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NICE gives go ahead to submit promising ovarian cancer treatment, ZEJULA®▼ (niraparib) to Cancer Drugs Fund

- *First ovarian cancer drug to be considered for new fast-track CDF process that could benefit up to 850 women in England and Wales*[1]
- *Niraparib is the first oral, once-daily PARP 1/2 inhibitor to be licenced for patients regardless of BRCA mutation or biomarker status*[2]

GERRARDS CROSS, UNITED KINGDOM, Thursday 8th February 2018 – TESARO UK Limited today announced that the *National Institute for Health and Care Excellence* (NICE) has issued draft guidance on ovarian cancer medicine, ZEJULA®▼ (niraparib), advising that it is a suitable candidate for use in the *Cancer Drugs Fund* (CDF).[3] The committee recognised the high unmet clinical need in ovarian cancer and concluded that a new treatment that extends periods of remission and improves quality of life would be greatly valued by patients and their families.[3]

Niraparib is used as a maintenance treatment for women with recurrent platinum-sensitive ovarian cancer. Unlike current licensed therapies in this innovative class of medicines, niraparib can be used to treat ovarian cancer regardless of a woman's BRCA gene mutation status. If CDF funding is approved, niraparib could offer a new treatment option to up to 850 women[1], while full overall survival data being assessed in a key study has time to mature.

"Niraparib is the first treatment of its class that can be used whether or not a woman has a BRCA mutation to be available in Europe. It is proven to delay the progression of platinum-sensitive ovarian cancer in recurrent disease and represents a valuable new option in this challenging disease for many women," said Dr. Rebecca Kristeleit, UCL Cancer Institute. "*The invitation for niraparib to be assessed for the CDF is an encouraging step forward towards making this medicine a reality for hundreds of women on the NHS. This is a chance for eligible UK women with relapsed disease to benefit from an effective targeted treatment for the first time in a decade."*

In the UK, about 7,400 women are diagnosed with ovarian cancer each year.[4] Unfortunately, it is often diagnosed at a later stage, when survival is at its lowest. The disease is the fifth most common cause of cancer death in women and has the highest mortality rate of all gynaecological cancers.[5] Five-year survival in England and Wales is among the lowest in Europe, and is well below the European average.[6]

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"Today's news is encouraging for the many UK women with ovarian cancer who are left with few treatment options once their cancer comes back," said Victoria Clare, Chief Executive Officer of Ovacome. *"Ovarian cancer survival here in the UK is lagging well behind many other countries in Europe and it is so important to these women and their families that they have sustained access to new therapies. We hope that the CDF submission is successful and patients are given access as quickly as possible."*

"*We are pleased that the NICE committee has recognised the high unmet need in ovarian cancer treatment,"* said Katherine Taylor, Chief Executive of Ovarian Cancer Action**.** *"Ovarian cancer has the highest mortality rate of all gynaecological cancers in the UK and new treatments are sorely needed. Every day matters for patients and their families and we hope that the CDF submission is successful and will deliver access to many women in England and Wales as soon as possible."*

Annwen Jones, Chief Executive of Target Ovarian Cancer, said: *"There are pitifully few treatment options for women with recurrent ovarian cancer, and even fewer to those women who do not have a mutation in the BRCA1 or BRCA2 gene, so today's response from NICE is positive. We must now hope that niraparib is approved for funding so that it can be made available at the earliest opportunity to a much larger representation of women with ovarian cancer."*

Submission to NICE was based on landmark NOVA trial, conducted in partnership with the UK's *National Cancer Research Institute* (NCRI), which evaluated niraparib compared to placebo as a maintenance treatment for patients with recurrent platinum-sensitive ovarian cancer who had a complete or partial response to chemotherapy.[7] Niraparib was shown to keep the disease at bay for twice as long as chemotherapy alone in women without the inherited germline (g) BRCA mutated ovarian cancer (9.3 vs. 3.9 months PFS, $p<0.001$) and almost four times longer for those with the gBRCA mutation (21.0 vs. 5.5 months PFS, $p<0.001$). This multinational large scale clinical trial included 10 sites across the UK, with additional UK women able to access niraparib through TESARO's Early Access Programme.

"*We are pleased that NICE has recognised niraparib as an innovative and promising treatment for this devastating condition with a poor prognosis."* said Asad Mohsin Ali, VP and General Manager, TESARO UK, Ireland and Nordics. "*We will continue to work closely with NICE and NHS England on our Cancer Drugs Fund submission to try to make this important medicine available as quickly as possible on the NHS."*

Niraparib will be reviewed by the Scottish Medicines Consortium (SMC) later this year. Niraparib is a once-daily, oral poly (ADP-ribose) polymerase (PARP) 1/2 inhibitor that is

indicated in the European Union 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 a complete or partial response to platinum-based chemotherapy.

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NOTES TO EDITORS

About ovarian cancer in the UK

The UK's ovarian cancer incidence rate is higher than that of its European neighbours. 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.[8] Ovarian cancer is the leading cause of death from gynaecological cancer in the UK, and its incidence is rising.[5] Every year 4,100 women lose their lives to ovarian cancer – that's 11 women every day.[4] Despite high initial response rates to platinum-based chemotherapy, approximately 85% of women with advanced ovarian cancer will experience a recurrence of the disease after first-line treatment.[9] With repeated courses of chemotherapy the efficacy also diminishes over time.[10]

About niraparib

Niraparib is a once-daily, oral poly (ADP-ribose) polymerase (PARP) 1/2 inhibitor that is indicated in the European Union 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 a complete or partial response to platinum-based chemotherapy.[2] In preclinical studies, niraparib concentrates in the tumor relative to plasma, delivering greater than 90% durable inhibition of PARP 1/2 and a persistent anti-tumour effect.[11]

The European marketing authorisation of niraparib was based on data from the ENGOT-OV16/NOVA trial, a double-blind, placebo-controlled, international Phase 3 study of niraparib that enrolled 553 patients with recurrent platinum sensitive ovarian cancer who had achieved either a partial response (PR) or complete (CR) to their most recent platinum-based chemotherapy. Approximately two-thirds of study participants did not have gBRCA mutations. Niraparib significantly increased progression-free survival (PFS) in patients with and without gBRCA mutations as compared to the control arm. Treatment with niraparib reduced the risk of disease progression or death by 73% in patients with gBRCA mutations (HR 0.27) and by 55% in patients without gBRCA mutations (HR 0.45). The magnitude of benefit was similar for patients entering the trial with a PR or a CR.[7]

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About TESARO

TESARO is an oncology-focused biopharmaceutical company devoted to providing transformative therapies to people bravely facing cancer. TESARO is currently growing its presence in the UK and partnering with the UK cancer community to provide transformative medicines for cancer patients. For more information, visit www.tesarobio.co.uk and follow us on Twitter and LinkedIn.

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