medicines patent pool

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ABEMACICLIB

ONCOLOGY
BREAST CANCER

Eli Lilly

DISEASE BURDEN

Breast cancer is the most common cancer in women and the second most common cancer worldwide. In 2022, there were over 2.29 million new cases of breast cancer in women. About two-thirds of breast cancers in women aged 50 years or younger are HR positive and HER2 negative.

CLINICAL RELEVANCE

Abemaciclib, in addition to endocrine therapy significantly improve progression-free survival of patients with hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (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.

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.

MANUFACTURING

The product requires a standard manufacturing process for tablets. There are no anticipated challenges in relation to excipients or final packaging. Due to a probable occupational exposure band (OEB) category 4, a special facility might be required. Shelf life is three years at room temperature.

MARKET

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

EU-M4All: The European Medicines Agency (EMA), in cooperation with the World Health Organization (WHO), can provide scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU). The procedure is called EU-Medicines for all or 'EU-M4all'; HER2: human epidermal growth factor receptor 2; HR: Hormone Receptor; LMICs: low-income, lower middle-income and upper middle-income countries as per World Bank classification; OEB: occupational exposure band; PK: pharmacokinetics; Swissmedic MAGHP: Swissmedic procedure for scientific advice and Marketing Authorisation for Global Health Products;