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New DARZALEX® (daratumumab) Data from GRIFFIN Study Show High Response Rate and Depth of Response in Patients with Newly Diagnosed Multiple Myeloma Who are Transplant-Eligible

- *Phase 2 GRIFFIN study presented at 17th IMW meeting is the fourth randomized study to investigate the clinical benefit of DARZALEX® in the frontline setting*
- *New results from Phase 2 PLEIADES study evaluating a DARZALEX® subcutaneous formulation also presented*

BOSTON, September 15, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today results from the randomized Phase 2 GRIFFIN ([MMY2004](#)) study showing that the addition of DARZALEX® (daratumumab) to bortezomib, lenalidomide and dexamethasone (VRd) induced higher response rates in newly diagnosed patients with multiple myeloma who were eligible for high-dose therapy and autologous stem cell transplantation (ASCT) compared with VRd alone. The data, selected as a late-breaking [abstract](#), were presented at the 17th International Myeloma Workshop (IMW) meeting in Boston.

“The GRIFFIN study is the second randomized study to investigate the benefit of daratumumab for patients with newly diagnosed multiple myeloma who are eligible for a transplant, and the first in combination with lenalidomide for this population,” said Peter M. Voorhees, M.D., GRIFFIN principal investigator at Levine Cancer Institute. “This study adds to the growing body of evidence for the addition of daratumumab to proteasome inhibitor/immunomodulatory combination therapy in the transplant setting.”

Results from the Phase 2 GRIFFIN study showed that by the end of six cycles of therapy and transplant, a greater percentage of patients receiving DARZALEX®-VRd achieved the primary endpoint of stringent complete response (sCR) compared with VRd alone (42 percent vs. 32 percent, respectively; Odds Ratio [OR] = 1.57; 95 percent confidence interval [CI], 0.87-2.82; P=0.1359), meeting the prespecified 2-sided alpha of 0.2 for a positive study.¹ The addition of DARZALEX® to VRd resulted in higher rates of overall response (99 percent vs. 92 percent), very good partial response or better (91 percent vs. 73 percent) and complete response (CR) or better (52 percent vs. 42 percent) compared with VRd alone, respectively.¹ Notably, the rate of minimal residual disease (MRD) negativity among patients achieving a CR or better more than doubled in the DARZALEX®-VRd arm compared with VRd alone (59 percent vs. 24 percent).¹ The most common (≥10 percent) Grade 3/4 treatment-emergent adverse events (TEAEs) for DARZALEX®-VRd were neutropenia (32 percent), lymphopenia (23 percent), thrombocytopenia (16 percent) and leukopenia (15 percent).¹ Grade 1/2 infections occurred more frequently in the DARZALEX®-VRd arm, but there was no difference in the rate of Grade 3/4 infections between the DARZALEX®-VRd and VRd arms.¹ Infusion-related reactions (IRRs) occurred in 41 percent of patients who received DARZALEX®-VRd, which were primarily Grade 1/2 and during the initial infusion.¹

“This primary analysis of the GRIFFIN study builds on the safety and efficacy data in the initial group of 16 patients presented at the 2018 American Society of Hematology Annual Meeting,” said Andree Amelsberg, M.D., MBA, Vice President, Oncology Medical Affairs, Janssen Biotech, Inc. “It provides further support for evaluation of DARZALEX® in the transplant-eligible patient population, which is important as we continue our work to discover new therapeutic approaches to improve outcomes for patients.”

