ImmunoGen Presents Comprehensive Updates for Mirvetuximab Soravtansine Combination Data in Ovarian Cancer at IGCS

September 29, 2022

Mirvetuximab Plus Bevacizumab Demonstrated Meaningful Efficacy in Recurrent FRα-Positive Ovarian Cancer Across a Broad Range of FRα Expression Regardless of Prior Treatment; Data to be Highlighted in Oral Presentation

Additional Clinical Benefit Outcomes from Pivotal SORAYA Study Also Reported

WALTHAM, Mass.--(BUSINESS WIRE)--Sep. 29, 2022-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced several data presentations for mirvetuximab soravtansine (mirvetuximab) at the 2022 International Gynecologic Cancer Society (IGCS) Annual Global Meeting in New York City. The presentations include: consolidated efficacy and safety data from a Phase 1b/2 study evaluating mirvetuximab in combination with Avastin® (bevacizumab) in folate receptor alpha (FRα)-positive recurrent ovarian cancer; the final analysis of a Phase 1b/2 study evaluating mirvetuximab in combination with carboplatin in patients with recurrent FRα-positive platinum-sensitive ovarian cancer; and the clinical benefit of mirvetuximab as a monotherapy in the SORAYA study. Two trial in progress posters from the mirvetuximab program will also be presented.

"We are pleased with the impressive anti-tumor activity and tolerability that these mirvetuximab doublets have generated in recurrent ovarian cancer," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "As we await the potential FDA approval of mirvetuximab this year, we are focused on establishing mirvetuximab as both the combination agent of choice and the new standard of care as a monotherapy in folate receptor alpha positive ovarian cancer."

MIRVETUXIMAB SORAVTANSINE AND BEVACIZUMAB IN FOLATE RECEPTOR ALPHA-POSITIVE OVARIAN CANCER: EFFICACY IN PATIENTS WITH AND WITHOUT PRIOR BEVACIZUMAB
Lead Author: David O'Malley, MD
Date/Time: October 1, 2022, 3:55 – 5:25 PM ET
Abstract: #496

The safety and efficacy of mirvetuximab in combination with bevacizumab were evaluated in 126 patients with recurrent FRα-positive ovarian cancer. The primary endpoint for the study is confirmed objective response rate (ORR) as assessed by RECIST v1.1 and secondary endpoints include duration of response (DOR) and progression-free survival (PFS).

Key findings:

- In the overall population, mirvetuximab plus bevacizumab demonstrated an ORR of 44% (95% CI, 35.6-53.6), a median DOR of 11.8 months (95% CI, 8.3-13.7), and median PFS of 8.2 months (95% CI, 6.8-9.9).
- Clinical activity was observed across all levels of FRα expression, with an ORR of 52% (95% CI, 38.6–64.5), 39% (95% CI, 25.8–53.9), and 31% (95% CI, 9.1–61.4) in high, medium, and low expression, respectively.
- In the bevacizumab-naïve population, anti-tumor activity was seen with an ORR of 58% (95% CI, 44.9-70.9), a median DOR of 11.8 months (95% CI, 8.3-12.9), and median PFS of 9.7 months (95% CI, 8.2-13.2).
- The safety profile of mirvetuximab plus bevacizumab reflects the profile of each agent as a monotherapy; the most common treatment-related adverse events (TRAEs) were low-grade, including diarrhea (59% all grade; 2% grade 3), blurred vision (56% all grade; 1% grade 3), and fatigue (51% all grade; 4% grade 3).

"Current treatments for patients with recurrent ovarian cancer are, unfortunately, characterized by limited efficacy and challenging side effects," said David O'Malley, MD, Professor, Director of Gynecologic Oncology at the Ohio State University and the James Cancer Center. "With activity across a broad range of FRα expression regardless of prior treatment, these data support mirvetuximab plus bevacizumab as an effective combination choice for those patients who are eligible for treatment. I look forward to further evaluating this promising and novel combination in the platinum-sensitive maintenance setting in the randomized Phase 3 GLORIOSA study."

MIRVETUXIMAB SORAVTANSINE AND CARBOPLATIN FOR TREATMENT OF PATIENTS WITH RECURRENT FOLATE RECEPTOR ALPHA–POSITIVE PLATINUM-SENSITIVE OVARIAN CANCER: A FINAL ANALYSIS
Lead Author: Kathleen N. Moore, MD
Date/Time: October 1, 2022, 2:05 - 2:35 PM ET
Abstract: #499

A final analysis of the Phase 1b/2 FORWARD II study evaluating the safety, tolerability, and preliminary activity of mirvetuximab and carboplatin in patients with FRα-positive recurrent platinum-sensitive ovarian cancer was conducted.

