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**New DARZALEX® (daratumumab) Data from GRIFFIN Study Show Deeper and Longer Responses in Patients with Newly Diagnosed Multiple Myeloma**

*Phase 2 GRIFFIN data presented at ASH 2020 show increased stringent complete response and minimal residual disease negativity rates with maintenance therapy for transplant-eligible patients*

**December 7, 2020 (HORSHAM, Pa.)** – The Janssen Pharmaceutical Companies of Johnson & Johnson announced new data from the randomized Phase 2 GRIFFIN study showing that the addition of DARZALEX® (daratumumab) to lenalidomide (Revlimid), bortezomib (VELCADE®) and dexamethasone (D-RVd), followed by DARZALEX® plus lenalidomide (D-R) maintenance therapy, resulted in deeper and improved responses, including minimal residual disease (MRD) negativity, compared to RVd followed by R alone in newly diagnosed, stem cell transplant-eligible patients with multiple myeloma.<sup>1</sup> These data investigating the use of DARZALEX® in combination with RVd, which were shared in separate oral and poster presentations at the American Society of Hematology (ASH) 2020 Annual Meeting, provide further evidence that this regimen may provide greater efficacy for transplant-eligible, newly diagnosed multiple myeloma (NDMM) patients than standard therapy. The oral presentation ([Abstract #549](#)) shared longer-term follow-up data, and the poster presentation ([Abstract #3243](#)) featured additional data from the safety run-in cohort.<sup>1,2</sup>

“The long-term GRIFFIN data show that maintenance therapy with DARZALEX in combination with lenalidomide (D-R) resulted in deeper responses compared to R alone in patients with multiple myeloma who are newly diagnosed and transplant-eligible,” said Peter Voorhees, M.D., Atrium Health’s Levine Cancer Institute and GRIFFIN study investigator. “These data indicate that the addition of DARZALEX to RVd followed by R maintenance results in improved response rates and depth of response during induction, consolidation and maintenance treatment cycles.”

### **Key Findings from GRIFFIN ([Abstract #549](#)):**

The GRIFFIN oral presentation featured updated safety and efficacy data based on longer follow-up for D-RVd and evaluated the potential role of D-R for maintenance therapy in patients with NDMM.<sup>1</sup>

- Initial findings of GRIFFIN:
  - At the end of post-transplant consolidation (median follow-up, 13.5 months) in the response-evaluable population, the stringent complete response (sCR) rate favored D-RVd vs. RVd (42.4 percent vs. 32.0 percent;  $P=0.0253$ ).<sup>1</sup>
  - The complete response (CR) or better rate also favored D-RVd vs. RVd (51.5 percent vs. 42.3 percent;  $P=0.0014$ ).<sup>1</sup>
- With an additional 12 months of D-R or R maintenance therapy (median follow-up of 27.4 months), responses continued to deepen and remained higher for the DARZALEX®-containing arm:<sup>1</sup>
  - At the clinical cutoff date, the sCR rate favored the DARZALEX®-containing arm (63.6 percent vs. 47.4 percent;  $P=0.0253$ ).<sup>1</sup>
  - The CR or better rate continued to favor D-RVd vs. RVd (81.8 percent vs. 60.8 percent;  $P=0.0014$ ).<sup>1</sup>
  - MRD negativity favored D-RVd vs. RVd (62.5 percent vs. 27.2 percent,  $P=0.0001$ ).
  - No new safety concerns were observed with D-R maintenance therapy.<sup>1</sup>
  - The 24-month progression-free survival (PFS) rate was 94.5 percent for D-RVd and 90.8 percent for RVd.<sup>1</sup>

### **Key Findings from GRIFFIN [Abstract #3243](#):**

The poster presentation shared final results of the safety run-in cohort (n=16 patients) from the GRIFFIN study. These additional data showed that maintenance therapy with DARZALEX® and lenalidomide (D-R) improved both the sCR rate and MRD negativity rate in patients with NDMM who underwent D-RVd induction, autologous stem cell transplant (ASCT) and D-RVd consolidation. This deepening of responses was associated with durable remissions, and no new safety signals were observed with maintenance therapy.<sup>2</sup>