In addition to GRIFFIN, data from the Phase 2 PLEIADES ([MMY2040](#)) study, presented during an oral session at the IMW meeting, showed that an investigational DARZALEX® subcutaneous (SC) formulation delivered in combination with standard-of-care treatment regimens showed similar clinical activity and safety to DARZALEX® intravenous (IV) regimens.² The study is the first to

evaluate SC DARZALEX® in different combination regimens for patients with newly diagnosed multiple myeloma as well as those who were relapsed/refractory to current treatment options.²

“We’re excited about the opportunity to progress the innovation represented by the DARZALEX® subcutaneous formulation, which can be administered over the course of minutes and has the potential to offer a reduction in infusion-related events as compared to the approved intravenous formulation,” said Craig Tendler, M.D., Vice President, Clinical Development and Global Medical Affairs, Oncology, Janssen Research & Development, LLC. “Data from the PLEIADES study demonstrates that the DARZALEX® subcutaneous formulation can also be safely administered in combination with standard backbone regimens used for treatment naïve and relapsed/refractory patients with multiple myeloma. It has been included in our recent submission of a Biologics License Application to the U.S. Food and Drug Administration seeking approval of a new DARZALEX® subcutaneous formulation for patients with multiple myeloma.”

Results from the PLEIADES study showed the median duration of administration was 5 minutes across all cohorts, compared with more than 3 hours with IV infusions.² Rates of any grade IRRs and injection-site reactions were 7.5 percent across all cohorts, with one Grade 3 IRR in one cohort and no Grade 4 IRRs.² Grade 3/4 TEAEs were reported by more than 50 percent of patients across cohorts, and TEAEs leading to treatment discontinuation were less than 8 percent in all cohorts.² Safety profiles in all cohorts were consistent with the IV administration of DARZALEX® in combination with these regimens.²

About the GRIFFIN Trial¹

The open-label Phase 2 GRIFFIN ([MMY2004](#)) study has enrolled and treated adult patients, age 29-70 years, with newly diagnosed multiple myeloma who were eligible for high-dose therapy/ASCT, including 16 patients in a safety run-in phase and more than 200 patients in the subsequent randomized portion of the study. During induction (Cycles 1-4) and consolidation (Cycles 5-6) in the randomized part of the study, all patients received 25 mg of lenalidomide orally on Days 1-14, 1.3 mg/m² 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. In the DARZALEX®-VRd arm, DARZALEX® 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), all patients received 10 mg daily of lenalidomide (15 mg beginning at Cycle 10 if tolerated) on Days 1-21 every 28 days. In the DARZALEX®-VRd arm, DARZALEX® 16 mg/kg IV was given every 56 days; this has been amended to give DARZALEX® every 28 days based on emerging

pharmacokinetic data. Maintenance therapy with lenalidomide may be continued beyond Cycle 32 per local standard of care.

About the PLEIADES Trial²

The non-randomized, open-label, parallel assignment Phase 2 PLEIADES ([MMY2040](#)) study included 199 adults with either newly diagnosed or relapsed/refractory multiple myeloma. Patients with newly diagnosed multiple myeloma were treated with 1,800 mg of the SC formulation in combination with either bortezomib, lenalidomide and dexamethasone (D-VRd) or bortezomib, melphalan and prednisone (D-VMP). Patients with relapsed or refractory disease were treated with 1,800 mg of the SC formulation plus lenalidomide and dexamethasone (D-Rd). The primary endpoint for the D-VMP and D-Rd cohorts was overall response rate. The primary endpoint for the D-VRd cohort was very good partial response or better rate. An additional cohort of patients with relapsed and refractory multiple myeloma treated with daratumumab plus carfilzomib and dexamethasone was subsequently added to the study.

About DARZALEX® (daratumumab)

DARZALEX® (daratumumab), the first CD38-directed antibody approved anywhere in the world, is the only CD38-directed antibody approved to treat multiple myeloma.³ CD38 is a surface protein that is present in high numbers on multiple myeloma cells, regardless of the stage of disease.⁴ DARZALEX® binds to CD38 and inhibits tumor cell growth causing myeloma cell death.³ DARZALEX® may also have an effect on normal cells.³ DARZALEX® is being evaluated in a comprehensive clinical development program across a range of treatment settings in multiple myeloma, such as in frontline and relapsed settings.^{5,6,7,8,9,10,11,12} Additional studies are ongoing or planned to assess its potential in other malignant and pre-malignant hematologic diseases in which CD38 is expressed, such as smoldering myeloma.^{13,14}

