EU Media Inquiries:
Satu Kaarina Glawe
Phone: +49 (0) 2638 947 9218
Mobile: +49 (172) 294 6264
Email: sglawe@its.jnj.com

Investor Relations:
Stan Panasewicz
Phone: +1 732-524-2524
Louise Mehrotra
Phone: +1 732-524-6491

Independent Data Monitoring Committee Recommends Early Stopping of Phase 3 Study of Ibrutinib in Relapsed/Refractory CLL/SLL Patients Based on a Planned Interim Analysis

Beerse / Belgium, 7 January 2014– Janssen-Cilag International NV (Janssen) today announced the early stopping of PCYC-1112-CA, the Phase 3 study of ibrutinib in the treatment of Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma (CLL/SLL), based on the recommendation of an Independent Data Monitoring Committee (IDMC), which concluded that the study showed a significant difference in progression-free survival (PFS) as compared to the control, the primary endpoint of the study.

Study PCYC-1112-CA (RESONATE) is an international, randomized, open-label Phase 3 clinical study including 391 patients with relapsed or refractory CLL/SLL with measurable nodal disease and who were not eligible for treatment with purine analog-based therapy, who had received at least one prior therapy. Patients were randomized to receive 420 mg of ibrutinib orally once daily or intravenous doses of ofatumumab, an approved treatment for relapsed/refractory CLL, over the course of 24 weeks. Both treatments were administered until disease progression or unacceptable toxicity.

The primary endpoint of the study is PFS; overall survival (OS) is a key secondary endpoint; others included overall response rate and safety.

"We're delighted with this outcome, and look forward to sharing these results with the scientific community and Health Authorities," said Peter F. Lebowitz, MD, PhD, Oncology Therapeutic Area Head, Janssen Research & Development, LLC. "This Phase 3 randomized study provides a useful head-to-head comparison of single agent ibrutinib versus ofatumumab, and builds upon the early evidence of clinical benefit observed in the ibrutinib Phase 2 programme."

The IDMC unanimously recommended stopping of the study early based on a planned interim analysis, in which statistically significant differences in PFS (as assessed by an independent review committee) and OS were observed. The IDMC agreed that these results suggest evidence of clinical benefit as well as a tolerable safety profile in patients receiving ibrutinib as compared to intravenous doses of ofatumumab. The IDMC also recommended that the sponsor provides access to ibrutinib to patients in the ofatumumab arm.

These results will be presented at an upcoming medical meeting and also will be submitted for publication in a peer-reviewed journal.

The company plans to initiate a Named Patient Programme for high risk patients with relapsed or refractory CLL/SLL or relapsed or refractory MCL (Mantle Cell Lymphoma) in Europe in the first half of 2014.

On October 30, 2013, Janssen submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for ibrutinib for the treatment of adult patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Leukemia (SLL) or relapsed or refractory Mantle Cell Lymphoma (MCL).

CLL/SLL and MCL belong to a group of blood cancers, known as B-cell malignancies, originating from B cells, a type of white blood cell (lymphocyte).[1] CLL/SLL and MCL are complex diseases that can be challenging to treat. As a result, many patients will relapse after a specific treatment and may require multiple treatments over the course of their disease.

#ENDS#

About Ibrutinib

Ibrutinib is the first in a class of medicines called Bruton's tyrosine kinase (BTK) inhibitors. BTK is an important protein involved in mediating the cellular signaling pathways which control B cell maturation and survival. In malignant B cells, there is excessive signaling through the B cell receptor signaling (BCR) pathway, which includes BTK. The malignant cell ignores the natural signal to die and continues to develop and proliferate. Malignant cells migrate and adhere to protective environmental areas such as the lymph nodes where they proliferate and survive. Ibrutinib is the first in a new class of drugs specifically designed to target and inhibit BTK. Ibrutinib forms a strong covalent bond with BTK, which inhibits the excessive transmission of cell survival signals within the malignant B cells and stops their excessive build up in these protected environmental areas. The efficacy and safety of ibrutinib alone and in combination with other treatments is being studied in several blood cancers.[2,3,4,5,6]

About Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Leukemia (SLL)

CLL is a usually slow growing blood cancer that most commonly originates from B cells, a type of white blood cell (lymphocyte) that develops in the bone marrow. B cells are part of the immune system and play an important role in fighting infection in the body. CLL is the most common adult leukemia in the Western world, with the median age at diagnosis being primarily those over 70 years old. The incidence rates among men and women in Europe are approximately 5.87 and 4.01 cases per 100,000 persons per year, respectively. CLL is a chronic disease; median overall survival ranges between 18 months and more than 10 years according to the stage of disease. When cancer cells are located mostly in the lymph nodes, the disease is called small lymphocytic lymphoma (SLL).[7,8,9,10,11,12]

