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MIRASOL Insights in PROC: A Biomarker-Driven Approach

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This medical industry feature, titled "MIRASOL Insights in PROC: A Biomarker-Driven Approach," is sponsored by AbbVie US Medical Affairs.

Here's your host, Dr. Charles Turck.

Dr. Turck:
Welcome to ReachMD. I'm Dr. Charles Turck, and today, we'll be discussing long-term efficacy and safety data from the phase three MIRASOL trial in patients with platinum-resistant ovarian cancer, or PROC.

Joining me to review these data is Dr. Cecelia Boardman. She's a gynecologic oncologist with Virginia Gynecologic Oncology, which is part of the Sarah Cannon Cancer Network at HCA Henrico Doctors' Hospital in Richmond.

Dr. Boardman, welcome to the program.

Dr. Boardman:
Thank you so much for having me.

Dr. Turck:
Before we get started, let's take a moment to review the indication, boxed warning, and select important information for mirvetuximab soravtansine-gynx.

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INDICATION

Mirvetuximab soravtansine-gynx is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- Mirvetuximab soravtansine-gynx can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.
- Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of mirvetuximab soravtansine-gynx, every other cycle for the first 8 cycles, and as clinically indicated.
- Administer prophylactic artificial tears and ophthalmic topical steroids.
- Withhold mirvetuximab soravtansine-gynx for ocular toxicities until improvement and resume at the same or reduced dose.
- Discontinue mirvetuximab soravtansine-gynx for Grade 4 ocular toxicities.

Please see additional Important Safety Information at the end of this video.

WARNING and PRECAUTIONS

- Ocular disorders, pneumonitis, peripheral neuropathy, and embryo-fetal toxicity.

ADVERSE REACTIONS

- The most common (≥20 %) adverse reactions, including lab abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

Please see additional Important Safety Information at the end of this video.

Dr. Turck:
Let's set the stage for us, Dr. Boardman, what does PROC look like in clinical practice, and why does it remain such a challenging disease to treat?

Dr. Boardman:
If we take a step back, epithelial ovarian cancer—including fallopian tube and primary peritoneal cancers—remains the deadliest gynecologic malignancy.[1] While frontline platinum chemotherapy is effective, most patients develop recurrence, and many ultimately develop platinum resistance.[2-4] Platinum resistance is defined as a recurrence that develops within six months of the last platinum-based chemotherapy.[5]

Ovarian cancer that's platinum-resistant is one of the most difficult settings we manage. Prognosis is poor,[2,4,6] survival is usually measured in months,[7-9] and most patients will have received multiple prior lines of therapy by the time they reach this stage.[5]

Standard nonplatinum chemotherapies, sometimes given in combination with bevacizumab, have produced modest results, with objective response rates generally less than 15 percent, median progression-free survival of about three to four months, and overall survival at just over one year.[2,5,7-11] It's worth noting that responses are usually modest in the platinum-resistant space, and complete response is rare.[2,7,8,10]

On top of that, the toxicity burden of chemotherapy often limits patients' ability to continue therapy.[5,12] So we need additional therapy options in this setting.

Dr. Turck:
Thanks for that background on PROC and current chemotherapy options, Dr. Boardman. Now, one of the things that's changed the treatment landscape is biomarker-driven therapy. Folate receptor alpha is one of these biomarkers—would you explain its role in ovarian cancer and how testing fits into practice?

Dr. Boardman:
Sure. So Folate Receptor Alpha, FRα, is a surface protein that's expressed in up to 90 percent of epithelial ovarian cancers and is more prevalent in high-grade serous tumors.[13-18] As a biomarker, its expression is conserved through the continuum of the cancer journey, so testing at diagnosis will give a consistent result to testing later at recurrence.[19]

Clinically, the key is identifying patients with high FRα expression, meaning at least 75 percent of tumor cells stain at a two- or three-plus intensity by immunohistochemistry.[5] Roughly one in three patients with advanced ovarian cancer, about 35 percent, will test positive for FRα-high.[20,21]

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That's where mirvetuximab soravtansine-gynx, the first-in-class antibody-drug conjugate targeting FRα, comes in. It's approved as monotherapy in adults with FRα-high PROC, and it's a Category 1, Preferred option in the NCCN Guidelines for Ovarian Cancer in the PROC setting, where at least 75 percent of tumor cells are positive for FRα.[21,22]

Dr. Boardman:
The FDA has approved the VENTANA FOLR1 RxDx immunohistochemistry assay to identify FRα-high patients. And NCCN Guidelines for Ovarian Cancer recommend molecular analysis in recurrent disease, including FRα testing, to guide the use of targeted therapies.[22,23]

Biomarker testing not only identifies eligible patients, but also allows us to move towards targeted options for appropriate patients. The

question then becomes whether this translates into better outcomes, and that's exactly what the phase three MIRASOL trial set out to determine.

Dr. Turck:
Well, why don't we dive into that study?