In the U.S., DARZALEX® received initial FDA approval in [November 2015](#) as a monotherapy for patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory agent, or who are double refractory to a PI and an immunomodulatory agent.¹⁵ DARZALEX® received additional approvals in [November 2016](#) in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.¹⁶ In [June 2017](#), DARZALEX® received approval in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a PI.¹⁷ In [May 2018](#), DARZALEX® received approval in combination with

bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for ASCT, making it the first monoclonal antibody approved for newly diagnosed patients with this disease.¹⁸ In [March 2019](#), a supplemental Biologics License Application was submitted to the U.S. FDA seeking approval of DARZALEX® in combination with bortezomib, thalidomide and dexamethasone for newly diagnosed patients with multiple myeloma who are eligible for ASCT based on the Phase 3 CASSIOPEIA study. Most recently, in [June 2019](#), DARZALEX® received approval in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are transplant ineligible.¹⁹

In [August 2012](#), Janssen Biotech, Inc. entered into a global license and development agreement with Genmab A/S, which granted Janssen an exclusive license to develop, manufacture and commercialize DARZALEX®.²⁰ For the full U.S. Prescribing Information, please visit www.DARZALEX.com.

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.^{21,22} When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow.^{20,21} In 2019, it is estimated that 32,110 people will be diagnosed and 12,960 will die from the disease in the U.S.²³ While some patients with multiple myeloma have no symptoms, most patients are diagnosed due to symptoms, which can include bone fracture or pain, low red blood counts, tiredness, high calcium levels, kidney problems or infections.²⁴

IMPORTANT SAFETY INFORMATION³

CONTRAINDICATIONS

DARZALEX® (daratumumab) is contraindicated in patients with a history of severe hypersensitivity (eg, anaphylactic reactions) to daratumumab or any of the components of the formulation.

WARNINGS AND PRECAUTIONS

Infusion Reactions – DARZALEX® can cause severe and/or serious infusion reactions, including anaphylactic reactions. In clinical trials, approximately half of all patients experienced an infusion reaction. Most infusion reactions occurred during the first infusion and were Grade 1-2. Infusion reactions can also occur with subsequent infusions. Nearly all reactions occurred during infusion or within 4 hours of completing DARZALEX®. Prior to the introduction of post-infusion medication in

clinical trials, infusion reactions occurred up to 48 hours after infusion. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, laryngeal edema, and pulmonary edema. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, and hypotension.

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt infusion for reactions of any severity and institute medical management as needed. Permanently discontinue therapy if an anaphylactic reaction or life-threatening (Grade 4) reaction occurs and institute appropriate emergency care. For patients with Grade 1, 2, or 3 reactions, reduce the infusion rate when re-starting the infusion.

To reduce the risk of delayed infusion reactions, administer oral corticosteroids to all patients following DARZALEX[®] infusions. Patients with a history of chronic obstructive pulmonary disease may require additional post-infusion medications to manage respiratory complications. Consider prescribing short- and long-acting bronchodilators and inhaled corticosteroids for patients with chronic obstructive pulmonary disease.

Interference with Serological Testing – Daratumumab binds to CD38 on red blood cells (RBCs) and results in a positive Indirect Antiglobulin Test (Indirect Coombs test). Daratumumab-mediated positive indirect antiglobulin test may persist for up to 6 months after the last daratumumab infusion. Daratumumab bound to RBCs masks detection of antibodies to minor antigens in the patient's serum. The determination of a patient's ABO and Rh blood type are not impacted. Notify blood transfusion centers of this interference with serological testing and inform blood banks that a patient has received DARZALEX[®]. Type and screen patients prior to starting DARZALEX[®].

