TESARO and Medison Enter Into Exclusive Distribution Agreement to Commercialize ZEJULA® in Israel

April 11, 2018

medison.png

- **Agreement covers all indications for ZEJULA, excluding prostate cancer**

ZUG, Switzerland and PETACH TIKVA, Israel, April 11, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, and Medison Pharma Ltd., Israel's leading commercial partner for innovative pharmaceuticals, today announced an exclusive distribution agreement to commercialize ZEJULA® (niraparib), an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor, in Israel. ZEJULA is currently approved in the United States and Europe as a monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete response or partial response to platinum-based chemotherapy, regardless of *BRCA* mutation or biomarker status.

Under terms of the agreement, Medison will have the exclusive right to commercialize ZEJULA in all indications, excluding prostate cancer, in Israel. Medison will also be responsible for any potential patient access programs prior to regulatory approval. Further terms of the agreement were not disclosed.

“TESARO is committed to globalizing our mission, bringing transformative therapies to those facing cancer. This is an important step forward for us and the many patients in Israel who may benefit from ZEJULA,” said Orlando Oliveira, Senior Vice President and General Manager, TESARO International. “We are proud to enter this agreement with Medison which, alongside a track record of bringing important therapies to patients across a number of oncology indications, offers a tremendous potential for collaboration as a source for innovation.”

“We are excited about the opportunity to provide ZEJULA to cancer patients in our region. We plan to expedite access to ZEJULA via an early patient access program and will work closely with regulators to bring ZEJULA to patients here as quickly as possible,” said Meir Jakobsohn, Founder and CEO, Medison Pharma. "Through our corporate venture arm with a dedicated research team, Medison partners with innovative biopharmaceutical companies, providing us access to best-in-class assets across a number of disease areas. We are happy to find in TESARO a partner that understands the mutual value which can be achieved through strategic collaboration.”

ZEJULA is not currently approved for use in Israel.

About ZEJULA® (Niraparib)
Niraparib is marketed in the United States and Europe under trade name ZEJULA. ZEJULA (niraparib) is a poly(ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. In preclinical studies, ZEJULA concentrates in the tumor relative to plasma, delivering greater than 90% durable inhibition of PARP 1/2 and a persistent antitumor effect.

ZEJULA is the most utilized PARP inhibitor among women with ovarian cancer in the U.S., with more than 4,000 patients treated in 2017. Following European Commission approval in November 2017, ZEJULA is the first and only PARP inhibitor in Europe authorized for marketing for the maintenance treatment of patients with recurrent ovarian cancer, regardless of *BRCA* mutation status. TESARO’s clinical development program for ZEJULA incorporates monotherapy and combination approaches for multiple tumor types including ovarian, breast, and lung cancer.

Janssen Biotech has licensed rights to develop and commercialize ZEJULA specifically for patients with prostate cancer worldwide, except in Japan. Takeda Pharmaceutical Company Limited has licensed rights for all potential indications for ZEJULA in Japan, as well as rights in South Korea, Taiwan, Russia and Australia, excluding prostate cancer. TESARO has an agreement with Zai Lab for the clinical development and co-marketing of ZEJULA in China.

ZEJULA Select Important Safety Information
Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) was reported in patients treated with ZEJULA in some clinical studies. Discontinue ZEJULA if MDS/AML is confirmed. Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia) have been reported in patients treated with ZEJULA. Do not start ZEJULA until patients have recovered from hematological toxicity caused by previous chemotherapy (? Grade 1). Monitor complete blood counts weekly for the first month, monthly for the next 11 months of treatment, and periodically after this time.

Hypertension and hypertensive crisis have been reported in patients treated with ZEJULA. Monitor blood pressure and heart rate monthly for the first year and periodically thereafter during treatment with ZEJULA. Closely monitor patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Based on its mechanism of action, ZEJULA can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for six months after receiving the final dose. Because of the potential for serious adverse reactions in breastfed infants from ZEJULA, advise a lactating woman not to breastfeed during treatment with ZEJULA and for one month after receiving the final dose.

About TESARO
TESARO is an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients by acquiring, developing and commercializing safer and more effective therapeutics. For more information, visit www.tesarobio.com, and follow us on Twitter and LinkedIn.

About Medison
Medison, Israel’s leading innovative pharmaceutical partner, is an exclusive Israeli partner for global healthcare companies such as Amgen®, Biogen®, Ipsen®, Servier®, Array Biopharma®, Puma Biotechnology® and more. Backed by three generations of experience in the healthcare industry since 1937, Medison has built and maintained long-standing relations with HMOs, local medical centers and physicians. Medison is uniquely qualified to provide the complete spectrum of integrated services for international companies looking to enter or expand their presence in the Israeli market. Medison runs a corporate venture arm with a

dedicated research team boasting deep scientific and commercial backgrounds. Medison's corporate venture arm operates a scouting program to cater its partners, and is an active investor in life science projects around drug development and digital health.

TESARO Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding TESARO, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements regarding the potential commercialization of niraparib in Israel, and our niraparib clinical development strategy. Forward-looking statements in this release involve substantial risks and uncertainties that could cause our research and development programs, clinical results, regulatory outcomes, and financial and other results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among other risks related to the acceptance of niraparib in the marketplace, competition, the uncertainties inherent in the execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from clinical trials, uncertainties surrounding potential actions by regulatory authorities, uncertainties regarding the expected timing and magnitude of certain expenditures, risks related to manufacturing and supply, risks related to intellectual property, and other matters that could affect our financial results, the results of our ongoing and planned development programs, and/or the availability or commercial potential of our products and drug candidates. TESARO undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see TESARO's Annual Report on Form 10-K for the year ended December 31, 2017.

TESARO Global Investor and Media Contact
Jennifer Davis
Vice President, Corporate Affairs & Investor Relations
+1-781-325-1116
jdavis@tesarobio.com

TESARO Media Contact Outside the U.S.:
Shannon Altimari
Head of Corporate Affairs, International
+41 (0) 41 588 08 68
saltimari@tesarobio.com

Medison Contact
Gil Gurfinkel
Vice President, Corporate Development
+972 (0) 3 9250 374
Gil@medison.co.il

Primary Logo

Source: TESARO, Inc.