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Advancing Care in Pretreated HR+/HER2- mBC

ReachMD Announcer:
Welcome to *Project Oncology* on ReachMD. This medical industry feature, titled "Advancing Care in Pretreated HR-Positive, HER2-Negative Metastatic Breast Cancer," has been created and paid for by Gilead Oncology.

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Here's your host, Dr. Charles Turck.

Dr. Turck:
Hello, this is *Project Oncology* on ReachMD, and I'm Dr. Charles Turck. Joining me to discuss TRODELVY®, a Trop-2–directed antibody-drug conjugate also known as sacituzumab govitecan-hziy, are Drs. Aashini Master and Neil Iyengar. Dr. Master is a breast medical oncologist and Associate Professor at UCLA Health in Los Angeles. She also serves as the Clinical Director of the High Risk Breast Program. And Dr. Iyengar is the Co-Director of the Breast Oncology Program and Director of the Cancer Survivorship Service at Winship Cancer Institute at Emory University.

Dr. Master, Dr. Iyengar, welcome to the program.

Dr. Master:
Thanks, it's good to be with both of you today.

Dr. Iyengar:
Likewise, it's a pleasure to be here.

Dr. Turck:
Now, before we begin, let's take a moment to review the Indication and some Important Safety Information for TRODELVY.

ReachMD Announcer:
INDICATION
TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

IMPORTANT SAFETY INFORMATION
BOXED WARNING: NEUTROPENIA AND DIARRHEA

- TRODELVY can cause severe, life-threatening, or fatal neutropenia. Withhold TRODELVY for absolute neutrophil count below

1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Primary prophylaxis with G-CSF is recommended for all patients at increased risk of febrile neutropenia. Initiate anti-infective treatment in patients with febrile neutropenia without delay.
- TRODELVY can cause severe diarrhea. Monitor patients with diarrhea and give fluid and electrolytes as needed. At the onset of diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤ Grade 1 and reduce subsequent doses.

CONTRAINDICATIONS

- Severe hypersensitivity reaction to TRODELVY.

To see full Prescribing Information, including BOXED WARNING, please click on the link on the ReachMD landing page or visit TRODELVYHCP.com, and please stay tuned for continued Important Safety Information later in this video.

Dr. Turck:
So, Dr. Master, now that we've heard some Important Safety Information, can you start us off by sharing some of the challenges your patients with pretreated HR-positive, HER2-negative metastatic breast cancer face?

Dr. Master:
Absolutely. So unfortunately, patients with HR-positive, HER2-negative metastatic breast cancer who become refractory to first-line endocrine-based therapy often face limited therapeutic options and poor survival outcomes.[1–4]

In fact, the five-year relative survival rate for this female breast cancer subtype is just 37 percent, highlighting a significant unmet need for this patient population.[4]

In the post-endocrine setting, there's no established standard of care or clearly defined treatment sequence, and patients are often left with few options following progression on single-agent chemotherapy.[1–3]

Dr. Turck:
Thanks Dr. Master. So, with that in mind, Dr. Iyengar, could you tell us about TRODELVY and how it may differ from other treatment options?

Dr. Iyengar:
Certainly, I'd be happy to. TRODELVY is the first FDA-approved Trop-2–directed antibody-drug conjugate, or ADC.[5,6]

Let me briefly explain its proposed mechanism of action. Trop-2 is a trophoblast cell-surface antigen expressed in more than 80 percent of breast cancers and is also overexpressed in many other solid tumors.[7–10] And so TRODELVY was designed to deliver a potent cytotoxic payload called SN-38 to Trop-2-expressing cells, including cancer cells. SN-38 is a topoisomerase one inhibitor that prevents repair of DNA damage and leads to apoptosis and cell death.[5,11–13]

What makes TRODELVY distinct from other ADCs is that the payload is bound to a humanized monoclonal antibody by a hydrolysable CL2A linker. So when TRODELVY binds to Trop-2 and gets internalized by the cell, the CL2A linkers will release the cytotoxic payload to kill tumor cells.[5] It also has a high drug-to-antibody ratio of about eight to one.[13]

I should note that the payload can act on both Trop-2 expressing cells and surrounding cells after intracellular release, enabling a so-called "bystander effect."[13–16] Another thing to keep in mind is that the mechanism of action is suggested based on preclinical data, which may not correlate with clinical outcomes.[5]

That said, I think we should take target, payload, and linker into consideration when choosing an ADC as a treatment option for our patients.