Neutropenia and Thrombocytopenia – DARZALEX[®] may increase neutropenia and/or thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to the manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. DARZALEX[®] dose delay may be required to allow recovery of neutrophils and/or platelets. No dose reduction of DARZALEX[®] is recommended. Consider supportive care with growth factors for neutropenia or transfusions for thrombocytopenia.

Interference with Determination of Complete Response – Daratumumab is a human IgG kappa monoclonal antibody that can be detected on both the serum protein electrophoresis (SPE)

and immunofixation (IFE) assays used for the clinical monitoring of endogenous M-protein. This interference can impact the determination of complete response and of disease progression in some patients with IgG kappa myeloma protein.

Adverse Reactions – The most frequently reported adverse reactions (incidence $\geq 20\%$) were: infusion reactions, neutropenia, thrombocytopenia, fatigue, asthenia, nausea, diarrhea, constipation, decreased appetite, vomiting, muscle spasms, arthralgia, back pain, pyrexia, chills, dizziness, insomnia, cough, dyspnea, peripheral edema, peripheral sensory neuropathy, bronchitis, pneumonia and upper respiratory tract infection.

DARZALEX® in combination with lenalidomide and dexamethasone (DRd): The most frequent ($\geq 20\%$) adverse reactions for newly diagnosed or relapsed refractory patients were, respectively, infusion reactions (41%, 48%), diarrhea (57%, 43%), nausea (32%, 24%), fatigue (40%, 35%), pyrexia (23%, 20%), upper respiratory tract infection (52%, 65%), muscle spasms (29%, 26%), dyspnea (32%, 21%), and cough (30%, 30%). In newly diagnosed patients, constipation (41%), peripheral edema (41%), back pain (34%), asthenia (32%), bronchitis (29%), pneumonia (26%), decreased appetite (22%), and peripheral sensory neuropathy (24%) were also reported. In newly diagnosed patients, serious adverse reactions ($\geq 2\%$ compared to Rd) were dehydration (2%), bronchitis (4%), and pneumonia (15%), and treatment-emergent Grade 3-4 hematology laboratory abnormalities ($\geq 20\%$) were leukopenia (35%), neutropenia (56%), and lymphopenia (52%). In relapsed/refractory patients, serious adverse reactions ($\geq 2\%$ compared to Rd) were pneumonia (12%), upper respiratory tract infection (7%), influenza (3%), and pyrexia (3%), and treatment-emergent Grade 3-4 hematology laboratory abnormalities ($\geq 20\%$) were neutropenia (53%) and lymphopenia (52%).

DARZALEX® in combination with bortezomib, melphalan, and prednisone (DVMP): The most frequently reported adverse reactions ($\geq 20\%$) were upper respiratory tract infection (48%), infusion reactions (28%), and peripheral edema (21%). Serious adverse reactions ($\geq 2\%$ compared to the VMP arm) were pneumonia (11%), upper respiratory tract infection (5%), and pulmonary edema (2%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities ($\geq 20\%$) were lymphopenia (58%), neutropenia (44%), and thrombocytopenia (38%).

DARZALEX® in combination with bortezomib and dexamethasone (DVd): The most frequently reported adverse reactions ($\geq 20\%$) were peripheral sensory neuropathy (47%), infusion reactions (45%), upper respiratory tract infection (44%), diarrhea (32%), cough (27%), peripheral edema

(22%), and dyspnea (21%). The overall incidence of serious adverse reactions was 42%. Serious adverse reactions ($\geq 2\%$ compared to Vd) were upper respiratory tract infection (5%), diarrhea (2%), and atrial fibrillation (2%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities ($\geq 20\%$) were lymphopenia (48%) and thrombocytopenia (47%).

DARZALEX[®] in combination with pomalidomide and dexamethasone (DPd): The most frequent adverse reactions ($>20\%$) were fatigue (50%), infusion reactions (50%), upper respiratory tract infection (50%), cough (43%), diarrhea (38%), constipation (33%), dyspnea (33%), nausea (30%), muscle spasms (26%), back pain (25%), pyrexia (25%), insomnia (23%), arthralgia (22%), dizziness (21%), and vomiting (21%). The overall incidence of serious adverse reactions was 49%. Serious adverse reactions reported in $\geq 5\%$ of patients included pneumonia (7%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities ($\geq 20\%$) were anemia (30%), neutropenia (82%), and lymphopenia (71%).

