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J&J announces USFDA approval of IMBRUVICA

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This approval is based on results from the Phase 3 iLLUMINATE study

The Janssen Pharmaceutical Companies of Johnson & Johnson has announced the U.S. Food and Drug Administration (FDA) approval of IMBRUVICA® (ibrutinib) in combination with obinutuzumab in treatment-naïve patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), the most common form of leukemia in adults.

This is the first approval for a non-chemotherapy combination regimen for treatment-naïve patients with CLL/SLL, and marks the tenth FDA approval for IMBRUVICA since its U.S. launch in November 2013. The approval expands the label for IMBRUVICA in frontline CLL/SLL beyond its use as a monotherapy to include combination use with obinutuzumab.

This approval is based on results from the Phase 3 iLLUMINATE study.

Craig Tendler, Vice President, Clinical Development and Global Medical Affairs, Janssen Research & Development said, “This label update builds upon the established efficacy and safety of IMBRUVICA in the frontline treatment of patients with CLL/SLL, as a monotherapy or in combination with other treatments. This milestone represents our continued commitment to develop IMBRUVICA-based, non-chemotherapy regimens to address the clinical needs of patients living with CLL/SLL.”

IMBRUVICA, a Bruton's tyrosine kinase (BTK) inhibitor, is jointly developed and commercialized by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie company.