Dr. Turck:
Now coming back to you, Dr. Master, how is sacituzumab govitecan-hziy, also known as TRODELVY, designated in the NCCN Clinical Practice Guidelines?

Dr. Master:
So, sacituzumab govitecan-hziy is the first and only Trop-2-directed ADC to be designated as an NCCN Category 1 preferred regimen in pretreated HR-positive, HER2-negative metastatic breast cancer. Specifically, it's recommended for adult patients with unresectable locally advanced or metastatic HR-positive, HER2-negative breast cancer who have received prior treatment. This includes:

- endocrine therapy,
- a CDK4/6 inhibitor, and
- at least two lines of chemotherapy, one including a taxane, with at least one of those lines given in the metastatic setting.

And it may be used in the second line if a patient isn't a candidate for fam-trastuzumab deruxtecan-nxki. Also, sacituzumab govitecan-hziy may be considered for later-line, if not used in the second line of therapy.[17]

However, it's important to note that the NCCN recommendation differs from the sacituzumab govitecan-hziy Prescribing Information. Category 1 indicates that based upon high-level evidence, such as one or more randomized phase three trials or high-quality, robust meta-analyses, there's uniform NCCN consensus of at least 85 percent or more support from the Panel that the intervention is appropriate. But NCCN makes no warranties regarding their content, use, or application, and disclaims responsibility for their application or use in any way.[17]

Dr. Turck:
Thanks, Dr. Master. Now as I understand it, the Phase Three TROPiCS-02 trial contributed to the FDA-approval of TRODELVY in pretreated HR+/HER2-negative metastatic breast cancer. Dr. Iyengar, could you share the clinical evidence that supports its use for patients navigating this difficult journey?

Dr. Iyengar:
Of course. So, the TROPiCS-02 trial evaluated TRODELVY compared to single-agent chemotherapy. This was a randomized, active-controlled, open-label trial that included 543 participants with unresectable locally advanced or metastatic HR+/HER2-negative breast cancer.[5,18,19]

Patients were eligible if they:

- progressed after at least one endocrine therapy, a CDK4/6 inhibitor, and a taxane in any setting;
- received two to four lines of chemotherapy for metastatic disease; and
- had measurable disease as defined by the Response Evaluation Criteria in Solid Tumors, or RECIST, 1.1.[5,18,19]

In terms of the study arms, 272 patients were administered 10 milligrams per kilogram of intravenous TRODELVY on days one and eight of a 21-day treatment cycle, while 271 patients received investigator-selected single-agent chemotherapy, including eribulin, vinorelbine, gemcitabine, or capecitabine.[5,18,19]

Treatment was continued until the patient experienced disease progression or unacceptable toxicity.[5,18,19]

Now as for endpoints, the primary was progression-free survival, assessed by blinded independent central review using RECIST 1.1 criteria. And a key secondary endpoint was overall survival.[5,18,19]

Dr. Turck:
So let's dive deeper into the key findings from the TROPiCS-02 trial. Dr. Master, how did the efficacy of TRODELVY compare to traditional chemotherapy?

Dr. Master:
So, TRODELVY achieved a significant and clinically meaningful median progression-free survival benefit of five and a half months compared to four months for single-agent chemotherapy. This corresponded to a hazard ratio of 0.66, with a 95 percent confidence interval of 0.53 to 0.83, and a P-value of 0.0003, meaning that patients treated with TRODELVY had a 34 percent reduced risk of progression or death. And so, TRODELVY presents a potential opportunity to delay disease progression or death for our patients.[5,18]

Dr. Turck:
And turning to you, Dr. Iyengar, were there any other results that stood out to you?

