Imbruvica granted fourth Breakthrough status

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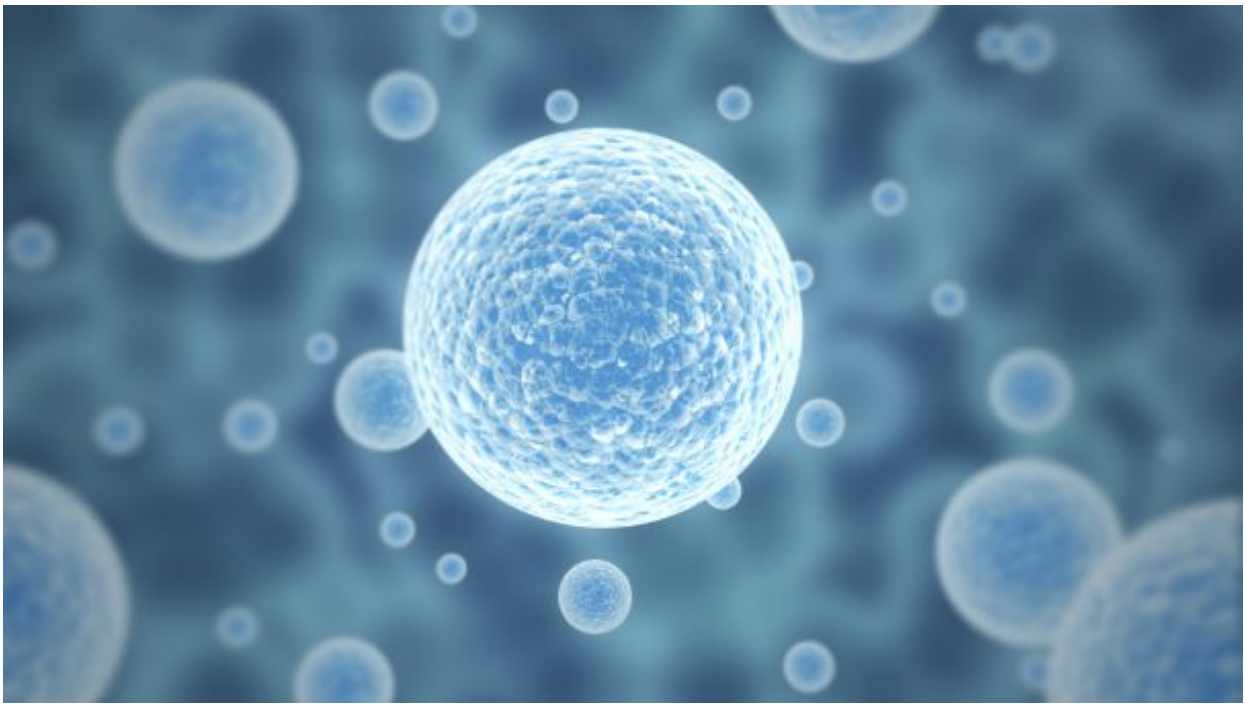
June 30, 2016



AbbVie's Imbruvica (ibrutinib) has gained its fourth Breakthrough Therapy Designation from the FDA – this time for the treatment of chronic graft versus host disease (cGVHD) after the failure of one or more lines of systemic therapy.

The drug's Breakthrough Therapy Designation (BTD) request came on the back of positive results from a preliminary phase 1b/2 study investigating its safety and efficacy in patients with steroid-dependent or refractory cGVHD.

Preliminary results from the trial – previously presented at the European Society for Blood and Marrow Transplantation (ESBM) and ASCO – indicated that the drug was well tolerated, achieving a partial response in all five of the evaluable patients enrolled in the study following three months of treatment.

"This fourth Breakthrough Therapy Designation from the FDA shows the promise of Imbruvica and its unique mechanism of action as a potential therapy beyond blood cancers, including chronic graft-versus-host-disease, a severe inflammatory condition with currently no approved therapies specifically for these patients," said Danelle James, head of oncology at Pharmacyclics, joint developers of the drug. "We are committed to continuing to evaluate the potential benefit ibrutinib may offer in treating blood cancers, solid tumours and other health conditions with unmet medical needs."

The FDA also granted ibrutinib Orphan Drug Designation (ODD) for the condition, a status, similar to BTD, that is intended to speed up the development of and access to a drug in a particular clinical setting based on the belief that it could be more effective than existing first line treatments.

The drug had already achieved plenty of success in other fields, most recently through a BTD and ODD for the treatment of chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) in patients with a chromosome 17 deletion mutation.

Data presented from the RESONATE and RESONATE-2 trials at this year's ASCO meeting further boosted the profile of the drug in CLL and SLL, showing the drug could extend lives no matter in what line of therapy it was used.

Prior to that, in February 2013, the drug was also given a BTD and ODD in refractory mantle cell lymphoma and Waldenström's macroglobulinaemia.

For cGVHD – a potentially life-threatening condition caused by immune cells present in a transplant attacking the donor's body that can occur following allogeneic stem cell or bone marrow transplantation – ibrutinib gives a potential new treatment option to patients with a disorder that has no specifically designated therapies.

Currently, extended treatment with prescribed glucocorticoids is the preferred treatment, however, research has shown that the long-term use of steroids can cause serious health complications.

The drug is expected to be a blockbuster for AbbVie and co-developers Pharmacyclics and Janssen, with sales expected to reach $1 billion this year and $3 billion by 2020.