ZANUBRUTINIB

ONCOLOGY
CHRONIC LYMPHOCYTIC LEUKEMIA

Beigene

DISEASE BURDEN

Chronic Lymphocytic Leukaemia (CLL) is the most common type of leukaemia in Western countries, making up about 25% to 30% of all leukaemia cases. In some countries of Central Sub-Saharan Africa, the death rate from CLL is rising rapidly.

CLINICAL RELEVANCE

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

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 rare 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. No challenges with respect to excipients or final packaging. Shelf life is 3 years at room temperature.

MARKET

Zanubrutinib is available in very few LMICs. Beigene has recently announced a partnership with the Max Foundation focused on 29 low- and middle-income countries over the next three years.