Updated Efficacy and Safety Results of Subcutaneous Daratumumab Plus Lenalidomide Versus Lenalidomide Alone as Maintenance Therapy in Newly Diagnosed Multiple Myeloma After Transplant: AURIGA Study

Larry D Anderson Jr[1], Alfred Chung[2], Laahn Foster[3], Chakra Chaulagain[4], Erin M Pettijohn[5], Andrew Cowan[6], Caitlin Costello[7], Sarah M Larson[8], Douglas W Sborov[9], Kenneth H Shain[10], Rebecca Silbermann[11], Peter M Voorhees[12], Robert Rifkin[13], Maria Krevvata[14], Mai Ngo[15], Sharmila Patel[16], Vipin Khare[16], Annelore Cortoos[16,a], Thomas S Lin[16], Ashraf Badros[17]

[1]Myeloma, Waldenstrom's and Amyloidosis Program, Simmons Comprehensive Cancer Center, UT Southwestern Medical Center, Dallas, TX, USA; [2]Department of Medicine, University of California San Francisco, San Francisco, CA, USA; [3]Division of Hematology Oncology, University of Virginia, Charlottesville, VA, USA; [4]Department of Hematology and Oncology, Myeloma and Amyloidosis Program, Cleveland Clinic Florida, Weston, FL, USA; [5]Cancer and Hematology Centers of Western Michigan, Grand Rapids, MI, USA; [6]Division of Medical Oncology, University of Washington, Seattle, WA, USA; [7]Moores Cancer Center, University of California San Diego, La Jolla, CA, USA; [8]Division of Hematology and Oncology, David Geffen School of Medicine at UCLA, Los Angeles, CA, USA; [9]Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, USA; [10]Department of Malignant Hematology, H Lee Moffitt Cancer Center, Tampa, FL, USA; [11]Knight Cancer Institute, Oregon Health & Science University, Portland, OR, USA; [12]Levine Cancer Institute, Atrium Health Wake Forest University School of Medicine, Charlotte, NC, USA; [13]US Oncology Research, Rocky Mountain Cancer Centers, Denver, CO, USA; [14]Johnson & Johnson, Spring House, PA, USA; [15]Cytel, Cambridge, MA, USA; [16]Johnson & Johnson, Horsham, PA, USA; [17]Greenebaum Cancer Center, University of Maryland, Baltimore, MD, USA; [a]affiliation at the time of study conduct

WHAT DO THESE RESULTS MEAN?

Long-term maintenance treatment with daratumumab plus lenalidomide helped patients with newly diagnosed multiple myeloma (MM) who already completed induction therapy and underwent an autologous stem cell transplant to control their disease and live longer without their MM getting worse compared with lenalidomide alone. There were also no new side effects of concern with daratumumab plus lenalidomide

WHAT WAS THE PURPOSE OF THIS STUDY?

- Researchers wanted to see if a combination of 2 drugs, daratumumab plus lenalidomide, worked better than lenalidomide alone as long-term maintenance therapy in patients with newly diagnosed MM who already completed induction therapy, underwent autologous stem cell transplant, and still had MM cells in their bone marrow (referred to as minimal residual disease positivity)

WHO WAS IN THE STUDY AND HOW WAS IT CARRIED OUT?

- The AURIGA study (NCT03901963) was conducted by randomly assigning patients to receive either daratumumab plus lenalidomide or lenalidomide alone as long-term maintenance therapy
- The main goal of this analysis was to compare how well each treatment controlled the patients' disease, with no detectable MM cells found in their bone marrow (referred to as minimal residual disease negativity)

Patients 18-79 years old
with newly diagnosed MM who completed induction treatment and underwent autologous stem cell transplant

Patients assigned to treatment group

Up to 36 cycles of maintenance treatment:

Daratumumab + lenalidomide **OR** Lenalidomide

Patients assessed

Primary assessment:
- Minimal residual disease negativity at the 10^{-5} threshold (no detectable MM cells out of 100,000 healthy bone marrow cells)

