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PHASE 3 DATA HIGHLIGHT BENEFITS OF USING VELCADE® WITHIN FRONTLINE TREATMENT OF MANTLE CELL LYMPHOMA, WITH RESULTS SHOWING SIGNIFICANTLY LONGER PROGRESSION-FREE SURVIVAL COMPARED TO STANDARD OF CARE

Investigational study reports potential benefits of VELCADE (bortezomib)-based combination therapy when used as an initial treatment in this rare blood cancer

NOTE: this press release relates to ASCO congress abstract #8500

BEERSE, BELGIUM, JUNE 1, 2014 - Janssen-Cilag International NV today announced that data from a Phase 3 study highlighted that treating patients with newly-diagnosed Mantle Cell Lymphoma (a rare blood cancer) with a treatment combination including VELCADE® (bortezomib) in the frontline setting offers significant improvements in progression-free survival (PFS) and a range of secondary endpoints, compared to a current standard of care.

Results showed that, compared to the treatment combination R-CHOP*, the VELCADE-based regimen, VR-CAP† increased Progression-Free Survival (PFS) (the time patients live without their disease progressing) by 59 percent amongst previously-untreated patients with MCL (median PFS 24.7 vs. 14.4 months; HR 0.63; p<0.001).[1] Results were presented by Franco Cavalli, MD, Scientific Director of the Oncology Institute of Southern Switzerland at the 50th Annual Meeting of the American Society for Clinical Oncology (ASCO).

“Mantle Cell Lymphoma is an aggressive blood cancer and treatment options for newly diagnosed patients are limited.” said Professor Cavalli, lead investigator on the study. “This study clearly demonstrates a range of potential benefits in using a bortezomib-based frontline therapy in Mantle Cell Lymphoma patients. In addition to the significant improvement in progression-free survival, it is encouraging that a relatively short treatment duration with the bortezomib-based regimen results in a longer time until the next chemotherapy is needed.”

The study, LYM-3002, is a randomized, open-label, active-controlled, multicenter, international prospective Phase 3 study which includes 487 patients with newly-diagnosed MCL who were ineligible or not

* Rituximab, cyclophosphamide, doxorubicin, vinicristine and prednisone (R-CHOP)
† VELCADE, rituximab, cyclophosphamide, doxorubicin and prednisone (VR-CAP)

considered for bone marrow transplantation. Its objective is to compare the efficacy and safety of the combination of VR-CAP (VELCADE IV in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone) with a current standard of care in frontline MCL, R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone). The primary endpoint was progression-free survival (PFS).[1]

At a median follow-up of 40 months, median PFS was 24.7 months (VR-CAP) vs. 14.4 months (R-CHOP) (HR=0.63 [0.50, 0.79], P<0.001) as assessed by an independent review committee. Median overall survival (OS), a key secondary endpoint, had not been reached for patients who received VR-CAP, although a median OS of 56 months was observed in patients treated with R-CHOP (HR 0.80; P=0.17). Though not a pre-specified endpoint, the four-year survival rate showed a trend towards prolonged survival with VR-CAP. At four years, survival was reported as 64.4 percent in the experimental arm vs. 53.9 percent in the control arm.[1] The overall response rate (ORR) was 92 percent in the VR-CAP arm compared to 90 percent in the control arm (OR=1.4; P=0.275]. The complete response rate (CR+CRu) was 53 percent in the VR-CAP arm compared to 42 percent in the control arm (OR=1.7; P=0.007].[1]

“This is one of the largest studies ever conducted on newly-diagnosed patients with Mantle Cell Lymphoma and these data represent a landmark in our understanding of the benefits of using a VELCADE-based regimen as frontline therapy,” said Jane Griffiths, Company Group Chairman, Janssen Europe, the Middle East and Africa (EMEA). “Limited treatment options exist for patients with this rare blood cancer, so these data are encouraging news for patients.”