DARZALEX[®] as monotherapy: The most frequently reported adverse reactions ($\geq 20\%$) were infusion reactions (48%), fatigue (39%), nausea (27%), back pain (23%), pyrexia (21%), cough (21%), and upper respiratory tract infection (20%). The overall incidence of serious adverse reactions was 33%. The most frequent serious adverse reactions were pneumonia (6%), general physical health deterioration (3%), and pyrexia (3%). Treatment-emergent Grade 3-4 hematology laboratory abnormalities ($\geq 20\%$) were lymphopenia (40%) and neutropenia (20%).

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal. Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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 DARZALEX® (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 materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies 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 behavior 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 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q 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. 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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¹ Voorhees P et al. Addition of Daratumumab (DARA) to Lenalidomide, Bortezomib, and Dexamethasone (RVd) Improves Depth of Response in Patients (pts) With Transplant-eligible Newly Diagnosed Multiple Myeloma (NDMM): Primary Efficacy Analysis of the GRIFFIN Study. 2019 International Myeloma Workshop meeting. September 2019.

² Chari A et al. Subcutaneous (SC) Daratumumab (DARA) in Combination With Standard Multiple Myeloma (MM) Treatment Regimens: An Open-label, Multicenter Phase 2 Study (PLEIADES). 2019 International Myeloma Workshop meeting. September 2019.

³ DARZALEX® Prescribing Information, June 2019.

⁴ Fedele G et al. CD38 Ligation in Peripheral Blood Mononuclear Cells of Myeloma Patients Induces Release of Protumorigenic IL-6 and Impaired Secretion of IFN γ Cytokines and Proliferation. *Mediators Inflamm.* 2013;564687.

⁵ Janssen Research & Development, LLC. A Study Comparing Daratumumab, Lenalidomide, and Dexamethasone With Lenalidomide and Dexamethasone in Relapsed or Refractory Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 July 24].

Available at: <https://clinicaltrials.gov/ct2/show/NCT02076009?term=mmmy3003&rank=1> Identifier: NCT02136134.

⁶ Janssen Research & Development, LLC. Addition of Daratumumab to Combination of Bortezomib and Dexamethasone in Participants With Relapsed or Refractory Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 July 24]. Available at:

<https://clinicaltrials.gov/ct2/show/NCT02136134?term=mmmy3004&rank=1> Identifier: NCT02076009.

⁷ Janssen Research & Development, LLC. A Study to Evaluate Daratumumab in Transplant Eligible Participants With Previously Untreated Multiple Myeloma (Cassiopeia). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 July 24]. Available at:

<https://clinicaltrials.gov/ct2/show/NCT02541383?term=mmmy3006&rank=2> NLM Identifier: NCT02541383.

⁸ Janssen Research & Development, LLC. A Study of Combination of Daratumumab and Velcade (Bortezomib) Melphalan-Prednisone (DVMP) Compared to Velcade Melphalan-Prednisone (VMP) in Participants With Previously Untreated Multiple Myeloma In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 July 24]. Available at:

<https://clinicaltrials.gov/ct2/show/NCT02195479?term=mmmy3007&rank=1> Identifier: NCT02195479.

⁹ Janssen Research & Development, LLC. Study Comparing Daratumumab, Lenalidomide, and Dexamethasone With Lenalidomide and Dexamethasone in Participants With Previously Untreated Multiple Myeloma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 July 24]. Available at: <https://clinicaltrials.gov/ct2/show/NCT02252172?term=mmmy3008&rank=1> Identifier:

NCT02252172.