- Initial findings from the safety run-in for GRIFFIN:
  - By the end of post-transplant consolidation, the sCR rate was 56 percent.
  - MRD negativity ( $10^{-5}$ ) at the end of consolidation was observed in 50 percent of patients, and no patients were MRD negative at  $10^{-6}$ .<sup>2</sup>
- New findings:
  - The sCR rate improved to 94 percent by the end of both 12 and 24 months of D-R maintenance therapy.
  - By the end of 24 months of D-R maintenance therapy, 81 percent of patients were MRD negative at  $10^{-5}$ , with five patients (31 percent) MRD negative at  $10^{-6}$ .<sup>2</sup>
  - At a median follow-up of 40.8 months, three of 16 patients had progressed, with estimated 24-month and 36-month PFS rates of 94 percent and 78 percent, respectively.<sup>2</sup>
  - With longer follow-up, including two years of D-R maintenance therapy, no new safety concerns were identified.<sup>2</sup>

“We continue to be encouraged by the GRIFFIN data showing deeper and improved responses in patients with newly diagnosed, ASCT-eligible multiple myeloma,” said Andree Amelsberg, M.D., MBA, Vice President, Oncology Medical Affairs, Janssen Scientific Affairs, LLC. “These data show promising results for patients with newly diagnosed multiple myeloma, and we remain committed to exploring the full potential of DARZALEX and DARZALEX *FASPRO*.”

### **About the GRIFFIN Study<sup>3</sup>**

The Phase 2 GRIFFIN ([NCT02874742](https://clinicaltrials.gov/ct2/show/study/NCT02874742)) study has enrolled and treated more than 200 adults ages 18-70 years with NDMM and who are eligible for high-dose therapy/ASCT.

In the safety run-in cohort, patients received 25 mg of lenalidomide orally on Days 1-14; 1.3 mg/m<sup>2</sup> 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 during the induction and consolidation phases (Cycles 1-6). DARZALEX<sup>®</sup> 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 phase (Cycles 7-32), patients received 10 mg daily of lenalidomide (15 mg beginning at Cycle 10 if tolerated) on Days 1-21 every 28 days and DARZALEX<sup>®</sup> 16 mg/kg IV every 56 days; this was amended to every 28 days based upon emerging clinical pharmacokinetic data demonstrating improved target saturation with every-4-week maintenance dosing. Maintenance

therapy with lenalidomide may be continued beyond Cycle 32 in both arms, per local standard of care.

In the subsequent randomized Phase 2 portion of the study, approximately 200 patients were randomized and received treatment with RVd, induction and consolidation, ASCT and maintenance therapy with lenalidomide; or DARZALEX® and RVd, ASCT and maintenance therapy with DARZALEX® and lenalidomide.

### **About DARZALEX®**

Janssen is committed to exploring the potential of DARZALEX® (daratumumab) for patients with multiple myeloma across the spectrum of the disease. DARZALEX® has been approved in eight indications, three of which are in the frontline setting, including newly diagnosed patients who are transplant eligible and ineligible.

DARZALEX® has become a backbone therapy in the treatment of multiple myeloma, having been used in the treatment of more than 150,000 patients worldwide and more than 68,000 patients in the U.S. alone since its U.S. FDA approval in 2015. DARZALEX® is the first CD38-directed antibody approved globally to treat multiple myeloma.

