TRASTUZUMAB SUB-CUTANEOUS

ONCOLOGY
BREAST CANCER

Roche

DISEASE BURDEN

There were more than 2.2 million new cases of breast cancer in 2020 globally. In LMICs, the majority of the patients are diagnosed at an advanced/metastatic stage and at least 30% of cases are characterized by overexpression of human epidermal growth factor receptor 2 (HER2 positive).

CLINICAL RELEVANCE

Cancer-free survival is significantly improved in HER2-positive breast cancer patients who receive one year of trastuzumab treatment after adjuvant chemotherapy. The subcutaneous administration method is quicker, saving time and money to health systems, and is preferred by patients compared to the intravenous formulation.

INTELLECTUAL PROPERTY LANDSCAPE

Trastuzumab primary patents expired in 2012. Secondary patents on the subcutaneous formulation have been filed and granted widely in LMICs and are expected to expire in 2030.

SERVICE DELIVERY ENABLERS

Diagnosis of breast cancer is provided in the public health sector in many LMICs, but a high proportion of cases is only detected at an advanced/metastatic stage of the disease. Generic companion treatments are usually available. The subcutaneous formulation could simplify service delivery and enable more people to be treated with the existing health infrastructure in LMICs.

REGULATORY

Product approved by stringent regulatory authorities. Potential sublicensees could of trastuzumab sub-cutaneous could rely on mechanisms like Swissmedic MAGHP, EU-M4all or WHO PQ (if included in pilot program) for quality assurance. Complete biosimilarity exercise with respect to analytical similarity, preclinical and clinical assessment needs to be done. Phase III clinical trial waiver might be possible if there is already an approved intravenous product by the applicant.

MANUFACTURING

Complex manufacturing process since product is a monoclonal antibody. Aseptic processing is required. Occupation exposure band (OEB) level 3, manufacturing precautions necessary. Hyaluronidase, a biologic is added as excipient. No challenges with respect to final packaging. Shelf life is 21 months under refrigeration.

MARKET

While biosimilar formulations of intravenous trastuzumab are available in many LMICs, subcutaneous formulation availability is very limited and hence its access in many LMICs, despite its advantages for patients and health systems.