Overall, among patients receiving VR-CAP compared to R-CHOP, serious adverse events (AE) were reported in 38 percent vs. 30 percent of patients and grade ≥3 AEs were reported in 93 percent vs. 85 percent. Discontinuations of the trial due to AEs were nine percent (VR-CAP) vs. seven percent (R-CHOP) and on-treatment drug-related deaths were two percent vs. three percent.[1]

Other secondary endpoint results for patients receiving VR-CAP vs. R-CHOP included:[1]

- 30.5 vs. 16.1 months median time to progression (HR 0.58; P<0.001)
- 44.5 vs. 24.8 months median time to subsequent anti-lymphoma treatment (HR 0.50; P<0.001)
- 40.6 vs. 20.5 months median treatment-free interval (HR 0.50; P<0.001)

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NOTES TO EDITORS

About VELCADE (bortezomib)[2]

VELCADE (bortezomib) is a medicine currently licensed in the EU to treat the blood-based cancer, multiple myeloma. It contains an active substance called bortezomib and is the first in a specific class of medicines known as proteasome inhibitors. Proteasomes are present in all cells and play an important role in controlling cell function, growth and also how cells interact with the other cells around them. Bortezomib reversibly interrupts the normal working of cell proteasomes causing myeloma cancer cells to stop growing and die.

VELCADE has a predictable safety profile and a favorable benefit–risk ratio. The most common side effects reported with VELCADE (bortezomib) include fatigue, gastrointestinal adverse events, transient thrombocytopenia and neuropathy.[2]

VELCADE is the market leader in the treatment of frontline non-transplant eligible multiple myeloma. It is co-developed by Millennium: The Takeda Oncology Company, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, and Janssen Pharmaceutical Companies. Millennium: The Takeda Oncology Company is responsible for commercialization of VELCADE in the U.S.; Janssen Pharmaceutical Companies are responsible for commercialization in Europe and the rest of the world. Takeda Pharmaceutical Company Limited and Janssen Pharmaceutical K.K. co-promote VELCADE in Japan. VELCADE is approved in more than 90 countries and has been used to treat more than 550,000 patients worldwide.

VELCADE (bortezomib) in Mantle Cell Lymphoma

In Europe, VELCADE is not currently licensed to treat Mantle Cell Lymphoma (MCL). VELCADE's approved indications can be viewed online at:[2]
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000539/human_med_001130.jsp&mid=WC0b01ac058001d124

In 2006, the United States FDA approved VELCADE for the treatment of patients with MCL who have received at least one prior therapy. VELCADE has subsequently been approved for the treatment of relapsed MCL in 53 additional countries, including Canada and Switzerland.

About Mantle Cell Lymphoma

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.[3,4,5,6]

About Janssen

Janssen-Cilag International NV is one of the Janssen Pharmaceutical Companies. Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology (e.g. multiple myeloma and prostate cancer), immunology (e.g. psoriasis), neuroscience (e.g. schizophrenia, dementia and pain), infectious disease (e.g. HIV/AIDS,

hepatitis C and tuberculosis) and cardiovascular and metabolic diseases (e.g. diabetes). Driven by our commitment to patients, we develop sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, based on partnerships of trust and transparency. More information can be found on www.janssen-emea.com. Follow us on www.twitter.com/janssenEMEA for our latest news.

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 disease area strongholds that focus on hematologic malignancies and prostate 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; and safe and effective identification and treatment of early changes in the tumor microenvironment.

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 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: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; 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; general industry conditions including 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 Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2013, including in Exhibit 99 thereto, and our 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 statements as a result of new information or future events or developments.

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REFERENCES

1. Cavalli et al. Randomized Phase 3 study of rituximab, cyclophosphamide, doxorubicin, and prednisone plus vincristine (R-CHOP) or bortezomib (VR-CAP) in newly diagnosed mantle cell lymphoma (MCL) patients (pts) ineligible for bone marrow transplantation (BMT). ASCO 2014 Abstract #8500.
2. VELCADE European Public Assessment Report (EPAR). Available from http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000539/human_med_001130.jsp&mid=WC0b01ac058001d124 (accessed May 2014)
3. 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.
4. 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.
5. Smedby KE, Hjalgrim H. Epidemiology and etiology of mantle cell lymphoma and other non-Hodgkin lymphoma subtypes. Semin Cancer Biol 2011;21:293-8.
6. 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.