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Assessing G-CSF Prophylaxis with Sacituzumab Govitecan in mTNBC

Announcer:

You're listening to *Project Oncology* on ReachMD, and this episode is sponsored by Gilead Sciences, Inc. Here's your host, Dr. Charles Turck.

Dr. Turck:

Welcome to *Project Oncology* on ReachMD. I'm Dr. Charles Turck, and joining me to discuss the role of G-CSF prophylaxis in managing neutropenia in patients with metastatic triple-negative breast cancer receiving sacituzumab govitecan are Drs. Kelly McCann and Gregory Vidal. Dr. McCann is a hematologist-oncologist and an Assistant Professor at the David Geffen School of Medicine at UCLA. Dr. McCann, thanks for being here today.

Dr. McCann:

Thank you.

Dr. Turck:

And Dr. Gregory Vidal is a medical oncologist and the Director of Clinical Research at the West Cancer Center and Research Institute in Memphis. He's also an Associate Professor at the University of Tennessee Health Science Center. Dr. Vidal, it's great to have you with us as well.

Dr. Vidal:

Thank you very much for inviting me.

Dr. Turck:

Now, starting with you, Dr. McCann, the updated label for sacituzumab govitecan states that primary prophylaxis with G-CSF is recommended for all patients who are at increased risk of febrile neutropenia. From your perspective, why is that update important, and what does that mean for clinical decision-making in everyday practice?

Dr. McCann:

So the black box label was added to the FDA label in March 2025. So sacituzumab govitecan was approved without it for quite a while. It was added because patients can have severe neutropenia develop as a result of sacituzumab govitecan, particularly if they have a *UGT1A1*28* mutation—if they're homozygous for that.

And so we just want to keep our patients very safe by making sure that we prevent neutropenia from developing in the first place.

Dr. Turck:

And building off of that, Dr. Vidal, when you are assessing a patient's risk of febrile neutropenia, what factors guide your decision to initiate G-CSF from the first cycle?

Dr. Vidal:

Certainly right now in practice, I institute G-CSF support first line. There are patients, obviously, who are coming into the start of sacituzumab that we're most concerned about for neutropenia, meaning those patients are highly pretreated, they have gotten a lot of chemotherapy in the early setting, and had neutropenia as an issue, and so therefore, you're going to expect that neutropenia may continue. Or there are some patients, especially Black patients—there's benign ethnic neutropenia—who are coming in with a lower white count to begin with, and that's their normal. The expectation is they're likely to drop. Dr. McCann talked about the *UGT1A1*-homozygous patients, and we see that a little bit higher in patients of African descent also, and so those patients are higher

risk.

Older patients and patients with other comorbid factors who are taking other concurrent medications that may impact their white counts—all of these we take into consideration when we're deciding about a patient. But I will tell you, if a patient is coming in at normal levels, I usually give them the benefit of the doubt, because I know I want to give them at least the best opportunity for best response. So I start at full dose for most patients, add G-CSF, and respond based on whether or not they're neutropenic throughout the process or not.

Dr. Turck:

Now, coming back to you, Dr. McCann, I'd like to talk about the recent safety analysis from the ASCENT-03 and -04 trials, which were presented at the 2025 San Antonio Breast Cancer Symposium. In ASCENT-03, primary G-CSF prophylaxis was associated both with lower rates and reduced severity of neutropenia in patients receiving sacituzumab govitecan. And in ASCENT-04, the incidence of grade three or higher neutropenia was 35 percent in treatment arm patients who received G-CSF compared to 50 percent in those who did not.

So what stands out to you about those findings, and what's your take on how they support the role of G-CSF in clinical practice?

Dr. McCann:

I think this data analysis was very important because it led to G-CSF being recommended on the FDA label. And that makes it much easier for us to be able to get a G-CSF approved by health insurance for our patients. Before then, I would usually start my patients at a lower dose of 7.5 micrograms per kilogram, primarily to see if they are going to become neutropenic, because we want to keep them safe. And then I could use a secondary prophylaxis strategy.

So I think that—in addition to the PRIMED study and some of the Flat Iron database statistics—has shown that patients really do benefit from using primary prophylaxis with G-CSF to keep them on a high dose of the sacituzumab govitecan and to keep them safe and out of the hospital.