CD38 is a surface protein that is present in high numbers on multiple myeloma cells, regardless of the stage of disease.<sup>4</sup> DARZALEX® binds to CD38 and inhibits tumor cell growth causing myeloma cell death.<sup>5</sup> DARZALEX® may also have an effect on normal cells.<sup>4</sup> Data across eight Phase 3 clinical trials, in both the frontline and relapsed settings, have shown that DARZALEX®-based regimens resulted in significant improvement in progression-free survival and/or overall survival.<sup>5,6,7,8,9,10,11,12</sup>

### **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.<sup>13,14</sup> When damaged, these plasma cells rapidly spread and replace normal cells with tumors in the bone marrow. In 2020, it is estimated that more than 32,000 people will be diagnosed and close to 13,000 will die from the disease in the U.S.<sup>15</sup> 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 cell counts, tiredness, high calcium levels, kidney problems or infections.<sup>15</sup>

## **DARZALEX® INDICATIONS**

DARZALEX® (daratumumab) is indicated for the treatment of adult patients with multiple myeloma:

- In combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- In combination with bortezomib, melphalan, and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
- In combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor
- As monotherapy in patients 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

## **DARZALEX® IMPORTANT SAFETY INFORMATION**

### **CONTRAINDICATIONS**

DARZALEX® 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-Related Reactions**

DARZALEX® can cause severe and/or serious infusion-related reactions including anaphylactic reactions. In clinical trials (monotherapy and combination: N=2066), infusion-related reactions occurred in 37% of patients with the Week 1 (16 mg/kg) infusion, 2% with the Week 2 infusion, and cumulatively 6% with subsequent infusions. Less than 1% of patients had a Grade 3/4

infusion-related reaction at Week 2 or subsequent infusions. The median time to onset was 1.5 hours (range: 0 to 73 hours). Nearly all reactions occurred during infusion or within 4 hours of completing DARZALEX<sup>®</sup>. 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.

When DARZALEX<sup>®</sup> dosing was interrupted in the setting of ASCT (CASSIOPEIA) for a median of 3.75 months (range: 2.4 to 6.9 months), upon re-initiation of DARZALEX<sup>®</sup>, the incidence of infusion-related reactions was 11% for the first infusion following ASCT. Infusion-related reactions occurring at re-initiation of DARZALEX<sup>®</sup> following ASCT were consistent in terms of symptoms and severity (Grade 3 or 4: <1%) with those reported in previous studies at Week 2 or subsequent infusions. In EQUULEUS, patients receiving combination treatment (n=97) were administered the first 16 mg/kg dose at Week 1 split over two days, ie, 8 mg/kg on Day 1 and Day 2, respectively. The incidence of any grade infusion-related reactions was 42%, with 36% of patients experiencing infusion-related reactions on Day 1 of Week 1, 4% on Day 2 of Week 1, and 8% with subsequent infusions.

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids. Frequently monitor patients during the entire infusion. Interrupt DARZALEX<sup>®</sup> infusion for reactions of any severity and institute medical management as needed. Permanently discontinue DARZALEX<sup>®</sup> 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-related reactions, administer oral corticosteroids to all patients following DARZALEX<sup>®</sup> 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 is not impacted. Notify blood transfusion centers of this

interference with serological testing and inform blood banks that a patient has received DARZALEX<sup>®</sup>. Type and screen patients prior to starting DARZALEX<sup>®</sup>.

### **Neutropenia and Thrombocytopenia**

DARZALEX<sup>®</sup> may increase neutropenia and thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX<sup>®</sup> until recovery of neutrophils or for recovery of platelets.

### **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.

### **Embryo-Fetal Toxicity**

Based on the mechanism of action, DARZALEX<sup>®</sup> can cause fetal harm when administered to a pregnant woman. DARZALEX<sup>®</sup> may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX<sup>®</sup> and for 3 months after the last dose.

The combination of DARZALEX<sup>®</sup> with lenalidomide, pomalidomide, or thalidomide is contraindicated in pregnant women, because lenalidomide, pomalidomide, and thalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, pomalidomide, or thalidomide prescribing information on use during pregnancy.

### **ADVERSE REACTIONS**

The most frequently reported adverse reactions (incidence  $\geq 20\%$ ) were: upper respiratory infection, neutropenia, infusion-related reactions, thrombocytopenia, diarrhea, constipation, anemia, peripheral sensory neuropathy, fatigue, peripheral edema, nausea, cough, pyrexia, dyspnea, and asthenia. The most common hematologic laboratory abnormalities ( $\geq 40\%$ ) with DARZALEX<sup>®</sup> are: neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

Please [click here](#) to see the full Prescribing Information.

