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**Information on the Niraparib U.S. Expanded Access Program for Patients with Recurrent Ovarian Cancer**

TESARO recently announced that it has initiated an expanded access program (EAP) in the United States for the investigational PARP inhibitor, niraparib. Through this program, niraparib is being made available for eligible women with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer following a complete or partial response to platinum-based chemotherapy who don't qualify for a niraparib clinical trial.

This EAP is being administered on behalf of TESARO by the Idis Managed Access division of Clinigen Group plc.

If you are a patient and are interested in participating in the niraparib EAP, you should speak with your physician to understand if niraparib is an appropriate treatment option for you. All requests for access to niraparib through the niraparib EAP must come through a treating physician.

Niraparib is an investigational therapy and is not approved for any indication in any markets. TESARO is currently conducting clinical trials to evaluate the safety and efficacy of niraparib in women with ovarian and breast cancer.

**FAQs**

**1. What is an EAP (Expanded Access Program)?**

Under its expanded access program rules, the U.S. Food and Drug Administration (FDA) works with companies to allow access to investigational therapies outside of a clinical trial to patients with serious or life-threatening illnesses for whom there are no comparable or satisfactory alternate therapies. For more information, visit www.fda.gov/expandedaccess.

2. **What is the difference between the EAP and the ongoing clinical trials of niraparib?**

An expanded access program is not a clinical trial. The goal of this early access program is to provide a mechanism by which eligible women who may potentially benefit from treatment with niraparib can gain access to this investigational therapy if they do not qualify for clinical trials.

TESARO has established a comprehensive development program to evaluate the safety and efficacy of niraparib in patients with ovarian cancer across stages and treatment settings. This includes the QUADRA trial and PRIMA trial, which are currently enrolling patients. The NOVA trial is ongoing, but is no longer recruiting new patients.

A number of international, investigator-led trials of niraparib in ovarian cancer are also ongoing. For more information about ongoing clinical trials of niraparib, please visit www.clinicaltrials.gov.

**3. I am a U.S. physician and believe my patient may be a candidate for the niraparib EAP. How can I find out more information about participating?**

Physicians seeking more information about the niraparib EAP can call Idis Managed Access at 1-877-768-4303 or email niraparibUSEAP@clinigengroup.com for further details. These channels are specifically for U.S.-based doctors who may have eligible patients.

**4. Do patients participating in the niraparib EAP have to pay for the drug?**

No. Niraparib is an investigational therapy. Patients in the U.S. who receive niraparib through the expanded access program will not pay for niraparib while they are participating in the expanded access program. If niraparib is approved by the FDA, the expanded access program will conclude, and patients will transition from the EAP and work with their physician to obtain a prescription in order to continue treatment.

TESARO is committed to making niraparib accessible to patients. The patient support program, TOGETHER with TESARO, is available to help eligible patients in the U.S. following conclusion of the program. Case managers will work with physicians to support continued treatment of each patient following FDA approval of niraparib. If you have questions about insurance coverage, please talk to your physician or call the TOGETHER with TESARO care team at 1-844-2TESARO (1-844-283-7276).

**5. What about patients who are not eligible to participate in this expanded access program? How can they receive niraparib?**

Patients should discuss their treatment options with their physician.

In addition to the niraparib EAP, niraparib is currently being evaluated in a comprehensive clinical development program that includes TESARO-sponsored and investigator-initiated research in ovarian cancer and other cancers. Patients or physicians seeking more information about available niraparib clinical trial options can visit www.clinicaltrials.gov or contact TESARO Medical Information at 1-844-4TESARO (1-844-483-7276).

**6. What about patients outside the U.S.? How can they receive niraparib?**

Patients should always discuss their treatment options with their physician.

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Niraparib is currently being evaluated in a comprehensive, international clinical development program that includes TESARO-sponsored and investigator-initiated research in ovarian cancer and other cancers. Patients or physicians seeking more information about local niraparib clinical trial options can visit www.clinicaltrials.gov.

TESARO plans to expand the niraparib EAP to include countries in Europe during the first half of 2017.