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NEWS RELEASE

U.S. FDA Oncologic Drugs Advisory Committee votes in favor of the benefit-risk profile of DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) for high-risk smoldering multiple myeloma

2025-05-20

ODAC recommendation based on the positive progression-free survival and clinical benefit in the Phase 3 AQUILA study

If approved, DARZALEX FASPRO® would be the first treatment to potentially delay or prevent progression to multiple myeloma

RARITAN, N.J., May 20, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ) announced today the U.S. Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) voted (6-2) in favor of the benefit-risk profile of single-agent DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) for the treatment of adult patients with high-risk smoldering multiple myeloma (HR-SMM). An application for the approval of DARZALEX FASPRO® for adult patients with HR-SMM was **submitted** to the FDA in November 2024.

The vote highlights a pivotal moment in the care of patients most likely to develop active multiple myeloma (MM), potentially altering the course of disease and treatment. DARZALEX FASPRO® is a foundational therapy in MM, and if approved in this indication, would provide a potential path for earlier intervention.

No treatments are approved specifically to treat HR-SMM. In 2024, it was estimated that more than 35,000 people would be diagnosed with MM in the U.S., and approximately 15 percent of newly diagnosed MM cases are classified as smoldering. While patients diagnosed with HR-SMM are asymptomatic, approximately 50 percent are likely to develop active disease within two to three years. The current standard of care (SOC) for smoldering multiple

myeloma (SMM), even those considered high-risk, is active monitoring ("Watch and Wait") until progression, which may lead to therapeutic intervention only after the detection of end-organ damage.

"Early intervention in high-risk smoldering multiple myeloma demonstrated a reduction in the risk of progression or death," said Sen Zhuang, M.D., Vice President, Oncology Clinical Research, Johnson & Johnson Innovative Medicine. "The proactive approach demonstrated in the AQUILA study is an example of Johnson & Johnson's aspiration to get in front of cancer by providing a platform to treat disease before progression to active disease."

The committee reviewed data from the AQUILA study, a Phase 3, randomized, open-label trial which evaluated the efficacy and safety of DARZALEX FASPRO® versus SOC active monitoring in patients with HR-SMM.[1] Results were initially **presented** at the 2024 American Society of Hematology (ASH) Annual Meeting and simultaneously **published** in The New England Journal of Medicine.[2]

"High-risk smoldering multiple myeloma remains a challenging clinical conundrum with no approved therapies, and earlier intervention may delay or even prevent progression to active multiple myeloma," said Peter Voorhees, M.D., Atrium Health / Levine Cancer Institute, Charlotte, N.C.‡ "We appreciate the balance the committee provided when assessing the risks and benefits of finite treatment at this stage and its recognition of the promise of DARZALEX FASPRO."

The recommendation reinforces Johnson & Johnson's vision for the future of oncology – one where early diagnosis and treatments become standard, and where science moves us closer to a world without cancer. With bold choices over time, J&J is dedicated to our mission of evolving the treatment paradigm of patients with multiple myeloma.

The ODAC is convened upon request of the FDA to review and evaluate safety and efficacy data of human drug products for use in the treatment of oncologic diseases. The committee provides non-binding recommendations based on its evaluation; however, final decisions on approval of the drug are made by the FDA.

About the AQUILA Study

AQUILA (**NCT03301220**) is a randomized, multicenter Phase 3 study comparing treatment with DARZALEX FASPRO® to active monitoring in patients with smoldering multiple myeloma (SMM). The primary endpoint is progression-free survival (PFS), defined as progression to active multiple myeloma (MM) as assessed by an independent review committee, according to IMWG diagnostic criteria for MM (SLiM-CRAB), or death. Major secondary endpoints included overall response rate, PFS on first-line MM treatment (PFS2), and overall survival.

About Multiple Myeloma

Multiple myeloma is a blood cancer that affects a type of white blood cell called plasma cells, which are found in the bone marrow.[3] In multiple myeloma, these malignant plasma cells proliferate and replace normal cells in the bone

marrow.[4] Multiple myeloma is the second most common blood cancer worldwide and remains an incurable disease.[5] In 2024, it is estimated that more than 35,000 people will be diagnosed with multiple myeloma in the U.S. and more than 12,000 will die from the disease.[6] People with multiple myeloma have a 5-year survival rate of 59.8 percent. While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems or infections.[7,8]

About Smoldering Multiple Myeloma

Smoldering multiple myeloma (SMM) is an asymptomatic intermediate disease state of multiple myeloma characterized by abnormal monoclonal bone marrow plasma cell (BMPC) proliferation and abnormally high levels of circulating M proteins with absence of myeloma-defining events. SMM is associated with a 10 percent annual risk of progressing to multiple myeloma (MM) or a related disorder, but half of patients with high-risk SMM progress to MM and are at risk of developing severe symptoms and organ damage within just two years of diagnosis.

