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Darzalex®▼ (daratumumab) Combination Regimens Show Positive Results for Newly Diagnosed and Relapsed Patients with Multiple Myeloma

Updated Phase 3 ALCYONE results featured as oral presentation at ASH 2018 show improved progression-free survival in newly diagnosed patients

Data from Phase 2 LYRA and GRIFFIN studies support the safety and efficacy of daratumumab combination treatments in newly diagnosed and relapsed patients, including the feasibility of a split first dose

BEERSE, BELGIUM, December 1, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today long-term results from the Phase 3 ALCYONE study showing that the addition of Darzalex® (daratumumab) to bortezomib, melphalan and prednisone (VMP) continued to demonstrate significant improvement in progression-free survival (PFS) in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation (ASCT).[1] These data (Abstract #156), as well as updates from the Phase 2 LYRA (Abstract #152) and

GRIFFIN (Abstract #151) studies in patients with multiple myeloma, were featured during an oral abstract session at the 60th American Society of Hematology (ASH) Annual Meeting in San Diego, CA.

Long-term Phase 3 ALCYONE results for daratumumab frontline combination therapy[1]

At a median follow-up of 27.8 months, study results showed the addition of daratumumab to VMP reduced the risk of disease progression or death by 57 percent compared to VMP alone (Hazard Ratio [HR] = 0.43; 95 percent confidence interval [CI] 0.35-0.54, p<0.0001).[1] Daratumumab-VMP resulted in a 24 month PFS rate of 63 percent compared to 36 percent with VMP alone.[1] The median PFS for daratumumab-VMP has not yet been reached, whereas the control arm of VMP alone had a median PFS of 19.1 months.[1] In addition, a significantly higher overall response rate (ORR) (91 percent vs. 74 percent, respectively) was observed with the daratumumab combination compared to VMP alone.[1] Daratumumab-VMP resulted in deeper responses, significantly improving the rate of very good partial response (VGPR) or better (73 percent vs. 50 percent) and more than doubling the rate of stringent complete response (sCR) (22 percent vs. 8 percent) compared to VMP alone.[1] Daratumumab-VMP induced a higher rate of sustained minimal residual disease (MRD) negativity compared to VMP alone (10 percent vs. 2 percent, respectively).[1] The previously reported primary results of this study formed the basis of the European Commission approval of daratumumab in combination with VMP in patients with newly diagnosed multiple myeloma who are ineligible for ASCT.

"Longer-term data from the pivotal ALCYONE trial show that daratumumab combination therapy continued to show improvement in progression-free survival and response rates in newly diagnosed patients with multiple myeloma, including older patients who are less likely to respond to treatment," said Meletios A. Dimopoulos, M.D., Professor and Chairman of the Department of Clinical Therapeutics at the National and Kapodistrian University of Athens School of Medicine, Athens, Greece, and principal investigator. "These promising results support the use of daratumumab earlier in the treatment paradigm when transplant ineligible patients are more likely to benefit from therapy, and that continued therapy with daratumumab confers benefit."

In the ALCYONE study, the most common Grade 3/4 treatment-emergent adverse events (TEAEs) during Cycle 10 and onward for daratumumab-VMP included anaemia (4 percent), neutropenia (2 percent) and bronchitis (1 percent).[1] No new safety signals emerged, and Grade 3/4 infections continued to be manageable.[1]

Phase 2 LYRA and GRIFFIN data support efficacy and safety of daratumumab in newly diagnosed patients, including those who are eligible for high-dose therapy/ASCT, and in relapsed patients[2,3]

Response rates from the Phase 2 LYRA study were presented for the investigational use of daratumumab plus cyclophosphamide, bortezomib, and dexamethasone (CyBorD) in patients with newly diagnosed and relapsed multiple myeloma.[2] The ORR and VGPR or better rates in 86 newly diagnosed patients were 79 percent and 44 percent, respectively, after 4 Cycles and increased to 81 percent and 56 percent, respectively, at the end of induction (median 6 Cycles).[2] In addition, the VGPR or better rate in 14 relapsed multiple myeloma patients was 57 percent after 4 Cycles and increased to 64 percent at the end of induction, and the ORR stayed consistent at 71 percent (median 7.5 Cycles).[2] The 18-month PFS rate was 78 percent in non-transplant newly diagnosed patients and 53 percent in relapsed patients.[2] Additionally, the study, which investigated splitting the first dose of daratumumab to shorten the infusion time on Cycle 1, Day 1 (C1D1), showed a safety profile consistent with previous studies.[2] Infusion reactions (IRs) occurred in 49 percent of patients on C1D1 and four percent on Cycle 1, Day 2 (C1D2). Fifty-four percent of newly diagnosed patients experienced IRs, the most frequent being chills (14 percent), dyspnea, pruritus and nausea (8 percent each), and cough (7 percent). Fifty-seven percent of relapsed patients experienced IRs, the most frequent being cough (21 percent), hyperhidrosis, dyspnea, and chills (7 percent each). Only two patients experienced a Grade 3 IR, and there were no Grade 4 IRs. There were no daratumumab discontinuations due to IRs. Median infusion time was 4.5 hours for C1D1 and 3.8 hours for C1D2.[2] Grade 3/4 TEAEs were reported for 56 percent of patients and the most common (≥10 percent) was neutropenia (13 percent).[2]

