

CLINICAL RELEVANCE

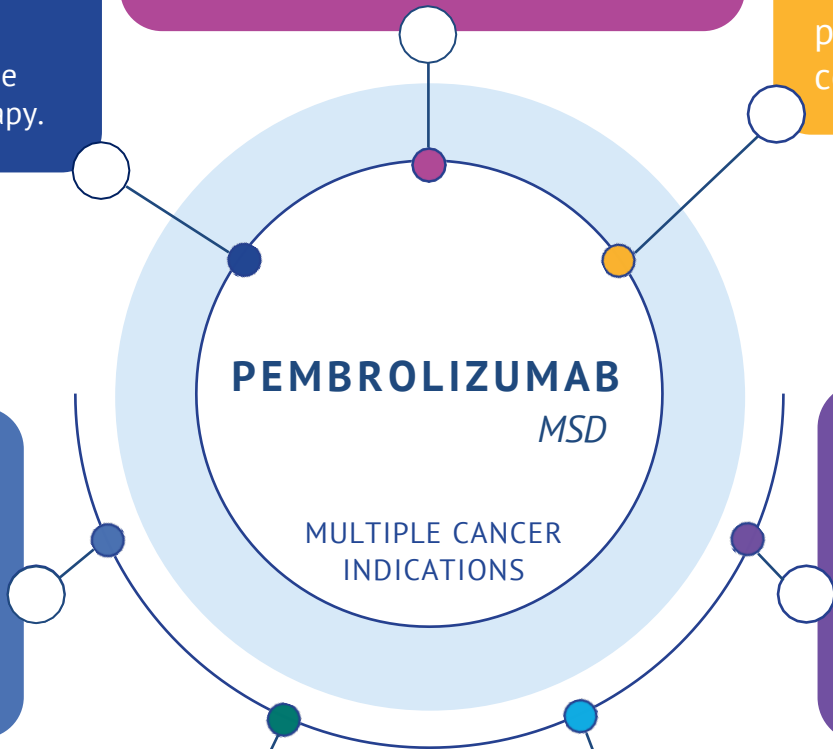
Pembrolizumab as a single agent reduces the risk of death in non-small cell lung cancer patients by 40%, significantly extending survival by more than a year with fewer side effects compared to traditional chemotherapy.

DISEASE BURDEN

Lung cancer stands as the second most frequent cancer worldwide, accounting for 1.2 million incident cases in LMICs during 2020.

PATENT LANDSCAPE

MSD holds the exclusive patent rights until 2028 with active pharmaceutical ingredient patent coverage in at least 15 LMICs.



SERVICE DELIVERY ENABLERS

Access to pembrolizumab and other immune checkpoint inhibitors is reported to be extremely low and challenging in LMICs.

REGULATORY

Product approved by SRAs. Generics can adopt standard procedures Swissmedic MAGHP, EU-M4all. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment needs to be done. No clinical trial waiver is possible.

MANUFACTURING

Manufacturing is complex since pembrolizumab is a monoclonal antibody. No challenges foreseen in relation to excipients or final packaging. Shelf life is two years under refrigeration.

MARKET ANALYSIS

Pembrolizumab is registered in only a limited number of LMICs. There is a potentially large market for pembrolizumab in LMICs.