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Regulatory clearances of targeted therapies boost precision oncology

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India's oncology market is entering a new phase as recent regulatory approvals signal a decisive shift toward precision medicine, moving beyond the long-dominant chemotherapy-led treatment model.

A series of approvals and late-stage regulatory reviews are expanding the use of immunotherapies, antibody-drug conjugates (ADCs) and targeted therapies across high-incidence cancers, setting the stage for faster market growth and intensifying competition.

According to Nirali Shah, pharma analyst at Ashika Group, the expanded approvals for MSD's Pembrolizumab (Keytruda), along with tumour-agnostic ADCs, next-generation tyrosine kinase inhibitors and immunotherapies underline the structural transition underway.

"India is clearly moving toward more targeted treatment pathways in high-burden cancers," she said, adding that several immuno-oncology combinations, ADCs and targeted agents are lined up for CDSCO review in the second half of the year. These approvals are expected to materially widen treatment options in lung, breast and gastrointestinal cancers.

Recent months have already seen multiple high-impact clearances. These include Servier India's Vorasidenib for brain cancer, combination immunotherapy approvals involving Ipilimumab and Nivolumab for hepatocellular carcinoma and melanoma, and new indication expansions for Keytruda. In addition, therapies such as Selpercatinib and AstraZeneca's Trastuzumab Deruxtecan have received regulatory approvals, strengthening the presence of precision oncology drugs in breast and gastric cancers.

INDUSTRY ESTIMATES SUGGEST INDIA'S PRECISION ONCOLOGY MARKET COULD NEARLY DOUBLE FROM AROUND $4.4 BILLION IN 2024 TO ABOUT $8.9 BILLION BY 2030

"These approvals are significant as they introduce outcome-based, precision medicine approaches into routine cancer care," said Nilaya Varma, co-founder and Group CEO of Primus Partners. "Combination immunotherapies, in particular, are expected to improve outcomes for patient segments that previously had limited therapeutic options."

The regulatory pipeline remains active. Reliance Life Sciences' biosimilar Nivolumab has received approval to enter Phase III trials for advanced non-small cell lung cancer, marking a key milestone for checkpoint inhibitor biosimilars in India.

Other therapies, including Lurbinectedin, Amivantamab and Fruquintinib, are progressing through late-stage clinical trials, while Indian drugmakers are advancing complex biosimilars and dual-antibody combinations into early clinical development. The approval of India's first indigenous CAR-T cell therapy for blood cancers last year has further strengthened the domestic innovation ecosystem.

Looking ahead to the second half, the oncology market is expected to see sustained demand growth alongside rising competitive intensity. ADCs, which combine targeted antibodies with cytotoxic drugs, are emerging as a major growth driver, with a growing pipeline globally and increasing interest from Indian pharmaceutical firms.

Industry estimates suggest India's precision oncology market could nearly double from around $4.4 billion in 2024 to about $8.9 billion by 2030. As multinational innovators accelerate label expansions and domestic players scale up biosimilars and in-licenced assets, industry participants expect improved access and affordability of advanced cancer therapies.