

DISEASE BURDEN

Among women worldwide, breast cancer is the most frequently diagnosed cancer and the leading cause of cancer-related death. About two-thirds of breast cancers in women aged 50 years or younger are hormone receptor (HR) positive and HER2 negative.

CLINICAL RELEVANCE

Abemaciclib, in addition to endocrine therapy significantly improve progression-free survival of patients with HR-positive, HER2-negative advanced breast cancer, while maintaining a safe profile compared to placebo.

INTELLECTUAL PROPERTY LANDSCAPE

Abemaciclib primary patents have been granted in more than 40 LMICs and are expected to expire in 2029 in most countries.

SERVICE DELIVERY ENABLERS

Diagnosis of breast cancer is provided in the public health sector in many LMICs, however with significant delays. Consequently, a high proportion of cases is only detected at an advanced/metastatic stage of the disease. Generic companion treatments are usually available.

MANUFACTURING

Standard manufacturing process for tablets. No challenges with respect to excipients or final packaging. Probable occupational exposure bands (OEB) category 4, special facility might be required. Shelf life is 3 years at room temperature.

ABEMACICLIB

ONCOLOGY BREAST CANCER

Eli Lilly

MARKET

B



Abemaciclib is available primarily in the private markets of a small number of LMICs. However, is more expensive than other hormonal receptor inhibitors.

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PRIORITY LIST

REGULATORY

Abemaciclib is approved by stringent regulatory authorities. Potential sublicensees of abemaciclib could rely on mechanisms like EU-M4all or Swissmedic MAGHP for quality assurance. Current guidance mentions the requirement of PK-based bioequivalence studies, however biowaiver options can be explored.

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