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Johnson and Johnson's (J&J) Janssen unit has announced that the European Commission (EU) has approved IMBRUVICA (ibrutinib) capsules, oral Bruton's tyrosine kinase (BTK) inhibitor. IMBRUVICA is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL), or adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in the first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.

The drug is co-developed by Cilag GmbH International (a member of the Janssen Pharmaceutical Companies) and Pharmacyclics Switzerland GmbH.

"MCL and CLL with 17p deletion are usually challenging and difficult-to-treat blood cancers that do not respond well to conventional therapies. They usually rapidly progress during or soon after chemotherapy leaving patients with very limited treatment options and poor survival," said professor Peter Hillmen, Haematology, St James's University Hospital, who is an investigator in the IMBRUVICA CLL clinical trial. He added, "Being able to use IMBRUVICA as a single agent offers a new option and gives renewed hope for physicians and their patients."

The approval of IMBRUVICA was based on data from the Phase III (RESONATE PCYC-1112) and Phase 1b-2 (PCYC-1102) studies in CLL, and the Phase II study (PCYC-1104) in MCL.

"We are delighted the European Commission has approved IMBRUVICA as a new treatment approach, which could prolong the lives of patients with these complex blood cancers," said Ms Jane Griffiths, company group chairman, Janssen, Europe, Middle East and Africa (EMEA). She added, "This is a positive step forward for patients, and Janssen is committed to looking into further areas of unmet need in blood cancers where IMBRUVICA could improve outcomes."