Dr. Iyengar:
Yes, I'd like to mention that TRODELVY also showed an overall survival benefit of 3.2 months longer than single-agent chemotherapy. More specifically, the median overall survival was 14.4 months for patients who received TRODELVY, compared to 11.2 months for those who underwent single-agent chemotherapy. This yielded a hazard ratio of 0.79, with a 95 percent confidence interval of 0.65 to 0.96, and a P value of 0.02.[5,6]

And then lastly, a prespecified descriptive analysis found that 61 percent of patients on TRODELVY were alive at 12 months, compared to 47 percent in the single-agent chemotherapy arm. The 95 percent confidence intervals were 55 to 66 percent for TRODELVY and 41

to 53 percent for chemotherapy. So while this adds some context, we need to interpret the 12-month overall survival data cautiously since they weren't powered for statistical analysis—which means they could represent chance findings.[6]

But overall, the clinical evidence positions TRODELVY as the only Trop-2–directed ADC to significantly extend overall survival and delay disease progression.[5,6]

Dr. Turck:
Now based on the findings from the TROPiCS-02 trial, Dr. Master, what safety considerations should healthcare providers keep in mind when prescribing TRODELVY?

Dr. Master:
TRODELVY has a well-characterized safety profile in patients with pretreated hormone receptor positive, HER2-negative metastatic breast cancer.[5,18]

The most common adverse reactions in TROPiCS-02, including lab abnormalities, noted in 25 percent or more of participants were:

- decreased leukocytes, 88 percent;
- decreased neutrophils, 83 percent;
- decreased hemoglobin, 73 percent;
- decreased lymphocytes, 65 percent;
- diarrhea, 62 percent;
- fatigue, 60 percent;
- nausea, 59 percent;
- alopecia, 48 percent;
- increased glucose, 37 percent;
- constipation, 34 percent; and
- decreased albumin, 32 percent.[5]

It's also important to point out that serious adverse reactions occurred in 28 percent of patients receiving TRODELVY, including diarrhea at five percent, febrile neutropenia at four percent, and neutropenia at three percent. Abdominal pain, colitis, neutropenic colitis, pneumonia, and vomiting were each reported at two percent.[5]

And so, that's why it's essential to have open conversations with patients early in their treatment journey about potential adverse reactions, and to work with them to develop management strategies—to help them be informed and prepared throughout treatment.[5]

Dr. Turck:
As a quick follow-up to that, Dr. Iyengar, what strategies can we use to proactively manage potential adverse reactions?

Dr. Iyengar:
Excellent question. Preparing our patients for potential side effects, like diarrhea and neutropenia, is key to helping them stay on TRODELVY as appropriate.[5]

If patients are educated on these adverse reactions, they're more likely to recognize and report symptoms early. This can help ensure timely intervention. For example, prophylactic or premedications can be initiated when clinically indicated, and dose modifications or interruptions can help manage symptoms while remaining on treatment when possible.[5]

Dr. Turck:
Well, we've certainly covered a lot today, but before we close, let's hear from you one last time, Dr. Master. Do you have any final insights you'd like to share with the audience?

Dr. Master:
I'd just like to reiterate that TRODELVY is the only Trop-2–directed ADC to show a statistically significant median overall survival benefit compared to single-agent chemotherapy in pretreated patients with HR-positive, HER2-negative metastatic breast cancer.[5] This underscores its importance as a treatment option for patients.[1,6]

And to echo Dr. Iyengar's point, level-setting with patients is key to the treatment experience. Patients have shared that it's important for us to set clear expectations to help them understand potential side effects, acknowledge that individual experiences may vary, and reassure them that support is available.[20]

Dr. Turck:
It's been such a great conversation with Drs. Aashini Master and Neil Iyengar, and I want to thank them both for sharing their valuable insights on using TRODELVY in patients with pretreated HR-positive, HER2-negative metastatic breast cancer. Dr. Master, Dr. Iyengar —really enjoyed speaking with you today.

Dr. Iyengar:
Thank you for having me.

Dr. Master:
Wonderful discussion, thank you.

Dr. Turck:
To learn more about how we can prepare patients for the potential adverse reactions associated with TRODELVY, be sure to check out the second episode of this two-part program, titled "Supportive Care in Patients with Pretreated HR-Positive, HER2-Negative Metastatic Breast Cancer."

Please stay tuned to hear Important Safety Information. And for ReachMD, I'm Dr. Charles Turck.