Key findings:

- In the overall efficacy evaluable patient group, the ORR was 71% (12 of 17); 18% (n=3) of patients had a CR and 53% (n=9) had a partial response.
    - Patients receiving mirvetuximab 6 mg/kg AIBW and carboplatin AUC5 had an ORR of 89%, median DOR of 12.1, and median PFS of 16.5 months.

- Patients with medium/high FRα-expressing tumors had an ORR of 80%, median DOR of 24.2, and median PFS of 15.0 months across all escalation cohorts
- The safety profile of mirvetuximab plus carboplatin reflects the safety profile of each agent as a monotherapy.

These findings support the evaluation of mirvetuximab plus carboplatin in Trial 420, a single-arm, Phase 2 study of mirvetuximab plus carboplatin in platinum-sensitive ovarian cancer patients with low, medium, or high expression of folate receptor alpha.

CLINICAL BENEFIT OF MIRVETUXIMAB SORAVTANSINE IN OVARIAN CANCER PATIENTS WITH HIGH FOLATE RECEPTOR ALPHA EXPRESSION: RESULTS FROM THE SORAYA STUDY
Lead Author: Robert L. Coleman, MD
Date/Time: September 30, 2022, 8:05 – 9:05 AM ET
Abstract: #376

SORAYA is a single-arm study of mirvetuximab in patients with platinum-resistant ovarian cancer whose tumors express high levels of FRα and who have been treated with one to three prior regimens – at least one of which included bevacizumab. Previously undisclosed waterfall plots will be presented.

Key findings:

- Mirvetuximab monotherapy resulted in clinically meaningful anti-tumor activity in patients with FRα-high platinum-resistant ovarian cancer: 71% of patients experienced tumor reduction, 51% had disease control (complete response, partial response, or stable disease for ≥12 weeks), and preliminary overall survival, with 46% of events reported, was 13.8 months.
- Safety and tolerability of mirvetuximab are consistent with that observed in previous studies; adverse events were primarily low-grade gastrointestinal and ocular events that generally resolved with supportive care or, if needed, dose modifications and the discontinuation rate due to TRAEs was 9%.
- Mirvetuximab demonstrated a favorable benefit-risk profile in patients with FRα-high platinum-resistant ovarian cancer and has the potential to be a practice-changing, biomarker-driven therapy.

ADDITIONAL PRESENTATIONS
Trial in progress posters from ImmunoGen's PICCOLO (Abstract #1556) trial of mirvetuximab in recurrent platinum-sensitive ovarian cancer and a Phase 2 (Abstract #1566) investigator-sponsored combination trial of mirvetuximab with Keytruda® (pembrolizumab) in patients with microsatellite stable recurrent or persistent endometrial cancer will also be presented.

Additional information can be found at igcs.org.

ABOUT MIRVETUXIMAB SORAVTANSINE
Mirvetuximab soravtansine (IMGN853) is a first-in-class ADC comprising a folate receptor alpha-binding antibody, cleavable linker, and the maytansinoid payload DM4, a potent tubulin-targeting agent, to kill the targeted cancer cells.

ABOUT IMMUNOGEN
ImmunoGen is developing the next generation of antibody-drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer our patients more good days. We call this our commitment to TARGET A BETTER NOW™.

Learn more about who we are, what we do, and how we do it at www.immunogen.com.

Avastin® and Keytruda® are registered trademarks of their respective owners.

FORWARD-LOOKING STATEMENTS
This press release includes forward-looking statements. These statements include, but are not limited to, ImmunoGen's expectations related to: the occurrence, timing, and outcome of potential preclinical, clinical, and regulatory events related to, and the potential benefits of, the Company's product candidates, including, but not limited to, the review of the Company's BLA to the FDA for mirvetuximab and full approval of mirvetuximab, and the potential of mirvetuximab to serve as a new standard of care for patients with folate receptor alpha positive ovarian cancer and as a combination agent of choice for patients with ovarian cancer; the timing and presentation of clinical data for mirvetuximab, including, but not limited to, the evaluation of mirvetuximab in combination with bevacizumab and the combination's evaluation in the Company's Phase 3 GLORIOSA trial, the evaluation of mirvetuximab in combination with carboplatin, data from the Company's PICCOLO trial, and data from a combination trial of mirvetuximab and Keytruda; and the Company's business and product development strategies. Various factors could cause ImmunoGen's actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this release. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the timing and outcome of the Company's preclinical and clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of preclinical studies, clinical trials, and regulatory processes; the Company's ability to financially support its product programs; the timing and outcome of the Company's anticipated interactions with regulatory authorities; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and the resulting impact on ImmunoGen's industry and business; and other factors as set forth in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2022, the Company's Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission on May 6, 2022 and August 1, 2022, and other reports filed with the Securities and Exchange Commission. The forward-looking statements in this press release speak only as of the date of this press release. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable law.

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