### **DARZALEX FASPRO™ INDICATIONS**

DARZALEX FASPRO™ is indicated for the treatment of adult patients with multiple myeloma:

- in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant
- in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy
- in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy
- as monotherapy, in patients 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

## **DARZALEX FASPRO™ IMPORTANT SAFETY INFORMATION**

### **CONTRAINDICATIONS**

DARZALEX FASPRO™ (daratumumab and hyaluronidase-fihi) is contraindicated in patients with a history of severe hypersensitivity to daratumumab, hyaluronidase or any of the components of the formulation.

### **WARNINGS AND PRECAUTIONS**

#### **Hypersensitivity and Other Administration Reactions**

Both systemic administration-related reactions, including severe or life-threatening reactions, and local injection-site reactions can occur with DARZALEX FASPRO™.

#### *Systemic Reactions*

In a pooled safety population of 490 patients who received DARZALEX FASPRO™ as monotherapy or in combination, 11% of patients experienced a systemic administration-related reaction (Grade 2: 3.9%, Grade 3: 1.4%). Systemic administration-related reactions occurred in 10% of patients with the first injection, 0.2% with the second injection, and cumulatively 0.8% with subsequent injections. The median time to onset was 3.7 hours (range: 9 minutes to 3.5 days). Of the

84 systemic administration-related reactions that occurred in 52 patients, 73 (87%) occurred on the day of DARZALEX *FASPRO*<sup>™</sup> administration. Delayed systemic administration-related reactions have occurred in less than 1% of the patients.

Severe reactions included hypoxia, dyspnea, hypertension and tachycardia. Other signs and symptoms of systemic administration-related reactions may include respiratory symptoms, such as bronchospasm, nasal congestion, cough, throat irritation, allergic rhinitis, and wheezing, as well as anaphylactic reaction, pyrexia, chest pain, pruritis, chills, vomiting, nausea, and hypotension.

Pre-medicate patients with histamine-1 receptor antagonist, acetaminophen and corticosteroids. Monitor patients for systemic administration-related reactions, especially following the first and second injections. For anaphylactic reaction or life-threatening (Grade 4) administration-related reactions, immediately and permanently discontinue DARZALEX *FASPRO*<sup>™</sup>. Consider administering corticosteroids and other medications after the administration of DARZALEX *FASPRO*<sup>™</sup> depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions.

#### *Local Reactions*

In this pooled safety population, injection-site reactions occurred in 8% of patients, including Grade 2 reactions in 0.6%. The most frequent (>1%) injection-site reaction was injection site erythema. These local reactions occurred a median of 7 minutes (range: 0 minutes to 4.7 days) after starting administration of DARZALEX *FASPRO*<sup>™</sup>. Monitor for local reactions and consider symptomatic management.

#### **Neutropenia**

Daratumumab may increase neutropenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Monitor patients with neutropenia for signs of infection. Consider withholding DARZALEX *FASPRO*<sup>™</sup> until recovery of neutrophils. In lower body weight patients receiving DARZALEX *FASPRO*<sup>™</sup> higher rates of Grade 3-4 neutropenia were observed.

#### **Thrombocytopenia**

Daratumumab may increase thrombocytopenia induced by background therapy. Monitor complete blood cell counts periodically during treatment according to manufacturer's prescribing information for background therapies. Consider withholding DARZALEX *FASPRO*<sup>™</sup> until recovery of platelets.

### **Embryo-Fetal Toxicity**

Based on the mechanism of action, DARZALEX *FASPRO*<sup>™</sup> can cause fetal harm when administered to a pregnant woman. DARZALEX *FASPRO*<sup>™</sup> may cause depletion of fetal immune cells and decreased bone density. Advise pregnant women of the potential risk to a fetus. Advise females with reproductive potential to use effective contraception during treatment with DARZALEX *FASPRO*<sup>™</sup> and for 3 months after the last dose.

