GSK India Oncology Second Innings: Can Jemperli, Zejula Set The Pace?

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GSK recommits to oncology in India with the debut of Jemperli and Zejula, backed by a tiered pricing approach, patient support program and efforts to address unmet needs in the biomarker ecosystem. Can it widen treatment access materially?

About a decade after a global asset swap deal that saw GSK divest its oncology products to Novartis, the UK-headquartered company is re-entering the high growth segment in India.

Key Takeaways

- GSK seeks to pioneer gyno-oncology solutions for patients in India, debuts Jemperli and Zejula.
- Senior leadership underscores precision medicine at fulcrum of oncology strategy.
- New oncology products competitively priced, significantly lower than in the West - eyes on Keytruda, Imfinzi.
- Can the patient support program, potential “assistance’ around testing, move the access needle?

Jemperli (dostarlimab) for endometrial cancer and Zejula (niraparib) for ovarian cancer are the first two products to hit the Indian market to begin with as the company seeks to pioneer gyno-oncology solutions for patients. India is also participating in ongoing trials aimed at extending the indication of dostarlimab to other cancers including non-small cell, lung, head and neck and colorectal.

“As an entry point for us, these two assets [Jemperli and Zejula] represent a significant milestone in terms of what impact we can have to begin with in gynecological malignancies. But over a period of time, really opening up these [additional] indications as and when we work closely with the regulators,” Bhushan Akshikar, managing director, GSK India, said at a media briefing.

Endometrial and ovarian cancers are among the top three gynecological cancers in India and by 2045 the incidence of these malignancies in the country is projected to increase by 78% and 69%, respectively.

As part of the asset swap with Novartis, GSK shed its oncology business in India, which was "significant both in terms of the depth and width of the portfolio as well as the top line revenue." This time round, GSK's ambition, more widely, is to change the course of disease, expanding from its current focus on blood and women's cancer into lung and gastrointestinal cancers, as well as other solid tumors.

"What's important is our oncology strategy is completely rooted around precision medicine, and to begin with immunotherapy, and therefore how Jemperli could set a new standard within IO treatment is the starting point," Akshikar said in response to queries from *Scrip*.

Products like the BCMA-targeted antibody-drug conjugate (ADC), Blenrep (belantamab mafodotin) are also potentially in the product line-up as part of the wider oncology strategy for India. Blenrep (for multiple myeloma) is approved in the EU, Japan, UK, Canada and Switzerland, with "constructive discussion" underway with the US Food and Drug Administration, with a new PDUFA date set for October 23, 2025, GSK said at the time of its Q2 results in July.

The 2014-15 GSK-Novartis transaction had seen oncology products like Tykerb (lapatinib), Revolade (eltrombopag), Votrient (pazopanib) and Hycamtin (topotecan) change hands in India.

India Competitive Landscape

On the competitive landscape for Jemperli in India, especially with star products like MSD's Keytruda (pembrolizumab) well entrenched in other indications, GSK underlined that Jemperli is the first and only approved PD-1 immunotherapy in India for the second-line treatment of mismatch repair-deficient (dMMR)/microsatellite instability-high (MSI-H) advanced or recurrent endometrial cancer.

"The current therapies, which are the cytotoxic chemotherapies that exist today, are not really working in the second line and you see a lot of poor prognoses as well as side-effects with these molecules. So immunotherapy is a targeted way to address this population of dMMR patients," Shalini Menon, EVP medical affairs, GSK India, told *Scrip*.

Keytruda is not currently approved for endometrial cancer in India, but the anti-PD-1 therapy has regulatory clearances for 17 indications, including as an adjuvant treatment for certain patients with renal cell carcinoma and early-stage, triple-negative breast cancer.

In July this year, AstraZeneca received regulatory approval in India for Imfinzi (durvalumab) in combination with carboplatin and paclitaxel for the first-line treatment of adults with primary advanced or recurrent endometrial cancer who are candidates for systemic therapy, followed by maintenance treatment with durvalumab in combination with olaparib in endometrial cancer that is mismatch repair proficient (pMMR).

"In endometrial cancer, probably we are the ones with the largest data in dMMR and also the only one approved in the second line by health authorities; this was backed by good evidence from the

GARNET study," Menon pointed out. The study showed that Jemperli achieved an objective response rate of 45.5%, with an estimated probability of maintained response of 93.3% and 83.7% at 12 and 24 months, respectively.

The executive also referred to Jemperli's convenient dosing frequency, whereby patients need to take 11 cycles through the year, which means fewer visits to the hospital for infusions. Other immunotherapies typically need 17-18 cycles.

Zejula, on the other hand, is the only PARP inhibitor approved in India for first-line monotherapy maintenance for all biomarker types in advanced ovarian cancer. It is given in a once-daily oral dose, making it a simple and convenient option for patients. The updated ad-hoc analysis of the phase-III PRIMA trial established that Zejula first-line maintenance monotherapy provided durable, long-term remission in women with newly diagnosed advanced ovarian cancer.

Tiered Pricing Strategy, Patient Support Program

GSK did not share specifics on the pricing of Jemperli and Zejula in India, but Akshikar maintained that the company has largely followed a tiered pricing model. He referred to the approach as something that GSK has "always practiced in the century of trust we have behind us."

"If you look at the average cost of treatment in the same immunotherapy category, we are competitively priced, which is significantly lower than what you would see anywhere in the Western world," he maintained.

Last year, GSK entered its 100th year of operations in India, with the managing director at the time highlighting how the company has been able to reinvent itself and thrive over the years.

GSK is also introducing a patient support program (PSP), "Phoenix," to "empower" patients to access the newly launched oncology therapies. "It gives an opportunity for us to create not just financial assistance, but a wider ecosystem of support programs," Akshikar said. "Given the need that cancer patients really have in terms of counselling, there will be a plethora of activities within the broader PSP."

Additionally, GSK is "evaluating the entire biomarker ecosystem" to see what the unmet needs are and expects to accordingly frame "some assistance on testing," Menon indicated, but clarified this is not part of the PSP.

Vinay Subramanian, GSK India's commercial head (oncology), referred to the company's targeted distribution model and dedicated field force with deep expertise in oncology. "We have a good distribution network across the country to ensure that our products reach even the tier 2, tier 3 markets," he asserted.

'Super Specialty Holy Grail'

On whether GSK might consider a second brand strategy for Jemperli and Zejula in India, Akshikar indicated that's not on the cards currently, but did not completely rule out interest in the model in the future.

"It's a significant moment for us because we are recommitting ourselves to the 'super specialty holy grail,' so to say, of oncology. At this stage, we really want to set ourselves up based on science, based on what we can bring to the entire oncology ecosystem as GSK. So, to begin with, there is nothing on plan to have a second brand," he told *Scrip*.

Nevertheless, the MD added that "as we evolve, once we have more indications opening up, that's an area we definitely will stay open to," but underlined that currently "we are going ahead without that."