About DARZALEX FASPRO® and DARZALEX®

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) **received** U.S. FDA approval in May 2020 and is approved for nine indications in MM, four of which are for frontline treatment in newly diagnosed patients who are transplant eligible or ineligible.[3,6] It is the only subcutaneous CD38-directed antibody approved to treat patients with MM. DARZALEX FASPRO® is co-formulated with recombinant human hyaluronidase PH20, Halozyme's ENHANZE® drug delivery technology.

DARZALEX® (daratumumab) received **U.S. FDA approval** in November 2015 and is approved in eight indications, three of which are in the frontline setting, including newly diagnosed patients who are transplant eligible and ineligible.[9]

DARZALEX® is the first CD38-directed antibody approved to treat MM.[9] DARZALEX®-based regimens have been used in the treatment of more than 618,000 patients worldwide.

In **August 2012**, Janssen Biotech, Inc. and Genmab A/S entered a worldwide agreement, which granted Janssen an exclusive license to develop, manufacture and commercialize daratumumab.

For more information, visit **https://www.darzalexhcp.com.**

DARZALEX FASPRO® INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) is indicated for the treatment of adult patients with

MM:

- In combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant
- 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 MM who have received at least one prior therapy
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (PI)
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory MM who have received one to three prior lines of 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 PI and an immunomodulatory agent or who are double refractory to a PI and an immunomodulatory agent

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DARZALEX FASPRO® 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®. Fatal reactions have been reported with daratumumab-containing products, including DARZALEX FASPRO®.

Systemic Reactions

In a pooled safety population of 1249 patients with MM (N=1056) or light chain (AL) amyloidosis (N=193) who received DARZALEX FASPRO® as monotherapy or in combination, 7 percent of patients experienced a systemic administration-related reaction (Grade 2: 3.2 percent, Grade 3: 0.7 percent, Grade 4: 0.1 percent). Systemic administration-related reactions occurred in 7 of patients with the first injection, 0.2 percent with the second

injection, and cumulatively 1 percent with subsequent injections. The median time to onset was 2.9 hours (range: 5 minutes to 3.5 days). Of the 165 systemic administration-related reactions that occurred in 93 patients, 144 (87 percent) occurred on the day of DARZALEX FASPRO® administration. Delayed systemic administration-related reactions have occurred in 1 percent of the patients.

Severe reactions included hypoxia, dyspnea, hypertension, tachycardia, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. 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, pruritus, chills, vomiting, nausea, hypotension, and blurred vision.

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®. Consider administering corticosteroids and other medications after the administration of DARZALEX FASPRO® depending on dosing regimen and medical history to minimize the risk of delayed (defined as occurring the day after administration) systemic administration-related reactions.

Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with daratumumab-containing products. If ocular symptoms occur, interrupt DARZALEX FASPRO® and seek immediate ophthalmologic evaluation prior to restarting DARZALEX FASPRO®.

Local Reactions
In this pooled safety population, injection-site reactions occurred in 7 percent of patients, including Grade 2 reactions in 0.8 percent. The most frequent (>1 percent) injection-site reaction was injection-site erythema. These local reactions occurred a median of 5 minutes (range: 0 minutes to 6.5 days) after starting administration of DARZALEX FASPRO®. 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® until recovery of neutrophils. In lower body weight patients receiving DARZALEX FASPRO®, 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® until recovery of platelets.

Embryo-Fetal Toxicity

Based on the mechanism of action, DARZALEX FASPRO® can cause fetal harm when administered to a pregnant woman. DARZALEX FASPRO® 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® and for 3 months after the last dose.

The combination of DARZALEX FASPRO® with lenalidomide, thalidomide, or pomalidomide is contraindicated in pregnant women because lenalidomide, thalidomide, and pomalidomide may cause birth defects and death of the unborn child. Refer to the lenalidomide, thalidomide, or pomalidomide 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®. Type and screen patients prior to starting DARZALEX FASPRO®.

Interference With Determination of Complete Response

Daratumumab is a human immunoglobulin G (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®-treated patients with IgG kappa myeloma protein.

