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Janssen gets indication expansion approval to treat CLL/ SLL

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Comapany's one hundred million Ke Ã?Â® (imatinib Ibrahimovic capsules) extended indications approved, First-line treatment for patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)



Johnson & Johnson, subsidiary Janssen Pharmaceutical Co., Ltd. announced that its one hundred million Ke ® (imatinib Ibrahimovic capsules) extended indications approved, First-line treatment for patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL).

Yi Ke ® in China is approved for the treatment of previously received at least one kind of chronic lymphocytic leukemia / small lymphocytic lymphoma patients and had previously received at least one therapeutic treatment of mantle cell lymphoma patients. CLL / SLL apply for first-line treatment indication received a "priority review" status granted by the State Drug Administration, which approved the one hundred million Ke ® to become China's first oral CLL / SLL first-line treatment of targeted therapies, can help more Patients benefit from this innovative therapy earlier to improve their quality of life.

Chronic lymphocytic leukemia is a blood tumor that affects the growth and progression of B lymphocytes. It is rare, and the annual incidence rate in China is estimated to be 0.27/100,000. Chronic lymphocytic leukemia and small lymphocytic lymphoma are different clinical manifestations of the same disease, the only difference being where the tumor cells appear.

When most tumor cells are located in the blood or bone marrow, the disease is called chronic lymphocytic leukemia; when the tumor cells are mainly located in the lymph nodes, the disease is called small lymphocytic lymphoma.

Professor Zhu Jun, Chairman of the China Anti-lymphoma Alliance, Secretary of the Party Committee of Beijing Cancer Hospital, and Director of the Department of Lymphoma, said: "This is approved for patients with chronic lymphocytic leukemia/small lymphocytic lymphoma who do not want to use traditional chemotherapy as a first-line treatment. Said to be good news, because many patients, especially elderly patients cannot tolerate the side effects of chemotherapy. One hundred million Ke ® was diagnosed with chronic lymphocytic leukemia / small lymphocytic lymphoma patient to provide a non-chemotherapy First-line innovative oral targeted therapy options."

One hundred million Ke ® (IBB imatinib capsules) orally once daily Bruton tyrosine kinase (BTK) inhibitor, having a high efficiency of 91%, chlorambucil contrast, significantly lower in patients The risk of disease progression and death, and is well tolerated, has been recommended for first-line treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma by multiple international and national treatment guidelines.

Among them, "Guidelines for the Diagnosis and Treatment of Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma in China (2018 Edition)" preferentially recommend Ibbutinib as a patient with poor physical condition or with del(17p)/TP53 gene mutation and IGHV First-line treatment options for patients with poor prognosis in CLL patients.

Blood tumor branch chairman of the Chinese Anti-Cancer Association, China chronic lymphocytic leukemia, Team Leader Prof. LI Jian-yong introduction: "100 million Ke ® clinical research data also shows that this new treatment options really give chronic lymphocytic leukemia / small lymphocytic bring clinical benefit in patients with lymphoma. in clinical studies CLL / SLL naive patients, the use of one hundred million Ke ® treated patients progression-free survival data is very strong and encouraging.

One hundred million Ke ® has been approved in 92 countries, and is widely used in more than 100,000 patients worldwide. In addition, in 2015, Ibbutini was awarded the “Best Drug Award” by the Galen Awards.