medicines patent pool

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ZANUBRUTINIB

ONCOLOGY
CHRONIC LYMPHOCYTIC LEUKEMIA

Beigene

DISEASE BURDEN

Chronic Lymphocytic Leukaemia (CLL) is the most common type of leukaemia, accounting for approximately 25% to 30% of all cases. In particular, Central sub-Saharan Africa has seen the biggest rise in death rates and overall health burden (taking into account both illness and early death), increasing by about 2.8% and 2.7% per year, respectively.

CLINICAL RELEVANCE

After median follow-up of 26 months, the progression-free survival was significantly longer with zanubrutinib compared to chemo-immunotherapy.

INTELLECTUAL PROPERTY LANDSCAPE

The primary patent on zanubrutinib was granted in few LMICs, including India, where it is expected to expire in 2034. Secondary patents on crystalline forms are expected to expire in 2037.

SERVICE DELIVERY ENABLERS

CLL is a relatively uncommon condition in LMICs. Access to diagnosis is still challenging. Blood count capacity is widely available, but more sophisticated tests required for the diagnosis are scarcely available or affordable in the majority of LMICs. Zanubrutinib can be used in monotherapy or in combination with other agents, the availability of which may be challenging in many countries.

REGULATORY

Zanubrutinib is approved by stringent regulatory authorities. Potential sublicensees of zanubrutinib could rely on mechanisms like USFDA Para III, EU-M4all or Swissmedic MAGHP for quality assurance. Bioequivalence studies are necessary. Biowaivers will not be an option.

MANUFACTURING

Standard manufacturing process for oral capsules. There are no anticipated challenges with respect to excipients or final packaging. Shelf life is three years at room temperature.

MARKET

Zanubrutinib is available in very few LMICs. Beigene has announced a partnership with the Max Foundation to provide access to zanubrutinib in 29 LMICS until 2026.

CLL: Chronic Lymphocytic Leukaemia; 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'; LMICs: low-income, lower middle-income and upper middle-income countries as per World Bank classification; Swissmedic MAGHP: Swissmedic procedure for scientific advice and Marketing Authorisation for Global Health Products; USFDA: The United States Food and Drug Administration