GSK introduces Jemperli and Zejula in India to expand oncology portfolio

Jemperli approved for second-line treatment of advanced endometrial cancer; Zejula approved as first-line maintenance monotherapy in advanced ovarian cancer

GSK announced the availability of Jemperli (dostarlimab) and Zejula (niraparib) in India, marking its foray into oncology.

Gynaecological cancers are among the most common cancers in women in India and are on the rise. Endometrial and ovarian cancers are among the top three gynaecological cancers in India. By 2045, the incidence of endometrial and ovarian cancer in India is projected to increase by 78 per cent and 69 per cent, respectively.

Endometrial cancer is a malignancy arising out of the endometrium, the inner lining of the uterus. Nearly a fourth of endometrial cancer patients in India are at an advanced stage. At this stage, chemotherapy remains a standard treatment but it is often associated with toxicity and poor long-term outcomes.

Jemperli is the first and only approved PD-1 immunotherapy for the second-line treatment of mismatch repair-deficient (dMMR)/microsatellite instability-high (MSI-H) advanced or recurrent endometrial cancer in India. Jemperli works by blocking the PD-1 pathway, a mechanism that cancer cells use to evade immune detection, thereby enabling immune cells to recognise and attack the tumour.

The efficacy of Jemperli is based on scientific evidence from the GARNET trial in patients with dMMR/MSI-H advanced or recurrent endometrial cancer. The study demonstrated that Jemperli achieved an objective response rate of 45.5 per cent, with an estimated probability of maintained response of 93.3 per cent and 83.7 per cent at 12 and 24 months, respectively. Combined with a safety profile, these findings showed potential for durable clinical benefit in a population where standard chemotherapy has historically offered limited efficacy and poor long-term outcomes.

Ovarian cancer is a malignancy which begins in the ovaries located on each side of the uterus. Zejula is the only PARP inhibitor approved as first-line monotherapy maintenance for all biomarker types in advanced ovarian cancer in India. It offers a once-daily oral dose.

The updated ad-hoc analysis of the phase-3 PRIMA trial demonstrated that Zejula first-line maintenance monotherapy provided durable, long-term remission in women with newly diagnosed advanced ovarian cancer. These women were at high risk for disease progression or death across all biomarker subgroups.

To support patient access, GSK is introducing ‘Phoenix’, a Patient Support Programme.

Bhushan Akshikar, Managing Director, GSK India, said: “The launch of Jemperli and Zejula marks a pivotal moment for GSK in India, as we foray into oncology with a strong focus on innovation-led, high-impact therapies. These therapies address a critical unmet need in

gynaecological cancers in India and represent meaningful progress in women's cancer care. With this launch, we are strengthening our long-term commitment to build the specialty medicine portfolio in India."

Dr Shalini Menon, EVP – Medical Affairs, GSK India, said: "Gynaecological cancers represent a growing public health challenge in India, especially among women above the age of 50, and those with obesity and metabolic syndrome. Jemperli introduces immunotherapy into the treatment paradigm for advanced or recurrent endometrial cancer, offering a targeted option for patients with dMMR tumours. Zejula expands access to a convenient, first-line maintenance therapy in advanced ovarian cancer."

The two molecules are supported by global clinical evidence and approvals from more than 40 countries including the US, UK and EU. In India, GSK is participating in ongoing oncology clinical trials aimed at extending the indication of dostarlimab to cancers including non-small cell lung, head and neck, and colorectal.

About Jemperli (dostarlimab)

Jemperli, a programmed death receptor-1 (PD-1) blocking antibody, is the backbone of GSK's ongoing immuno-oncology research and development programme. The clinical trial programme includes studies of Jemperli alone and in combination with other therapies in gynaecologic, colorectal and lung cancers.

In India, Jemperli is approved as monotherapy for the treatment of patients with dMMR/MSI-H recurrent or advanced endometrial cancer, whose disease has progressed on or after prior platinum-containing chemotherapy. This approval provides an immunotherapy option in the second-line setting, where existing treatments have historically been limited in both durability and clinical outcomes.

Jemperli was discovered by AnaptysBio, Inc. and licensed to TESARO, Inc. under a collaboration and exclusive licence agreement signed in March 2014. Under this agreement, GSK is responsible for ongoing research, development, commercialisation, and manufacturing of Jemperli and cobolimab (GSK4069889), a TIM-3 antagonist.

About Zejula (niraparib)

In India, Zejula is approved as a once-daily oral PARP inhibitor as monotherapy for first-line maintenance treatment for patients with advanced or relapsed epithelial ovarian cancer who are in complete or partial response to platinum-based chemotherapy, regardless of biomarker status. Zejula offers a maintenance option to delay disease progression.

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