ReachMD Announcer:
WARNINGS AND PRECAUTIONS

Neutropenia: Severe, life-threatening, or fatal neutropenia can occur as early as the first cycle of treatment and may require dose modification. Neutropenia occurred in 64% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 49% of patients. Febrile neutropenia occurred in 6%. Neutropenic colitis occurred in 1.4%. Primary prophylaxis with G-CSF is recommended starting in the first cycle of treatment in all patients at increased risk of febrile neutropenia, including older patients, patients with previous neutropenia, poor performance status, organ dysfunction, or multiple comorbidities. Monitor absolute neutrophil count (ANC) during treatment. Withhold TRODELVY for ANC below 1500/mm^3 on Day 1 of any cycle or below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever. Treat neutropenia with G-CSF and administer prophylaxis in subsequent cycles as clinically indicated or indicated in Table 2 of USPI.

Diarrhea: Diarrhea occurred in 64% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 11% of patients. One patient had intestinal perforation following diarrhea. Diarrhea that led to dehydration and subsequent acute kidney injury occurred in 0.7% of all patients. Withhold TRODELVY for Grade 3-4 diarrhea and resume when resolved to ≤ Grade 1. At onset, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (e.g., atropine) for subsequent treatments.

Hypersensitivity and Infusion-Related Reactions: TRODELVY can cause serious hypersensitivity reactions including life-threatening anaphylactic reactions. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 35% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.2%. The incidence of anaphylactic reactions was 0.2%. Pre-infusion medication is recommended. Have medications and emergency equipment to treat such reactions available for immediate use. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

Nausea and Vomiting: TRODELVY is emetogenic and can cause severe nausea and vomiting. Nausea occurred in 64% of all patients treated with TRODELVY and Grade 3-4 nausea occurred in 3% of these patients. Vomiting occurred in 35% of patients and Grade 3-4 vomiting occurred in 2% of these patients. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist as well as other drugs as indicated) for prevention of chemotherapy-induced nausea and vomiting (CINV). Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting and resume with additional supportive measures when resolved to Grade ≤ 1. Additional antiemetics and other supportive measures may also be employed as clinically indicated. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

Increased Risk of Adverse Reactions in Patients with Reduced UGT1A1 Activity: Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia and may be at

increased risk for other adverse reactions with TRODELVY. The incidence of Grade 3-4 neutropenia was 58% in patients homozygous for the UGT1A1*28, 49% in patients heterozygous for the UGT1A1*28 allele, and 43% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 21% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 9% in patients homozygous for the wild-type allele. Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on clinical assessment of the onset, duration and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 function.

Embryo-Fetal Toxicity: Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. TRODELVY contains a genotoxic component, SN-38, and targets rapidly dividing cells. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

ADVERSE REACTIONS

In the pooled safety population, the most common (≥ 25%) adverse reactions including laboratory abnormalities were decreased leukocyte count (84%), decreased neutrophil count (75%), decreased hemoglobin (69%), diarrhea (64%), nausea (64%), decreased lymphocyte count (63%), fatigue (51%), alopecia (45%), constipation (37%), increased glucose (37%), decreased albumin (35%), vomiting (35%), decreased appetite (30%), decreased creatinine clearance (28%), increased alkaline phosphatase (28%), decreased magnesium (27%), decreased potassium (26%), and decreased sodium (26%).

In the TROPiCS-02 study (locally advanced or metastatic HR-positive, HER2-negative breast cancer), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, nausea, alopecia, and constipation. The most frequent serious adverse reactions (SAR) (>1%) were diarrhea (5%), febrile neutropenia (4%), neutropenia (3%), abdominal pain, colitis, neutropenic colitis, pneumonia, and vomiting (each 2%). SAR were reported in 28% of patients, and 6% discontinued therapy due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the TROPiCS-02 study were reduced neutrophils and leukocytes.

DRUG INTERACTIONS

UGT1A1 Inhibitors: Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with TRODELVY.

UGT1A1 Inducers: Exposure to SN-38 may be reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

Please see full Prescribing Information, including BOXED WARNING by clicking on the link on the ReachMD landing page or visiting TRODELVYHCP.com.

ReachMD Announcer:

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