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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

A Closer Look at an IV-Administered Treatment Option for sHPT

ANNOUNCER: You're listening to ReachMD. This week's Medical Industry Feature, "*Spotlight on Nephrology: A Closer Look at an IV administered treatment option for sHPT,"* is sponsored by Amgen.

Parsabiv® (etelcalcetide) is indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on hemodialysis. Sensipar® (cinacalcet) is indicated for the treatment of secondary HPT in adult patients with CKD on dialysis.

Parsabiv® has not been studied in adult patients with parathyroid carcinoma, primary hyperparathyroidism, or with CKD who are not on hemodialysis and is not recommended for use in these populations. Sensipar® is not indicated for use in patients with CKD who are not on dialysis because of an increased risk of hypocalcemia.

Stay tuned for the complete Important Safety Information for Parsabiv® and Sensipar® at the end of this podcast. This program is intended for healthcare professionals only.

RUSSELL: Welcome to today's program on ReachMD. I'm Dr. John Russell. On today's program, we'll talk with experts in the field of nephrology to discuss the uptake in the use of Parsabiv® for adult patients with chronic kidney disease on hemodialysis who suffer from secondary hyperparathyroidism, also known as sHPT. I have two guests joining me today for this discussion. First up is Dr. David Henner, a nephrologist from Pittsfield, Massachusetts.

Dr. Henner, great having you with us today!

HENNER: Thanks for having me.

RUSSELL: Also joining us today is Debbie Glidden, a Nurse Practitioner from Orlando, Florida. Thanks for being here today Debbie.

GLIDDEN: My pleasure.

RUSSELL: So, let's start with you, Dr. Henner. One treatment option for sHPT is oral cinacalcet, which was FDA-approved in the US over a decade ago.[1] Seems like a long time without any advancement in the treatment of sHPT in my eyes. How do you feel about that?

HENNER: It is a long time, but there has been innovation. Particularly the FDA approval of Parsabiv® in 2017.[2] It's a calcimimetic that allows my care team to give sHPT therapy with IV administration while the patient is in the chair.[2] But we were unable to use it for all of 2017 due to lack of a reimbursement code. But even during that time, I learned about Parsabiv® and was already lining up patients in my head who I thought could be ideal candidates for this drug once reimbursement codes did become available.

RUSSELL: So, now prescribers are using Parsabiv® on all their appropriate sHPT patients?

HENNER: I wish that were true, but it's not that simple. Sometimes a patient must first fail on oral cinacalcet before they can request initiation of Parsabiv®.

RUSSELL: And what does "failure on cinacalcet" mean?

HENNER: That's a very good question—one that seems to have many different answers.

RUSSELL: I would assume not being able to control administration is a major frustration for you? When the inability to control administration causes issues, what does that mean for you?

HENNER: That often means Parsabiv®. I prefer to initiate Parsabiv® when a patient's lab values are out of the target range I have set for that patient. Even if the patient is at a seemingly lower PTH, like 600 or 700, if his labs are trending up, I might define that as failure and consider Parsabiv®.

RUSSELL: Interesting. Debbie Glidden, how do you feel about all of this?

GLIDDEN: Unfortunately, as much as we'd like it to be the case, there isn't one black & white definition of cinacalcet failure. It really has to be considered from patient to patient. A PTH of 600 looks great if that patient started out at 2000. But if that patient with a 600 PTH was once comfortably at 300, that's a different story. KDIGO Guidelines tell me that a patient's PTH should be somewhere between around 130 to 600,[3] so that's what we aim for. And if a patient is not achieving those levels, it's going to compel me to take action. And sometimes, if a patient is supposed to be taking oral cinacalcet and I see their PTH jumping in and out of that range or consistently trending upward, that may also trigger me to adjust treatment.

RUSSELL: Thanks for sharing that insight. For those just tuning in, you're listening to ReachMD. I'm Dr. John Russell and today I'm speaking with Dr. David Henner and Nurse Practitioner Debbie Glidden about the use of Parsabiv® for adult patients with chronic kidney disease and secondary hyperparathyroidism.