The combination of DARZALEX *FASPRO*<sup>™</sup> with lenalidomide is contraindicated in pregnant women, because lenalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide prescribing information on use during pregnancy.

### **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 administration. 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 *FASPRO*<sup>™</sup>. Type and screen patients prior to starting DARZALEX *FASPRO*<sup>™</sup>.

### **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 DARZALEX *FASPRO*<sup>™</sup> treated patients with IgG kappa myeloma protein.

### **ADVERSE REACTIONS**

The most common adverse reaction ( $\geq 20\%$ ) with DARZALEX *FASPRO*<sup>™</sup> monotherapy is: upper respiratory tract infection. The most common adverse reactions with combination therapy ( $\geq 20\%$  for any combination) include fatigue, nausea, diarrhea, dyspnea, insomnia, pyrexia, cough, muscle spasms, back pain, vomiting, upper respiratory tract infection, peripheral sensory neuropathy, constipation, and pneumonia.

The most common hematology laboratory abnormalities ( $\geq 40\%$ ) with DARZALEX FASPRO™ are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

Please see full Prescribing Information at [www.DARZALEX.com](http://www.DARZALEX.com).

### **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](http://www.janssen.com). Follow us at [www.twitter.com/JanssenGlobal](https://www.twitter.com/JanssenGlobal) and [www.twitter.com/JanssenUS](https://www.twitter.com/JanssenUS). Janssen Research & Development, LLC, Janssen Scientific Affairs, 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 DARZALEX®. 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 Biotech, Inc., Janssen Research & Development, LLC, or 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 29, 2019, 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](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies 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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<sup>1</sup> Kaufman, JL et al. Daratumumab (DARA) Plus Lenalidomide, Bortezomib, and Dexamethasone (RVd) in Patients with Transplant-eligible Newly Diagnosed Multiple Myeloma (NDMM): Updated Analysis of GRIFFIN After 12 Months of Maintenance Therapy. Abstract #549. To be presented at 2020 American Society of Hematology Annual Meeting.

<sup>2</sup> Voorhees, PM et al. Daratumumab (DARA) Plus Lenalidomide, Bortezomib, and Dexamethasone (RVd) in Patients with Transplant-eligible Newly Diagnosed Multiple Myeloma (NDMM): Updated Efficacy and Safety Analysis of the Safety Run-in Population of GRIFFIN. Abstract #3243. To be presented at 2020 American Society of Hematology Annual Meeting.

<sup>3</sup> Janssen Research & Development, LLC. Study Comparing Daratumumab, Lenalidomide, Bortezomib, and Dexamethasone (D-RVd) Versus Lenalidomide, Bortezomib, and Dexamethasone (RVd) in Subjects With Newly Diagnosed Multiple Myeloma In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2016 August 22]. Available at: <https://clinicaltrials.gov/ct2/show/NCT02874742> Identifier: NCT02874742.

<sup>4</sup> 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 $\gamma$  Cytokines and Proliferation. *Mediators Inflamm.* 2013;564687.

<sup>5</sup> 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=mmv3003&rank=1> Identifier: NCT02136134.

<sup>6</sup> 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=mmv3004&rank=1> Identifier: NCT02076009.

<sup>7</sup> 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=mmv3006> Identifier: NCT02541383.

<sup>8</sup> 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=mmv3007&rank=1> Identifier: NCT02195479.

<sup>9</sup> 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].

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Available at: <https://clinicaltrials.gov/ct2/show/NCT02252172?term=mmy3008&rank=1> Identifier: NCT02252172.

<sup>10</sup> 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.

<sup>11</sup> 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.

<sup>12</sup> 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.

<sup>13</sup> Kumar, SK et al. Risk of progression and survival in multiple myeloma relapsing after therapy with IMiDs and bortezomib: a multicenter international myeloma working group study. *Leukemia*. 2012 Jan; 26(1):149-57.

<sup>14</sup> American Cancer Society. "What Is Multiple Myeloma?" Available at: <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-multiple-myeloma>. Accessed June 2019.

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