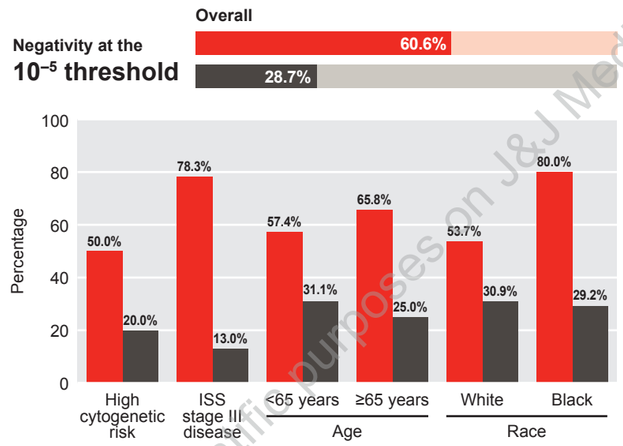
Secondary assessments presented here:
- Minimal residual disease negativity lasting 12 months or longer
- Progression-free survival
- Safety

WHAT WERE THE RESULTS?

Figure 1: Minimal residual disease negativity

■ Daratumumab + lenalidomide ■ Lenalidomide

More than double the patients treated with daratumumab plus lenalidomide had **no detectable MM cells found in their bone marrow** compared with lenalidomide alone



Negativity at the 10^{-6} threshold: 36.4% vs 13.9%

Almost 4 times the patients treated with daratumumab plus lenalidomide also **had no detectable MM cells found in their bone marrow for 12 months or longer** compared with lenalidomide alone

Negativity at the 10^{-5} threshold for ≥12 months: 29.3% vs 7.9%

Figure 2: Progression-free survival

Figure 3: Side effects

There were **no new side effects or safety concerns** with the addition of daratumumab to lenalidomide maintenance

	Daratumumab + lenalidomide	Lenalidomide
Severe/life-threatening side effects:		
Overall	75.0%	73.5%
Neutropenia	49.0%	45.9%
Infections	19.8%	14.3%
Leukopenia	10.4%	7.1%
High blood pressure	7.3%	4.1%
Pneumonia	6.3%	5.1%
Diarrhea	3.1%	5.1%
Treatment discontinuations due to side effects	12.5%	9.2%
Deaths due to side effects	2.1%	1.0%

Glossary of terms

Autologous stem cell transplant: In this procedure, a patient's own healthy stem cells are collected from their blood or bone marrow; these cells can make all the different types of blood cells (such as white blood cells, red blood cells, and platelets). These stem cells are then stored safely. After the patient receives high-dose chemotherapy to kill as many remaining MM cells as possible, the stored stem cells are returned to their body to help the bone marrow recover and start making healthy blood cells again

Maintenance treatment: Long-term treatment after completion of all other treatment phases (eg, induction and transplant), which is intended to help prevent MM cells from coming back

High cytogenetic risk: The presence of specific broken, missing, rearranged, or extra genes (which contain the instructions for building certain proteins) or chromosomes (which contain these genes) can impact normal cell functions. High cytogenetic risk indicates that one or more of these abnormal genes or chromosomes (specifically del[17p], t[4;14], and/or t[14;16]) is present and is associated with a greater risk for worse disease outcomes

Median progression-free survival: The time when half of the patients have lived without their MM getting worse (based on their doctor's assessment) and the other half have experienced a worsening of their disease or died

Induction treatment: The first treatment phase, which is intended to reduce the number of MM cells

Minimal residual disease: After treatment, there is sometimes a small number of MM cells still left in the patient's bone marrow that can be detected with very sensitive tests. These remaining MM cells could potentially cause the disease to come back
- MRD negativity at 10^{-5} threshold: No (less than 1) MM cells found in a sample of 100,000 healthy bone marrow cells
- MRD negativity at 10^{-6} threshold: No (less than 1) MM cells found in a sample of 1 million healthy bone marrow cells

ISS stage III disease: The International Staging System (ISS) is a rating of how advanced MM may be. There are 3 stages, with stage III indicating the greatest risk for more severe and aggressive MM

Leukopenia: A lower-than-normal number of white blood cells, called leukocytes, which help to fight infections. This means the patient's immune system is weaker, and they may be more likely to get infections

Neutropenia: A lower-than-normal number of neutrophils, which are a type of white blood cell that helps to fight off infections. This means the patient's immune system is weaker, and they may be more likely to get infections

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