ANNOUNCER: Here's some additional important safety information for Parsabiv® and Sensipar®. Parsabiv® is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including face edema and anaphylactic reaction, have occurred. Sensipar® treatment initiation is contraindicated if serum calcium is less than the lower limit of the normal range (8.4 mg/dL). And now, back to the program.

RUSSELL: So, focusing back on our conversation, Ms. Glidden, tell me about starting a patient on Parsabiv®.

GLIDDEN: First and foremost, I will write Parsabiv® when I feel it's important for us to control administration. We initiate Parsabiv® for appropriate patients in order to manage their sHPT. We start them out at the approved dose, which is 5 mg 3 times a week, at the end of hemodialysis. It's important to ensure that a patient's serum calcium is at or above the lower limit of normal before initiating Parsabiv. Following initiation, check the patient's calcium levels after one week, then every 4 weeks after that. Also, you need to check the patient's PTH levels after 4 weeks, then continue to check PTH based on whatever your practice does.[2] Of course, all dosing and monitoring information can be found in the package insert.

RUSSELL: So, then you just order Parsabiv® and go from there?

GLIDDEN: Once you've decided to prescribe the new drug, we need to work with our dialysis organization to make sure we get that patient on Parsabiv®.

RUSSELL: So, now I am curious if this is a common occurrence. So, I want to ask you, Dr. Henner, once you've decided to prescribe Parsabiv®, have you had trouble transitioning?

HENNER: The actual act of switching a patient from oral cinacalcet to Parsabiv® is easy—you just discontinue oral cinacalcet for at least 7 days and ensure serum calcium is at or above the lower limit of normal, then initiate Parsabiv® at the approved dose of 5 mg, 3 times a week.[2] That's no problem. Transitioning a patient to any new product can mean a lot of paperwork. It can seem daunting at first, but with time it becomes routine.

RUSSELL: So, as a follow up to that, Dr. Henner, what would you say to any clinicians out there who are wondering why they should bother?

HENNER: I would say, if you have a patient who you believe could benefit from a treatment like Parsabiv®, you have to advocate for them. And I do that every day. Ultimately, we've got to do what's right for our patients. I couldn't sleep at night unless I felt I did everything I could for my patients. That's my responsibility—and I think most nephrologists feel the same way.

RUSSELL: So, Debbie Glidden, you get the final word. Why do you think Parsabiv® is worth fighting for?

GLIDDEN: Again, I cannot stress enough the peace of mind I have knowing that I control administration with Parsabiv®. I've been in dialysis over 35 years and I've seen what these patients go through. It's not an easy life. That's why I fight for Parsabiv®— because I really care about my patients, and I've seen the difference that Parsabiv® makes, it works!

RUSSELL: Debbie Glidden, thanks for joining me today.

GLIDDEN: I appreciate the time!

RUSSELL: And Dr. Henner, I'd like to thank you as well.

HENNER: You're very welcome.

RUSSELL: Well, this has been a very helpful discussion, I want to thank Dr. David Henner and Nurse Practitioner Debbie Glidden for their time and insights in helping us understand more about the definition of cinacalcet failure and their views on treating appropriate patients with secondary hyperparathyroidism using Parsabiv®.

ANNOUNCER: And, now here's the complete important safety information for Parsabiv® and Sensipar®.

Contraindications:

Parsabiv® (etelcalcetide) is contraindicated in patients with known hypersensitivity to etelcalcetide or any of its excipients. Hypersensitivity reactions, including face edema and anaphylactic reaction, have occurred.

Sensipar® (cinacalcet) treatment initiation is contraindicated if serum calcium is less than the lower limit of the normal range (8.4 mg/dL).