Data presented on the Phase 2 GRIFFIN study investigated daratumumab in combination with bortezomib, lenalidomide and dexamethasone (VRd) in a 16-patient safety cohort of newly diagnosed patients with multiple myeloma who were eligible for high-dose therapy and ASCT.[3] Results showed that by the end of consolidation therapy following ASCT, all patients enrolled in the safety run-in obtained VGPR or better, and 63 percent achieved complete response (CR) or better, including 25 percent of patients who achieved sCR.[3] Additionally, 94 percent of patients remained progression-free on study treatment at a median follow-up of 16.8 months.[3] In addition, 8 of the 16 patients (50 percent) were MRD negative at a level of 10^{-5} by the end of consolidation.[3] Fourteen patients (88 percent) experienced Grade 3/4 TEAEs with 10 (63 percent) related to treatment with daratumumab.[3] The most common Grade 3/4 TEAEs (≥10 percent) included neutropenia,

pneumonia, thrombocytopaenia, lymphopenia, febrile neutropenia, leukopenia, rash and hypophosphataemia.[3] Thirteen patients (81 percent) experienced infections of any grade, including upper respiratory tract infection (six patients), pneumonia (four patients), bronchitis (two patients), and otitis and viral gastroenteritis (two patients each).[3] No deaths due to serious adverse events were reported and no patient discontinued treatment due to an adverse event.[3] These data suggest that daratumumab induction does not negatively impact stem cell mobilisation as all 16 patients underwent successful mobilisation with subsequent ASCT.[3]

"Daratumumab offers consistent clinical benefit across all lines of therapy in multiple myeloma and the positive data from the ALCYONE, LYRA and GRIFFIN studies build on the strong body of evidence supporting daratumumab-based regimens," said Dr Catherine Taylor, Haematology Therapy Area Lead, Europe, Middle East and Africa (EMEA), Janssen-Cilag Limited. "These are important findings for patients which also provide additional insight into the most effective ways to manage care."

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About the ALCYONE Trial[4]

The randomised, open-label, multicentre Phase 3 ALCYONE (MMY3007) study enrolled 706 newly diagnosed patients with multiple myeloma who were ineligible for high-dose chemotherapy with ASCT. The median age was 71 years (range: 40-93). Patients were randomised to receive up to nine Cycles of either daratumumab-VMP or VMP alone. In the daratumumab-VMP arm, patients received 16 mg/kg of daratumumab once weekly for the first week (Cycle 1), followed by once every three weeks (Cycles 2-9). Following the nine cycles, patients in the daratumumab-VMP arm continued to receive 16 mg/kg of daratumumab once every four weeks until disease progression.

About the LYRA Trial[5]

The ongoing, multicentre, single-arm, open-label Phase 2 LYRA (MMY2012) study enrolled 100 adult patients 18 years or older. Patients received 4-8 Cycles of daratumumab combination therapy comprised of oral cyclophosphamide 300 mg/m^2 on Days 1, 8, 15 and 22; subcutaneous bortezomib 1.5 mg/m^2 on Days 1, 8 and 15; and oral or IV dexamethasone 40 mg weekly every 28 days. Daratumumab was administered at 8 mg/kg IV on Days 1 and 2 of Cycle 1, 16 mg/kg weekly from Cycle 1, Day 8 through Cycle 2, 16 mg/kg every 2 weeks for Cycles 3-6, and 16 mg/kg every 4 weeks for Cycles 7-8. After induction, patients could undergo ASCT. All patients receive 12 cycles of maintenance daratumumab 16 mg/kg IV every 4 weeks.

