

IMBRUVICA[™] (ibrutinib) Media Backgrounder

Key Facts

- IMBRUVICA[™] (ibrutinib) is approved in the European Union for the treatment of:
 - adult patients with relapsed or refractory mantle cell lymphoma (MCL)¹
 - $\circ~$ adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.^1
- IMBRUVICA is the first in a new class of drugs called Bruton's tyrosine kinase (BTK) inhibitors.
- IMBRUVICA is a targeted single-agent oral therapy, taken once daily.¹ IMBRUVICA provides a treatment option for patients in the EU living with MCL or CLL.
 - CLL often eventually progresses; patients are faced with fewer treatment options and are often prescribed multiple lines of therapy as they relapse or become resistant to treatments.²
 - MCL is a rare, aggressive blood cancer associated with a poor prognosis.³

Mechanism of Action: Bruton's Tyrosine Kinase Inhibitor

- IMBRUVICA is not a chemotherapy, it is a once-daily, oral BTK inhibitor.¹
- The BTK protein transmits important signals that tell B cells to mature and is needed by specific cancer cells to multiply and spread.⁴

Published IMBRUVICA Clinical Results

- IMBRUVICA is the first single-agent to demonstrate a significant difference in progression free survival (PFS) and overall survival (OS) in patients with relapsed or refractory CLL.⁵
- Pivotal Phase 2 and Phase 3 studies have been published in the *New England Journal* of *Medicine*.^{5,6,7}
- The studies highlight findings in both MCL and CLL. These publications reported on Phase 3 RESONATE[™] (PCYC-1112-CA), Phase 2 PCYC-1102, both in CLL, and Phase 2 PCYC-1104 in MCL.^{5,6,7}

CLL and MCL Safety Results

- The most commonly occurring adverse reactions (≥ 20%) based on pooled data from 357 patients treated with IMBRUVICA in two Phase 2 clinical studies and one randomised Phase 3 study were: diarrhoea, musculoskeletal pain, upper respiratory tract infection, bruising, rash, nausea, pyrexia (fever), neutropenia (abnormally low number of white blood cells) and constipation.¹
- The most common grade 3/4 adverse reactions (\geq 5%) were anaemia, neutropenia, pneumonia and thrombocytopenia (low platelet count).¹

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Dosage

- The recommended dose of IMBRUVICA for patients with CLL is 420 mg (three capsules) once daily.¹
- The recommended dose of IMBRUVICA for patients with relapsed or refractory MCL is 560 mg (four capsules) once daily.¹

IMBRUVICA is co-developed by Cilag GmbH International (a member of the Janssen Pharmaceutical Companies) and Pharmacyclics Switzerland GmbH. In the European Economic Area, Janssen is the marketing authorisation holder. Janssen affiliates market IMBRUVICA in EMEA (Europe, Middle East and Africa) as well as the rest of the world, except for the United States, where both companies co-market it.

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References:

- 1. IMBRUVICA[™] (ibrutinib) Summary of Product Characteristics. October 2014.
- 2. Veliz M, Pinilla-Ibarz J. Treatment of relapsed or refractory chronic lymphocytic leukemia. *Cancer Control*. 2012 Jan;19(1):37-53.
- 3. Cancer Research UK. What is mantle cell lymphoma. Available from: <u>www.cancerresearchuk.org/cancer-help/type/non-hodgkins-lymphoma/about/types/mantle-cell-lymphoma</u>. Accessed September 2014.
- Genetics Home Reference. Isolated growth hormone deficiency. Available from: <u>http://ghr.nlm.nih.gov/condition/isolated-growth-hormone-deficiency</u>. Accessed September 2014.
- 5. Byrd JC, Brown JR, O'Brien S, et al. Ibrutinib versus of atumumab in previously treated chronic lymphoid leukemia. *N Engl J Med*. 2014:371:213-23.
- 6. Wang ML, Rule S, Martin P, et al. Targeting BTK with ibrutinib in relapsed or refractory mantlecell lymphoma. *N Engl J Med.* 2013:369:507-16.
- 7. Byrd JC, Furman RR, O'Brien S, et al. Targeting BTK with ibrutinib in relapsed chronic lymphocytic leukemia. *N Engl J Med.* 2013: 369:32-42.



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