¹⁰ Janssen Research & Development, LLC. A Study of VELCADE (Bortezomib) Melphalan-Prednisone (VMP) Compared to Daratumumab in Combination With VMP (D-VMP), in Participants With Previously Untreated Multiple Myeloma Who Are Ineligible for High-Dose Therapy (Asia Pacific Region). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 July 24]. Available at:

<https://clinicaltrials.gov/ct2/show/NCT03217812?term=MMY3011&rank=1> Identifier: NCT03217812.

¹¹ European Myeloma Network. Compare Progression Free Survival Btw Daratumumab/Pomalidomide/Dexamethasone vs Pomalidomide/Dexamethasone (EMN14). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 July 24] Available at:

<https://clinicaltrials.gov/ct2/show/NCT03180736?term=MMY3013&rank=2> Identifier: NCT03180736

¹² Amgen. Study of Carfilzomib, Daratumumab and Dexamethasone for Patients With Relapsed and/or Refractory Multiple Myeloma. (CANDOR). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 July 24] Available at:

<https://clinicaltrials.gov/ct2/show/NCT03158688?term=NCT03158688&rank=1> Identifier: NCT03158688.

¹³ Janssen Research & Development, LLC. A Study to Evaluate 3 Dose Schedules of Daratumumab in Participants With Smoldering Multiple Myeloma In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19]. Available at:

<https://clinicaltrials.gov/ct2/show/NCT02316106?term=smm2001&rank=1> Identifier: NCT02316106.

¹⁴ Janssen Research & Development, LLC. An Efficacy and Safety Proof of Concept Study of Daratumumab in Relapsed/Refractory Mantle Cell Lymphoma, Diffuse Large B-Cell Lymphoma, and Follicular Lymphoma In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2018 March 19]. Available at: <https://clinicaltrials.gov/ct2/show/NCT02413489?term=lym2001&rank=1> Identifier:

NCT02413489

¹⁵ Janssen Biotech, Inc. "DARZALEX® (daratumumab) Approved by U.S. FDA: First Human Anti-CD38 Monoclonal Antibody Available for the Treatment of Multiple Myeloma." Issued November 16, 2015.

¹⁶ Janssen Biotech, Inc. "DARZALEX® (daratumumab) Approved by U.S. FDA in Combination with Two Standard of Care Regimens for the Treatment of Patients with Multiple Myeloma Who Have Received At Least One Prior Therapy." Issued November 21, 2016.

¹⁷ Janssen Biotech, Inc. "DARZALEX® (daratumumab) Approved by the U.S. FDA in Combination with Pomalidomide and Dexamethasone for Patients with Multiple Myeloma Who Have Received At Least Two Prior Therapies." Issued June 16, 2017.

¹⁸ Janssen Pharmaceutical Companies of Johnson & Johnson. "Janssen Announces DARZALEX® (daratumumab) U.S. FDA Approval for Newly Diagnosed Patients with Multiple Myeloma who are Transplant Ineligible." Issued May 7, 2018.

¹⁹ Janssen Biotech, Inc. "Janssen Announces U.S. FDA Approval of DARZALEX® (daratumumab) in Combination with Lenalidomide and Dexamethasone for Newly Diagnosed Patients with Multiple Myeloma Who Are Transplant Ineligible." Issued June 27, 2019.

²⁰ Janssen Biotech, Inc. "Janssen Biotech Announces Global License and Development Agreement for Investigational Anti-Cancer Agent Daratumumab." Issued August 30, 2012.

²¹ Kumar SK et al. Leukemia. 2012 Jan; 26(1):149-57.

²² American Cancer Society. "What Is Multiple Myeloma?" Available at: <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma>. Accessed August 2018. Accessed September 2019.

²³ American Cancer Society. "Key Statistics for Multiple Myeloma." Available at: <https://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html>. Accessed September 2019.

²⁴ American Cancer Society. "Diagnosing Multiple Myeloma From Test Results." Available at: <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-diagnosis>. Accessed September 2019.