Dr. Boardman:
MIRASOL was a global, open-label, randomized phase three clinical trial involving more than 450 patients with FRα-high platinum-resistant disease. All patients had received one to three prior lines of therapy, and those who'd been treated for platinum-resistant disease were still eligible.[21]

Participants were randomized to receive either mirvetuximab monotherapy, which was dosed based on adjusted ideal body weight, or the investigator's choice of chemotherapy—weekly paclitaxel, pegylated liposomal doxorubicin, or topotecan. Patients were stratified by investigators choice of chemotherapy and number of prior lines of chemotherapy.[21]

Dr. Turck:
And that being said, Dr. Boardman, what stands out to you about the patient population and trial design?

Dr. Boardman:
First, I want to highlight that the patients enrolled in MIRASOL look very similar to what we see in clinical practice. Nearly half—47 percent—had received three prior lines of systemic therapy, and more than one third had already received treatment for platinum-resistant disease. That's important because it tells us that these patients had limited remaining treatment options.[21]

And the control arm really reflects the most commonly employed regimens that we would use in clinic.

Dr. Turck:
And what were the findings from MIRASOL in this population?

Dr. Boardman:
So if we take a look at the primary analysis, which had a median follow-up of 13.1 months, we saw that mirvetuximab demonstrated statistically significant improvements in multiple endpoints.[21]

The primary endpoint was progression-free survival, or PFS. Mirvetuximab demonstrated a significant improvement in the median PFS at 5.6 months compared to standard chemotherapy at four months, with a hazard ratio of 0.65 and a 95 percent confidence interval of 0.52 to 0.81.[21]

Overall survival, or OS, was a secondary endpoint. Here, we also saw a statistically significant improvement with mirvetuximab. The median OS in the mirvetuximab group was 16.5 months compared to 12.7 months with chemotherapy at a hazard ratio of 0.67 and a 95 percent confidence interval of 0.5 to 0.88.[21]

And the confirmed overall response rate was 42 percent in the mirvetuximab arm, with a 95 percent confidence interval of 36 to 49 and a sample size of 95, compared with 16 percent in the chemotherapy group, which had a 95 percent confidence interval of 12 to 22 and a sample size of 36. Of note, five percent of patients had a complete response on mirvetuximab, but none did with chemotherapy.[21]

Dr. Turck:
Dr. Boardman what stands out to you about these data?

Dr. Boardman:
So what stands out here is that MIRASOL is the first randomized phase three study in the platinum-resistant setting to show a statistically significant improvement in PFS, OS, and ORR for patients randomized to mirvetuximab compared with standard chemotherapy.[21]

Dr. Turck:
Given these efficacy results, how did the safety profile compare between arms?

Dr. Boardman:
The most commonly reported adverse reactions of any grade in patients receiving mirvetuximab were fatigue in 47 percent, blurred vision in 45 percent, peripheral neuropathy in 37 percent, and keratopathy in 37 percent. Other adverse reactions included abdominal pain, musculoskeletal pain, diarrhea, dry eye, constipation, and nausea, among others.[21]

In the chemotherapy arm, most common adverse reactions of any grade included fatigue in 41 percent, nausea in 29 percent, abdominal pain in 23 percent, and peripheral neuropathy in 23 percent.[21]

Serious adverse reactions were reported in 24 percent of patients receiving mirvetuximab. The most common of these were intestinal obstruction in five percent, abdominal pain in three percent, and pleural effusion in three percent.[21]

Fatal adverse reactions occurred in three percent of patients.[21]

Nine percent of patients discontinued mirvetuximab due to adverse reactions; the most common causes were pneumonitis in two percent, and blurred vision and peripheral neuropathy, both at one percent each.[21]

And adverse reactions led to dose delays in 54 percent of patients on mirvetuximab and dose reductions in 34 percent.[21]

Dr. Turck:
Now, ocular adverse reactions were a prominent safety signal, and they're reflected in the boxed warning. Would you tell us more about that?

Dr. Boardman:
Sure. Ocular adverse reactions were reported in 59 percent of patients, with 11 percent being grade three. These reactions included blurred vision, keratopathy, and dry eye. Nearly all of these events resolved to grade zero or one with appropriate management, and fewer than two percent of patients discontinued treatment because of them.[21,24]

From a practical standpoint, monitoring and prophylaxis for ocular adverse reactions are critical with mirvetuximab. You must have the patient complete an ophthalmic exam—including visual acuity and a slit lamp assessment—before starting mirvetuximab, at every other cycle for the first eight cycles, and then as clinically needed.[21]

It's also recommended to use ophthalmic topical steroids and lubricating eye drops while on mirvetuximab treatment. Topical steroids should only be prescribed or renewed after a slit lamp exam.[21]

Now, in addition to ocular monitoring, I also focus carefully on assessing and managing fatigue and neuropathy because these can impact patients' ability to stay on therapy. In MIRASOL, fatigue occurred in 47 percent of patients treated with mirvetuximab compared with 41 percent on chemotherapy, and peripheral neuropathy was reported in 37 percent versus 23 percent.[21]

Dr. Turck:
Let's now talk about results from MIRASOL's final analysis, which were presented at the 2025 Society of Gynecologic Oncology Annual Meeting on Women's Cancer. Taken together with the primary analysis, what did the longer-term data show us?