About Mantle Cell Lymphoma (MCL)

MCL is a rare and aggressive blood cancer that usually occurs in older adults, with the median age at diagnosis being 65 years. The disease typically begins in the lymph nodes, but can spread to other tissues such as bone marrow, liver and spleen. The incidence rates among men and women in Europe are approximately 0.64 and 0.27 cases per 100,000 persons per year, respectively. MCL patients generally have a poor prognosis. Median overall survival is typically three to four years, and only one to two years in patients following the first relapse. [13,14,15,16]

About Janssen

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology, immunology, neuroscience, infectious disease, and cardiovascular and metabolic diseases. Driven by our commitment to patients, Janssen develops innovative products, services and healthcare solutions to help people throughout the world. More information can be found at www.janssen-emea.com

Janssen in Oncology

In oncology, our goal is to fundamentally alter the way cancer is understood, diagnosed, and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on hematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualized use of our therapies; as well as safe and effective identification and treatment of early changes in the tumor microenvironment.

Janssen and Pharmacyclics Strategic Partnership

Ibrutinib is being co-developed as part of a strategic partnership between Janssen and Pharmacyclics, Inc. Both companies are responsible for the development, manufacturing and commercialisation of ibrutinib. In Europe, Janssen is the lead party for the commercialisation of ibrutinib, if approved. Details about the complete ibrutinib clinical programme are posted on clinicaltrials.gov. Pharmacyclics sponsored the PCYC-1112-CA study.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

# # #

References

1. National Cancer Institute. Definition: B cell. Available from: http://www.cancer.gov/dictionary?cdrid=45611. Accessed May 14, 2013.
2. Qiu Y, Kung HJ. Signaling network of the Btk family kinases. Oncogene 2000;19:5651-61.
3. Shaffer AL, Rosenwald A, Staudt LM. Lymphoid malignancies: the dark side of B-cell differentiation. Nat Rev Immunol. 2002;2:920-32.
4. Puri KD, di Paolo JA, Gold MR. B-cell receptor signaling inhibitors for treatment of autoimmune inflammatory diseases and B-cell malignancies. Int Rev Immunol 2013;32:397-427.
5. Woyach JA, Johnson AJ, Byrd JC. The B-cell receptor signaling pathway as a therapeutic target in CLL. Blood 2012;120:1175-84.
6. Akinleye A, Chen Y, Mukhi N, Song Y, Liu D. Ibrutinib and novel BTK inhibitors in clinical development. J Hematol Oncol 2013;6:59.
7. Parker, T. Chronic lymphocytic leukemia: prognostic factors and impact on treatment. Discovery Medicine. 2011; 57.
8. SEER Statistics. Fact Sheets: Chronic lymphocytic leukemia. Available from: http://seer.cancer.gov/statfacts/html/clyl.html. Accessed March 6, 2013.
9. American Cancer Society. Detailed guide: what is chronic lymphocytic leukemia. Available from: http://www.cancer.org/cancer/leukemia-chroniclymphocyticcll/detailedguide/leukemia-chronic-lymphocytic-what-is-cll. Accessed March 6, 2013.
10. Sant M, Allemani C, Tereanu C, et al. Incidence of hematologic malignancies in Europe by morphologic subtype: results of the HAEMACARE project. Blood 2010;116:3724-34.
11. Cancer Research UK. The most common types of non-Hodgkins lymphoma. Available from: http://www.cancerresearchuk.org/cancerhelp/type/non-hodgkins-lymphoma/about/types/the-most-common-types-of-non-hodgkins-lymphoma#sll. Accessed March 14, 2013.
12. Sagatys EM, Zhang L. Clinical and laboratory prognostic indicators in chronic lymphocytic leukemia. Cancer Control 2012;19:18-25.
13. McKay P, Leach M, Jackson R, et al. Guidelines for the investigation and management of mantle cell lymphoma. Br J Haematol 2012;159:405-26.

14. Leukemia and Lymphoma Society. Mantle Cell Lymphoma Facts. Available from: http://www.lls.org/content/nationalcontent/resourcecenter/freeeducationmaterials/lymphoma/pdf/mantlecelllymphoma.pdf. Accessed May 14, 2013.
15. Smedby KE, Hjalgrim H. Epidemiology and etiology of mantle cell lymphoma and other non-Hodgkin lymphoma subtypes. Semin Cancer Biol 2011;21:293-8.
16. Goy A, Bernstein SH, Kahl BS, et al. Bortezomib in patients with relapsed or refractory mantle cell lymphoma: updated time-to-event analyses of the multicenter phase 2 PINNACLE study. Ann Oncol 2009;20:520-5.