarcoma Initiative. An Introduction to Leiomyosarcoma of the Bone and Soft Tissue. Available at: **http://sarcomahelp.org/leiomyosarcoma.html**. Accessed: January 2015.

[4] The Liddy Shriver Sarcoma Initiative. What is Liposarcoma? Available at: **http://sarcomahelp.org/liposarcoma.html**. Accessed: January 2015.

[5]University of Rochester Medical Center. Liposarcoma. Available at: **http://www.urmc.rochester.edu/encyclopedia/content.aspx?ContentTypeID=134&ContentID=221**. Accessed: January 2015.

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