TESARO Announces Addition of ZEJULA to Cancer Drugs Fund in UK

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- *Inclusion in the Cancer Drugs Fund will give more women in England and Wales with recurrent, platinum-sensitive ovarian cancer access to ZEJULA via a managed access arrangement*
- *ZEJULA was launched in the private market in the UK at the end of 2017*

ZUG, Switzerland, June 01, 2018 (GLOBE NEWSWIRE) -- TESARO, Inc. (NASDAQ:TSRO), an oncology-focused biopharmaceutical company, today announced the National Institute for Health and Care Excellence (NICE) will make ZEJULA® (niraparib), the first PARP inhibitor shown to be effective in patients with a *BRCA* mutation as well as those without a *BRCA* mutation, available to women in England and Wales with recurrent platinum-sensitive ovarian cancer via the Cancer Drugs Fund (CDF)[1]. NICE has recommended ZEJULA via the CDF for women with a *BRCA* mutation who have received two lines of chemotherapy and in women without a *BRCA* mutation who have received two or more lines of chemotherapy.

"At TESARO, we continue to globalize our mission and bring transformative therapies to patients. We are pleased that NICE will now provide more women with recurrent ovarian cancer in England and Wales access to ZEJULA through the CDF," said Orlando Oliveira, Senior Vice President and General Manager, TESARO International. "Through close partnership with both NICE and NHS, TESARO can now offer ZEJULA as an option for second-line maintenance treatment, regardless of a patient's *BRCA* status."

The CDF is a source of funding for cancer drugs in England, providing patients access to promising new oncology treatments while NHS England and NICE analyze any additionally requested data to inform a final reimbursement decision on a new treatment or indication. Overall survival data for ZEJULA are not yet available, and as a result NICE has recommended ZEJULA for use within the CDF while further data are collected[2]. Interim funding is provided via the CDF, giving patients access to the treatment through a managed access arrangement.

"Recurrent ovarian cancer is an aggressive form of cancer where a key goal of treatment is to keep women in remission and off chemotherapy for as long as possible – allowing them the best chance for a good quality of life," said Jonathan Ledermann, Professor of Medical Oncology at the University College London Cancer Institute. "ZEJULA offers the chance to delay this cancer from returning or progressing for months, and possibly years in some cases. It is a significant step forward. Crucially, this decision opens the door for many women who, until now, have not had the option of maintenance treatment with a PARP inhibitor."

About Ovarian Cancer

In the UK, ovarian cancer has the highest mortality rate of all gynecological cancers[3]. It has one of the highest incidence rates in Europe[4] with survival rates among the lowest[5]. The rate of newly diagnosed cases of ovarian cancer in the UK is 16 per 100,000 of the population compared to the European average of 12.6 per 100,000[5]. Every year 4,100 women lose their lives to ovarian cancer – 11 women every day[6].

The most common symptoms of ovarian cancer include abdominal or pelvic pain, bloating, difficulty eating, and urinary urgency, all of which are commonly associated with less serious conditions. 60% of women with ovarian cancer are diagnosed in an advanced stage[7], when prognosis is poor. Although significant progress has been made in treatment of ovarian cancer, the disease recurs in approximately 85% of women with advanced ovarian cancer[8], at which point it may be incurable[9,10]. Recurrent ovarian cancer is the sixth most common cause of cancer death among women and has the highest mortality rate of all gynecological cancers.

About ZEJULA® (niraparib)

Niraparib is marketed in the United States and Europe under trade name ZEJULA®. ZEJULA 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 approved in 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 (CR) or partial response (PR) to platinum-based chemotherapy. The approval was based on data from the clinically rigorous ENGOT-OV16/NOVA trial, a double-blind, placebo-controlled, international Phase 3 study of ZEJULA that enrolled 553 patients with recurrent ovarian cancer who had achieved either a PR or CR to their most recent platinum-based chemotherapy. ZEJULA is the first once-daily, oral poly (ADP-ribose) polymerase (PARP)1/2 inhibitor to be approved in Europe that does not require *BRCA* mutation or other biomarker testing.

The primary endpoint of the trial was progression free survival (PFS). Approximately two-thirds of study participants did not have germline *BRCA* mutations. Progression in the NOVA study was determined by a robust, unbiased, blinded central review to be the earlier of radiographic or clinical progression. ZEJULA significantly increased PFS in patients with or without germline *BRCA* mutations as compared to the control arm. Treatment with ZEJULA reduced the risk of disease progression or death by 73% in patients with germline *BRCA* mutations (hazard ration (HR) 0.27) and by 55% in patients without germline *BRCA* mutations (HR 0.45). The magnitude of benefit was similar for patients entering the trial with a PR or a CR.

The approved starting dose of ZEJULA is 300 milligrams once per day. According to the European summary of product characteristics (SmPC), in patients below 58 kilograms, a starting dose of 200 milligrams once per day may be considered. The most commonly administered dose of ZEJULA over the course of the Phase 3 NOVA clinical trial was 200 milligrams once per day, following dose modification. Further exploratory analyses of the

NOVA study indicated that individual dose modification maintained efficacy and reduced the rate of new adverse events.[11]

ZEJULA (niraparib) 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.

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Primary Logo

Source: TESARO, Inc.