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TESARO Partners With Clinigen to Initiate European Managed Access Program for Niraparib in Patients With Recurrent Ovarian Cancer

WALTHAM, Mass., May 11, 2017 (GLOBE NEWSWIRE) -- TESARO Inc. (NASDAQ:TSRO) and Clinigen Group plc's (AIM:CLIN) ('Clinigen') Idis Managed Access division have partnered to launch a Managed Access Program (also known as an Early Access Program) in Europe for the investigational PARP 1/2 inhibitor, niraparib, for patients with recurrent ovarian cancer.

Niraparib is currently an investigational agent in Europe and as such has not been granted approval by the European Commission. The niraparib marketing authorization application is under review by the European Medicines Agency.

Niraparib was recently approved by the United States (U.S.) Food and Drug Administration under the brand name ZEJULA™ 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.

Approximately 65,000 women are diagnosed with ovarian cancer in Europe every year. Ovarian cancer is the fifth-most frequent cause of cancer death among women. Despite high initial response rates to platinum-based chemotherapy, 85% of women with advanced ovarian cancer will see a recurrence of the disease after first line treatment. The efficacy of chemotherapy also diminishes over time.

Steve Glass, Chief Commercial Officer, North America and Europe for Clinigen said, "Following the successful delivery of the niraparib Managed Access Program in the US, we are pleased to be partnering with TESARO once again, providing eligible women in Europe the opportunity to gain access to this important investigational therapy."

Martin Huber, M.D., Senior Vice President, Chief Medical Officer for TESARO said, "We are proud to partner with Clinigen on this important Managed Access Program for women bravely facing ovarian cancer. The team at Clinigen has proven to be a partner of choice for TESARO as we look to address the needs of the ovarian cancer community."

About Niraparib

In Europe, niraparib is an investigational oral, once-daily poly (ADP-ribose) polymerase (PARP) 1/2 inhibitor 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, niraparib concentrates in the tumor relative to plasma, delivering greater than 90% durable inhibition of PARP 1/2 and a persistent antitumor effect.

Managed Access Program Contact:

European based Healthcare Professionals can obtain details about the niraparib Managed Access Program by calling a Clinigen representative at: +44 1283 494 340 or emailing customer.services@clinigengroup.com.

About TESARO

TESARO is an oncology-focused biopharmaceutical company devoted to providing transformative therapies to people bravely facing cancer. For more information, visit www.tesarobio.com and follow us on [Twitter](#) and [LinkedIn](#).

About Clinigen Group

Clinigen Group plc (AIM:CLIN) is a global pharmaceutical and services company with a unique combination of businesses focused on providing access to medicines. Its mission is to deliver the right medicine to the right patient at the right time. The Group consists of five synergistic businesses focused in three areas of global medicine supply; clinical trial, unlicensed and licensed medicines.

Clinigen Clinical Trial Services is the global market leader in the management and supply of commercial medicines for clinical trials.

The Group is also the trusted global leader in ethically sourcing and supplying unlicensed medicines to hospital pharmacists and physicians for patients with a high unmet need, through three of its divisions: Idis Managed Access runs early access programs for innovative new medicines. Idis Global Access and Link Healthcare work directly with healthcare professionals to enable compliant access to unlicensed medicines on a global basis and niche essential licensed and generic medicines across Australasia, Africa and Asia (AAA region).

Clinigen Specialty Pharmaceuticals acquires global rights, revitalizes and markets its own portfolio of niche hospital products.

For more information, please visit www.clinigengroup.com.

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