.

Media Contact: Kate Hanna
Office: (416) 382-5017

Investor Contact: Stan Panasewicz
Office: (732) 524-2524

Investor Contact: Louise Mehrotra
Office: (732) 524-6491

Ibrutinib RESONATE™ Data Show Significant Improvements in Progression-Free Survival and Overall Survival in Patients with Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

Phase 3 data featured in the official press program of the 50th annual meeting of the American Society of Clinical Oncology and simultaneously published in the New England Journal of Medicine

TORONTO, ON, June 2, 2014 – Data from the international, multicenter Phase 3 RESONATE™ trial show single-agent ibrutinib, a targeted therapy, significantly lengthened progression-free survival (PFS) and overall survival (OS) in patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL). Janssen Inc. announced today that these data were presented during the official press program at the American Society of Clinical Oncology (ASCO) meeting in Chicago, IL and they were simultaneously published in a special edition of *The New England Journal of Medicine.*

The results from the RESONATE™ study show ibrutinib significantly improved PFS (median not reached vs. 8.1 months; HR 0.215, 95% CI, 0.146 to 0.317; P<0.0001) and OS (HR 0.434; 95% CI, 0.238 to 0.789; P=0.0049) compared to ofatumumab. The median PFS in the ibrutinib arm was not reached because of a lower rate of progression events than in the ofatumumab arm. These PFS results represent a 79 per cent reduction in the risk of disease progression or death from any cause in patients treated with ibrutinib compared to ofatumumab. The OS results represent a 57 per cent reduction in the risk of death in patients receiving ibrutinib compared to ofatumumab. Additionally, the overall response rate (ORR) was significantly higher in patients taking ibrutinib versus ofatumumab. Forty-three per cent of ibrutinib patients achieved a partial response (PR) compared to only four per cent of patients taking

ofatumumab (p<0.0001). Consistent results were seen in CLL/SLL patients with a deletion in the short arm of chromosome 17 (del 17p), a genetic mutation typically associated with poor prognosis.[1]

“The RESONATE data are particularly exciting for clinicians in Canada as they show a significant improvement in progression-free and overall survival in patients with relapsed or refractory CLL compared with our current treatments,” said Dr. Cynthia Toze, Member, Leukemia/BMT Program of British Columbia, Clinical Professor of Medicine, UBC. “The results demonstrate that ibrutinib, as a targeted therapy, is an effective and tolerable treatment option for patients with CLL who have relapsed or whose disease did not respond to first-line treatment.”*

About RESONATE™

RESONATE™ is a Phase 3, multi-center, international, open-label, randomized study that examined ibrutinib versus ofatumumab in relapsed or refractory patients with CLL/SLL who had received at least one prior therapy and were not considered appropriate candidates for treatment with purine analog-based therapy (n=391). Patients were administered either 420 mg oral ibrutinib (n=195) daily until progression or unacceptable toxicity or intravenous ofatumumab for up to 24 weeks (n=196, initial dose of 300 mg followed by 11 doses at 2,000 mg; dose and schedule consistent with local labeling).

Progression-free survival is the primary endpoint of the RESONATE™ study, with OS, ORR and safety as key secondary endpoints. The median follow-up was 9.4 months.

In January 2014, RESONATE™ was stopped early at the unanimous recommendation of an Independent Data Monitoring Committee (IDMC) based on a planned interim analysis which concluded that the study showed a significant difference in PFS as compared to the control (the primary endpoint of the study). The IDMC recommended that the sponsor provide access to ibrutinib to patients in the ofatumumab arm.

The most common Grade 3 or 4 adverse events (AEs) in the RESONATE™ trial (occurring in five per cent or more of patients) were neutropenia (decreased amount of neutrophils in the blood; 16 per cent in the ibrutinib arm vs. 14 per cent in the ofatumumab arm), pneumonia (seven per cent vs. five per cent), thrombocytopenia (decrease in platelets in the blood; six per cent vs. four per cent) and anemia (five per cent vs. eight per cent). The most commonly occurring side effects (AEs in 20 per cent or more of

patients) were diarrhea (48 per cent vs.18 per cent), fatigue (28 per cent vs. 30 per cent), pyrexia (fever; 24 per cent vs. 15 per cent), nausea (26 per cent vs.18 per cent), anemia (23 per cent vs. 17 per cent) and neutropenia (21 per cent vs. 15 per cent). Atrial fibrillation of any grade was noted more frequently in patients receiving ibrutinib (n=10 patients) versus ofatumumab (n=1 patient). Total treatment exposure was longer for the ibrutinib arm than the ofatumumab arm (median time: 8.6 months vs. 5.3 months).

Treatment discontinuations due to progressive disease were five per cent in the ibrutinib arm and 19 per cent in the ofatumumab arm. Four per cent of patients in both treatment arms (eight patients in the ibrutinib arm and seven patients in the ofatumumab arm) discontinued treatment due to adverse events in the clinical trial. Treatment discontinuation due to death occurred in four per cent of patients in the ibrutinib arm (eight patients) and five per cent of patients in the ofatumumab arm (nine patients). These events were most commonly infectious in nature.

About CLL and SLL

Chronic lymphocytic leukemia is a slow-growing blood cancer of white blood cells called lymphocytes, most commonly B cells.[1] Chronic lymphocytic leukemia is the most common type of leukemia in adults, and is more common in older adults over 60.[2] In Canada, it is estimated that about 2,400 adults were diagnosed with CLL in 2010.[2] 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.[3] Small lymphocytic leukemia is a slow-growing lymphoma in which too many immature white blood cells cause lymph nodes to become larger than normal.[1]

About Ibrutinib

Ibrutinib works by blocking a specific protein called Bruton's tyrosine kinase (BTK).[4] The BTK protein transmits important signals that tell B cells to mature and produce antibodies, and is needed by specific cancer cells to multiply and spread. [4,5] Ibrutinib targets and blocks BTK, inhibiting the spread and survival of cancer cells.[4]

Ibrutinib received U.S. approval via the FDA's Breakthrough Therapy Designation and is indicated for the treatment of patients with CLL who have received at least one prior therapy, and for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. Ibrutinib is

undergoing priority review at Health Canada in the area of CLL. Ibrutinib is being jointly developed and commercialized by Janssen Biotech, Inc. and Pharmacyclics, Inc.

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.ca for more information.

-30-

* Dr. Cynthia Toze was not compensated for any media work. She has been a paid consultant to Janssen Inc.

[1] American Cancer Society. "Leukemia--Chronic Lymphocytic". http://www.cancer.org/acs/groups/cid/documents/webcontent/003111-pdf.pdf. Accessed April 2014.
[2]The Leukemia and Lymphoma Society of Canada "CLL Incidence", http://www.llscanada.org/#/diseaseinformation/leukemia/chroniclymphocyticleukemia/incidence/. Accessed May, 2014.
[3] Veliz M, Pinilla-Ibarz J. Treatment of relapsed or refractory chronic lymphocytic leukemia. *Cancer Control*. 2012 Jan;19(1):37-53.
[4] IMBRUVICA Prescribing Information, February 2014.
[5] Genetics Home Reference. Isolated growth hormone deficiency. Available from: http://ghr.nlm.nih.gov/condition/isolated-growth-hormone-deficiency. Accessed April 2014.