ADVERSE REACTIONS

In MM, the most common adverse reaction (≥20 percent) with DARZALEX FASPRO® monotherapy is upper respiratory tract infection. The most common adverse reactions with combination therapy (≥20 percent for any combination) include fatigue, nausea, diarrhea, dyspnea, insomnia, headache, pyrexia, cough, muscle spasms, back pain, vomiting, hypertension, upper respiratory tract infection, peripheral sensory neuropathy, constipation, pneumonia, and peripheral edema.

The most common hematology laboratory abnormalities (≥40 percent) with DARZALEX FASPRO® are decreased leukocytes, decreased lymphocytes, decreased neutrophils, decreased platelets, and decreased hemoglobin.

Please **click here** to see the full Prescribing Information for DARZALEX FASPRO®.

DARZALEX® INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

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

- 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 MM who have received at least one prior therapy
- In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- In combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor
- In combination with carfilzomib and dexamethasone in patients with relapsed or refractory MM who have received one to three prior lines of 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

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. These

reactions can be life-threatening, and fatal outcomes have been reported. In clinical trials (monotherapy and combination: N=2066), infusion-related reactions occurred in 37 percent of patients with the Week 1 (16 mg/kg) infusion, 2 percent with the Week 2 infusion, and cumulatively 6 percent with subsequent infusions. Less than 1 percent 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®. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnea, hypertension, tachycardia, headache, laryngeal edema, pulmonary edema, and ocular adverse reactions, including choroidal effusion, acute myopia, and acute angle closure glaucoma. Signs and symptoms may include respiratory symptoms, such as nasal congestion, cough, throat irritation, as well as chills, vomiting, and nausea. Less common signs and symptoms were wheezing, allergic rhinitis, pyrexia, chest discomfort, pruritus, hypotension and blurred vision.

When DARZALEX® 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®, the incidence of infusion-related reactions was 11 percent for the first infusion following ASCT. Infusion-related reactions occurring at re-initiation of DARZALEX® following ASCT were consistent in terms of symptoms and severity (Grade 3 or 4: <1 percent) 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 percent, with 36 percent of patients experiencing infusion-related reactions on Day 1 of Week 1, 4 percent on Day 2 of Week 1, and 8 percent with subsequent infusions.

Pre-medicate patients with antihistamines, antipyretics, and corticosteroids.

Frequently monitor patients during the entire infusion. Interrupt DARZALEX® infusion for reactions of any severity and institute medical management as needed. Permanently discontinue DARZALEX® 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® 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.

Ocular adverse reactions, including acute myopia and narrowing of the anterior chamber angle due to ciliochoroidal effusions with potential for increased intraocular pressure or glaucoma, have occurred with DARZALEX® infusion. If ocular symptoms occur, interrupt DARZALEX® infusion and seek immediate ophthalmologic evaluation prior to restarting DARZALEX®.

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®. Type and screen patients prior to starting DARZALEX®.

Neutropenia and Thrombocytopenia

DARZALEX® 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® until recovery of neutrophils or for recovery of platelets.

Interference With Determination of Complete Response

Daratumumab is a human immunoglobulin G (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® can cause fetal harm when administered to a pregnant woman. DARZALEX® 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® and for 3 months after the last dose.

The combination of DARZALEX® 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 ≥20 percent) 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 (≥40 percent) with DARZALEX® are: neutropenia, lymphopenia, thrombocytopenia, leukopenia, and anemia.

Please **click here** to see the full Prescribing Information.

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at **https://www.jnj.com/** or at **www.innovativemedicine.jnj.com**. Follow us at **@JNJInnovMed**. Janssen Research & Development, LLC, Janssen Biotech, Inc. and Janssen Global Services, LLC are Johnson & Johnson companies.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of DARZALEX FASPRO®. 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-Cilag International NV, Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Global Services, LLC, Janssen-Cilag, S.A., Janssen Scientific Affairs, LLC 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 most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at **http://www.sec.gov**, **http://www.jnj.com**, or on request from Johnson & Johnson.

None of Janssen-Cilag International NV, Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen Global Services, LLC, Janssen-Cilag, S.A., Janssen Scientific Affairs, LLC nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

‡ Peter Voorhees, M.D., Levine Cancer Institute, Charlotte, N.C., has provided consulting, advisory, and speaking services to Johnson & Johnson; he has not been paid for any media work.

Media contact:
Oncology Media Relations
Oncology_media_relations@its.jnj.com

Investor contact:
Lauren Johnson
investor-relations@its.jnj.com

U.S. medical inquiries:
+1 800 526-7736

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