Dr. Turck:

For those just tuning in, you're listening to *Project Oncology* on ReachMD. I'm Dr. Charles Turck, and I'm speaking with Drs. Kelly McCann and Gregory Vidal about using G-CSF prophylaxis to improve outcomes for patients with metastatic triple negative breast cancer receiving sacituzumab govitecan.

So, Dr. Vidal, now that we have some background on G-CSF, let's talk about applying this knowledge to practice. Is there a typical timeframe you administer G-CSF around the time you initiate sacituzumab govitecan?

Dr. Vidal:

I usually go back to when this drug was first approved at our center. Knowing from the data—from the ASCENT study and the amount of neutropenia we saw—we billed G-CSF on day eight. Keep in mind, you need a 14-day window to chemotherapy in order to use the long acting.

And we got a lot of denials, peer to peer, and we removed it. We did see more neutropenia, so generally, at that point, we were going to G-CSF at cycle two, day eight. Now, with the updated FDA, I'm doing cycle one day eight long-acting pegfilgrastim, because what I think we're seeing is lower amounts of neutropenia between cycle two, day one and cycle two, day eight.

We, in our clinic, based on insurances, also give a lot of our patients the nine injections, but there is an on-body patch that we give that you can put on cycle one, day eight that then gives the pegfilgrastim on cycle one, day nine. And if you're in a center or a geography where this is easily obtained, then that is also an option.

I know in Kelly's geography, a lot of patients have the ability to get the short acting to go home and self-inject between. And you can do that any time, usually, between day one and day eight also, although we can give it after. But it doesn't require this 14-day interval between chemotherapy.

In our geography, it's a little bit harder to give home injections, and so for my patient population, we usually do cycle one, day eight or day nine pegfilgrastim. And if we need to add G-CSF in between day one and day eight, we do the short acting. But that means that the patients would have to come into the center to get them for those three days, which impacts their convenience.

Dr. Turck:

Now before we wrap up, I'd like to ask each of you one final question. Starting with you, Dr. McCann, would you share some strategies for working with supportive care teams like nursing, pharmacy, and patient navigators to ensure timely and effective G-CSF prophylaxis when starting sacituzumab govitecan?

Dr. McCann:

So usually, when I start sacituzumab govitecan, I'll start at a lower dose, potentially at 7.5 micrograms per kilogram, because I want to see whether or not the patient is particularly prone to develop neutropenia. And then I do tend to also use the on-body pegfilgrastim so that the patients are able to get that medication without having to worry about going home and giving themselves shots.

Dr. Turck:

And finally, Dr. Vidal, should neutropenia occur despite use of G-CSF, how do you monitor and adjust doses? And are there any other ways that we can improve long-term outcomes?

Dr. Vidal:

Currently, the standard is that we do labs whenever the patients comes in for infusion before we start. So, at cycle one, day one, we get some labs, then cycle one, day eight, we check and then they come back again. We normally don't check in between.

Now, if a patient is neutropenic at cycle one, day eight, if I need to reduce, I would reduce and then recheck in a week. If we need to add the daily, short-acting pegfilgrastim, I would do that for the patients and then recheck. If that patient is still neutropenic in a week's time, that patient really does need a dose reduction, because their body's showing you that, one, they're not reacting as we would expect with the growth factor, but also, it may be a little bit too much for the bone marrow. And so therefore they need a little bit more support, which comes in the form of lower doses.

From the perspective of getting all of the supportive care involved, certainly my nurses are involved. We do have care support who calls the patients or that the patients calls in to help manage those patients along. If there is fever associated with neutropenia, that makes it a little bit more serious. And therefore, those patients would require antibiotics and sometimes even, maybe, inpatient hospitalizations. And so we do stay in close contact with patients who are neutropenic, especially after day eight, just to make sure that they're safe, and especially for patients that we're concerned about, like the elderly.

Patients who already have really serious comorbidities you have to pay attention to. They've already had one hit and a second hit could be detrimental, so we stay in close contact with those patients. But again, overall, if they're neutropenic, G-CSF; if they cannot or it's slow to recover, those patients definitely need a dose reduction.

Dr. Turck:

Well, with those closing comments in mind, I want to thank my guests, Drs. Kelly McCann and Gregory Vidal, for joining me to discuss how we can use G-CSF prophylaxis to optimize outcomes for patients who are receiving sacituzumab govitecan for metastatic triple-negative breast cancer.

Dr. McCann, Dr. Vidal, We appreciate you both joining us today.

Dr. Vidal:

Thank you very much.

Announcer:

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