About the GRIFFIN Trial[6]

The randomised, open-label Phase 2 GRIFFIN (MMY2004) study has enrolled and treated more than 200 adults 18-70 years eligible for high-dose therapy/ASCT,[7] including 16 patients in a safety run-in phase performed to assess potential dose limiting toxicities during Cycle 1 of daratumumab combination with VRd. Patients in the safety run-in received four infusion Cycles of daratumumab and VRd every 21 days followed by stem cell mobilisation, high-dose therapy and ASCT; two consolidation Cycles of daratumumab and VRd; and maintenance therapy with daratumumab and lenalidomide for Cycles 7-32. During induction and consolidation (Cycles 1-6), patients received 25 mg of lenalidomide orally on Days 1-14, 1.3 mg/m^2 of bortezomib subcutaneously on Days 1, 4, 8 and 11, and 20 mg of dexamethasone on Days 1, 2, 8, 9, 15 and 16 every 21 days. Daratumumab 16 mg/kg IV was given on Days 1, 8 and 15 of Cycles 1-4 and on Day 1 of Cycles 5-6. During maintenance (Cycles 7-32), patients receive 10 mg daily of lenalidomide (15 mg beginning at Cycle 10 if tolerated) on Days 1-21 every 28 days and daratumumab 16 mg/kg IV every 56 days; this was amended to every 28 days. Maintenance therapy with lenalidomide may be continued beyond Cycle 32 per local standard of care. In the subsequent randomised Phase 2 portion of the study, approximately 200 patients were randomised and received treatment with VRd, ASCT and maintenance therapy with lenalidomide or daratumumab and VRd, ASCT and maintenance therapy with daratumumab and lenalidomide.[7]

About daratumumab

Daratumumab is a first-in-class biologic targeting CD38, a surface protein that is highly expressed across multiple myeloma cells, regardless of disease stage.[8] Daratumumab is believed to induce tumour cell death through multiple immune-mediated mechanisms of action, including complement-dependent cytotoxicity (CDC), antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP), as well as through apoptosis, in which a series of molecular steps in a cell lead to its death.[9] A subset of myeloid derived suppressor cells (CD38+ MDSCs), CD38+ regulatory T cells (Tregs) and CD38+ B cells (Bregs) were decreased by daratumumab.[9] Daratumumab is being evaluated in a comprehensive clinical development programme across a range of treatment settings in multiple myeloma, such as in frontline and relapsed settings.[10,11,12,13,14,15,16,17] Additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant haematologic diseases in which CD38 is expressed, such as smouldering myeloma.[18,19] For more information, please see www.clinicaltrials.gov.

In Europe, daratumumab is indicated for use in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are

ineligible for autologous stem cell transplant, as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy, and in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.[9] For further information on daratumumab, please see the Summary of Product Characteristics at https://www.ema.europa.eu/documents/product-information/darzalex-epar-product-information_en.pdf.

In August 2012, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive licence to develop, manufacture and commercialise daratumumab.[20]

About Multiple Myeloma

Multiple myeloma (MM) is an incurable blood cancer that starts in the bone marrow and is characterised by an excessive proliferation of plasma cells.[21] More than 45,000 people were diagnosed with multiple myeloma in Europe in 2016, and more than 29,000 patients died.[22] Up to half of newly diagnosed patients do not reach five-year survival,[23] and almost 29% of patients with multiple myeloma will die within one year of diagnosis.[24]

Although treatment may result in remission, unfortunately, patients will most likely relapse as there is currently no cure.[25] Refractory multiple myeloma is when a patient's disease progresses within 60 days of their last therapy.[26,27] Relapsed cancer is when the disease has returned after a period of initial, partial or complete remission.[28] While some patients with MM have no symptoms at all, most patients are diagnosed due to symptoms that can include bone problems, low blood counts, calcium elevation, kidney problems or infections.[29] Patients who relapse after treatment with standard therapies, including PIs and immunomodulatory agents, have poor prognoses and few treatment options available.[30]

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/emea. Follow us at www.twitter.com/janssenEMEA for our latest news.

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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 the benefits of daratumumab for the treatment of patients with multiple myeloma. 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 materialise, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV, Janssen-Cilag Limited, Janssen Biotech, Inc., any of the Janssen Pharmaceutical Companies of Johnson & Johnson and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behaviour and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions 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 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q and in 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. Neither the Janssen Pharmaceutical Companies of Johnson & Johnson nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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