IMBRUVICA® (ibrutinib) RESONATE™-2 Data Show Significant Improvements in Progression-Free and Overall Survival Versus Chlorambucil in Previously Untreated Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

These Phase 3 data were presented at The American Society of Hematology (ASH) Annual Meeting and simultaneously published in The New England Journal of Medicine

TORONTO, ON, December 8, 2015 – Data from the Phase 3 RESONATE™-2 (PCYC-1115) trial show the use of IMBRUVICA® (ibrutinib) in previously untreated patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) was associated with a reduced risk of death by 84 per cent compared to chlorambucil, which is sometimes used as first line therapy.[1]

The study showed IMBRUVICA® was superior to chlorambucil in all efficacy endpoints measured in previously untreated patients with CLL or SLL aged 65 or older. IMBRUVICA® significantly prolonged progression-free survival (PFS), the study's primary endpoint, and overall survival (OS), a key secondary endpoint, also in addition to improving other hematologic measures. Janssen Inc. is announcing that these data were presented at the official press briefing for The American Society of Hematology (ASH) Annual Meeting in Orlando, Florida and simultaneously published in *The New England Journal of Medicine*.

"The RESONATE-2 data are very important because they represent the first demonstration of benefit and safety of novel targeted therapy in the frontline treatment setting. This provides evidence for a valuable new frontline treatment option for patients with CLL or SLL," said Dr. Carolyn Owen, hematologist, Foothills Medical Centre*. "The results show IMBRUVICA® was associated with a significant reduction in the risk of death, making it a beneficial treatment option for appropriate patients."

About RESONATE™-2[2]

RESONATE™-2 is an international, randomized, multi-center, open-label trial that shows IMBRUVICA® significantly prolonged PFS as determined by the Independent Review Committee (IRC) compared with chlorambucil. The study was conducted with 269 previously untreated patients age ≥65 years with CLL/SLL who were randomly assigned to receive ibrutinib or chlorambucil. The hazard ratio (HR) was 0.16 (95 per cent CI, 0.09-0.28; P<0.001), which represents a reduction of risk of progression or death by 84 per cent versus chlorambucil (median not reached vs. 18.9 months); the PFS rate at 18 months was 89.9 per cent versus 51.5 per cent for IMBRUVICA® and chlorambucil, respectively.

IMBRUVICA® also significantly prolonged OS (HR=0.16: 95 per cent CI. 0.05, 0.56; P=0.001) with an 18-month survival rate of 97.8 per cent, compared to 87.2 per cent for patients in the chlorambucil arm. Additionally, IMBRUVICA® was associated with a significantly higher overall response rate (ORR) (86 vs. 35 per cent; P<0.001) as assessed by the IRC and significantly increased the rate of sustained improvements in both hemoglobin and platelets.

The safety of IMBRUVICA® in this patient population was consistent with previously reported studies. It is worth noting that exposure to treatment and adverse event (AE) follow-up was nearly 2.5 times as long for IMBRUVICA® compared with chlorambucil and 87 per cent of patients randomized to IMBRUVICA® were still receiving it at the time of analysis. Overall, AEs leading to treatment discontinuation were less frequent with IMBRUVICA® than with chlorambucil (9 per cent vs. 23 per cent, respectively). The most common AEs (>20 per cent) of any Grade in the RESONATE-2 trial for IMBRUVICA® were diarrhea (42 per cent), fatigue (30 per cent), cough (22 per cent) and nausea (22 per cent). AEs for chlorambucil included nausea (39 per cent), fatigue (38 per cent), neutropenia (23 per cent), anemia (20 per cent) and vomiting (20 per cent). Hypertension occurred at a higher rate in the IMBRUVICA® arm (14 per cent; Grade 3 in 4 per cent, no Grade 4 or 5). All six patients with Grade 3 hypertension were managed with hypertensive medication and did not require IMBRUVICA® dose reduction or discontinuation. Four IMBRUVICA® patients experienced Grade 3 hemorrhage and one experienced Grade 4 hemorrhage.

There were three deaths in the IMBRUVICA® arm and 17 deaths on the chlorambucil arm over the median follow-up of 18.4 months. None of the patients who progressed on the IMBRUVICA® arm died during the subsequent follow-up period.

About CLL and SLL

Chronic lymphocytic leukemia is a slow-growing blood cancer of white blood cells called lymphocytes, most commonly B cells.[3] Chronic lymphocytic leukemia is the most common type of leukemia in adults, and is more common in older adults over 60.[4] In Canada, it is estimated that about 2,400 adults were diagnosed with CLL in 2010.[5] The disease 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.[6] Small lymphocytic lymphoma is a slow-growing lymphoma in which too many immature white blood cells cause lymph nodes to become larger than normal.[7]

About IMBRUVICA® (ibrutinib)

IMBRUVICA® contains the medicinal ingredient ibrutinib which is a targeted inhibitor of Bruton's tyrosine kinase (BTK). IMBRUVICA® blocks BTK activity, inhibiting cancer cell survival and spread.[8]

IMBRUVICA® is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL), including those with 17p deletion, who have received at least one prior therapy, or for the frontline treatment of patients with CLL with 17p deletion. Clinical effectiveness of IMBRUVICA® in the frontline setting is based on the benefit observed in CLL patients with 17p deletion who have received at least one prior therapy. Clinical trial data in the frontline setting are very limited. IMBRUVICA® is also approved in Canada for the treatment of patients with relapsed or refractory mantle cell lymphoma (MCL), and was approved for this use with conditions, pending the results of trials to verify its clinical benefit.

About Janssen Inc.

Janssen Inc. is one of the Janssen Pharmaceutical Companies of Johnson & Johnson, which are dedicated to addressing and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we bring innovative products, services and solutions to people throughout the world. Please visit www.janssen.com for more information.

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Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Inc., and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including the uncertainty of clinical success and of obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 28, 2014, including in Exhibit 99 thereto, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

* Dr. Owen is an investigator on the RESONATE-2 trial; she was not compensated for any media work. She has been a paid consultant to Janssen Inc.

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[8] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. Updated September 14, 2015