Dr. Boardman:
So, with a median follow-up of 30.5 months at this final analysis data cutoff, MIRASOL gives us one of the longest follow-up datasets available in PROC.[24]

What we saw in the longer term follow-up was that mirvetuximab demonstrated a median PFS of 5.6 months compared to 4 months with chemotherapy at a hazard ratio of 0.63.[21,24]

And the median OS remained at 16.8 months with mirvetuximab versus 13.3 months in the chemotherapy arm, with a hazard ratio of 0.68 at the 30.5 month follow-up.[21,24] Turning to the safety findings from the final analysis, overall:[21,24]

Fewer grade three or higher adverse reactions were observed with mirvetuximab, with 44 percent in the final analysis compared to 55 percent in the chemotherapy arm.

Patients in the mirvetuximab group also had lower rates of treatment-emergent adverse reactions that were reported as serious or led to treatment discontinuation. And no new safety signals were identified with longer follow-up.

Hematologic toxicities, including Grade Three or Four adverse reactions, were less frequent with mirvetuximab than with chemotherapy. This included any-grade neutropenia in 11 percent with mirvetuximab versus 29 percent with chemotherapy, and anemia in 10 percent versus 34 percent.[21,24] This finding is especially relevant in patients who have already received multiple lines of platinum because many of them have fragile bone marrow with limited functional reserve. Finally, alopecia was reported in only about one percent of patients on mirvetuximab.[21,24]

Dr. Turck:

Thanks for walking us through the data, Dr. Boardman. Now, let's step back and put these results into the larger clinical context. What practical considerations should clinicians keep in mind when using this therapy in their practice?

Dr. Boardman:
That's a great question. The first step is identifying the right patients through FRα testing. Building testing into routine clinical workflows may help ensure we don't miss patients who could benefit from this treatment.[21] And that's critical because when patients progress, you want to be able to start treatment right away rather than facing delays with a scheduling a biopsy and waiting for results.

ReachMD Announcer:
In terms of clinical guidance, mirvetuximab is now included in the NCCN Guidelines for Ovarian Cancer as the only Category 1, Preferred option for patients with FRα-high platinum-resistant disease, where at least 75 percent of tumor cells are positive for FRα.[22]

Dr. Boardman:
Mirvetuximab provides an important option for patients whose disease is no longer responsive to platinum-based chemotherapy, and I'd like to note that all the improvements in progression-free survival, overall survival, and response rate that we've been discussing were achieved with mirvetuximab as monotherapy.[21,24] In the PROC setting, having a targeted option with a defined safety and efficacy profile may support more individualized treatment planning.

Dr. Turck:
That's a great overview of both the evidence and the practical considerations. And I want to thank my guest, Dr. Cecelia Boardman, for helping us better understand the role of FRα testing and the clinical evidence supporting mirvetuximab in platinum-resistant ovarian cancer.

Dr. Boardman, it was great speaking with you today.

Dr. Boardman:
Thank you so much for having me.

Dr. Turck:
For ReachMD, I'm Dr. Charles Turck.

Please stay tuned to hear the Important Safety Information.

ReachMD Announcer:
Important Safety Information

WARNING: OCULAR TOXICITY

- Mirvetuximab soravtansine-gynx can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.
- Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of mirvetuximab soravtansine-gynx, every other cycle for the first 8 cycles, and as clinically indicated.
- Administer prophylactic artificial tears and ophthalmic topical steroids.
- Withhold mirvetuximab soravtansine-gynx for ocular toxicities until improvement and resume at the same or reduced dose.
- Discontinue mirvetuximab soravtansine-gynx for Grade 4 ocular toxicities.

WARNINGS AND PRECAUTIONS

Ocular Disorders

Mirvetuximab soravtansine-gynx can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 59% of patients with ovarian cancer treated with mirvetuximab soravtansine-gynx. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution; 38% had partial improvement (defined as a decrease in severity by one or more grades from the

worst grade at last follow-up). Ocular adverse reactions led to permanent discontinuation of mirvetuximab soravtansine-gynx in 1% of patients.

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with mirvetuximab soravtansine-gynx are recommended. Advise patients to avoid use of contact lenses during treatment with mirvetuximab soravtansine-gynx unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue mirvetuximab soravtansine-gynx based on severity and persistence of ocular adverse reactions.

ADVERSE REACTIONS

The most common (≥20%) adverse reactions, including lab abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

DRUG INTERACTIONS

DM4 is a CYP3A4 substrate. Closely monitor patients for adverse reactions with mirvetuximab soravtansine-gynx when used concomitantly with strong CYP3A4 inhibitors.

USE IN SPECIAL POPULATIONS

Lactation

Advise women not to breastfeed during treatment with mirvetuximab soravtansine-gynx and for 1 month after the last dose.

Hepatic Impairment

Avoid use of mirvetuximab soravtansine-gynx in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

Dosage Form and Strength: Mirvetuximab soravtansine-gynx is available as a 100 mg/20 mL injection.

INDICATION

Mirvetuximab soravtansine-gynx is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

Review full prescribing information for additional information at www.rxabbvie.com or contact AbbVie Medical Information at 1-800-633-9110 or go to abbviemedinfo.com.

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