Hypocalcemia:

Parsabiv® and Sensipar® lower serum calcium and can lead to hypocalcemia, sometimes severe. Life threatening events and fatal outcomes associated with hypocalcemia have been reported in patients treated with Sensipar®, including pediatric patients. The safety and effectiveness of Sensipar® have not been established in pediatric patients.

Significant lowering of serum calcium can cause QT interval prolongation and ventricular arrhythmia. Cases of QT prolongation and ventricular arrhythmia have been reported in patients treated with Sensipar®. Patients with conditions that predispose to QT interval prolongation and ventricular arrhythmia may be at increased risk for QT interval prolongation and ventricular arrhythmias if they develop hypocalcemia due to Parsabiv® or Sensipar®. Closely monitor corrected serum calcium and QT interval in patients at risk on Parsabiv® or Sensipar®.

Significant reductions in corrected serum calcium may lower the threshold for seizures. Patients with a history of seizure disorder may be at increased risk for seizures if they develop hypocalcemia due to Parsabiv® or Sensipar®. Monitor corrected serum calcium in patients with seizure disorders on Parsabiv® or Sensipar®.

Concurrent administration of Parsabiv® or Sensipar® with calcium-lowering drugs including other calcimimetics could result in severe, life-threatening hypocalcemia. Parsabiv® and Sensipar® should not be given together. Patients switching from Sensipar® to Parsabiv® should discontinue Sensipar® for at least 7 days prior to initiating Parsabiv®. Closely monitor corrected serum calcium in patients receiving Parsabiv® or Sensipar® and concomitant therapies known to lower serum calcium.

Measure corrected serum calcium prior to initiation of Parsabiv®. Do not initiate in patients if the corrected serum calcium is less than the lower limit of normal. Monitor corrected serum calcium within 1 week after initiation or dose adjustment and every 4 weeks during treatment with Parsabiv®. Measure PTH 4 weeks after initiation or dose adjustment of Parsabiv®. Once the maintenance dose has been established, measure PTH per clinical practice.

Serum calcium and serum phosphorus should be measured within 1 week and PTH should be measured 1 to 4 weeks after initiation or dose adjustment of Sensipar®. Once the maintenance dose has been established, serum calcium and serum phosphorus should be measured approximately monthly, and PTH every 1 to 3 months.

Hypotension, Worsening Heart Failure and/or Arrhythmias:

In Parsabiv® clinical studies, cases of hypotension, congestive heart failure, and decreased myocardial performance have been reported. Closely monitor patients treated with Parsabiv® for worsening signs and symptoms of heart failure.

In Sensipar® post marketing use, isolated, idiosyncratic cases of hypotension, worsening heart failure, and/or arrhythmia were reported in patients with impaired cardiac function. The causal relationship to Sensipar® therapy could not be completely excluded and may be mediated by reductions in serum calcium levels.

Upper Gastrointestinal Bleeding:

Cases of gastrointestinal (GI) bleeding, mostly upper GI bleeding, have occurred in patients using calcimimetics, including Sensipar®, from post marketing and clinical trial sources. In clinical studies, 2 patients treated with Parsabiv® in 1253 patient years of exposure had upper GI bleeding at the time of death. There were too few cases to determine whether these cases were related to Parsabiv®. The exact cause of GI bleeding in these patients is unknown. Patients with risk factors for upper GI bleeding, such as known gastritis, esophagitis, ulcers or severe vomiting, may be at increased risk for GI bleeding with Parsabiv® or Sensipar®. Monitor patients for worsening of common Parsabiv® or Sensipar® GI adverse reactions and for signs and symptoms of GI bleeding and ulcerations during Parsabiv® or Sensipar® therapy.

Adynamic Bone

Adynamic bone may develop if PTH levels are chronically suppressed.

Adverse Reactions

In clinical trials of patients with secondary HPT comparing Parsabiv® to placebo, the most common adverse reactions were blood calcium decreased (64% vs. 10%), muscle spasms (12% vs. 7%), diarrhea (11% vs. 9%), nausea (11% vs. 6%), vomiting (9% vs. 5%), headache (8% vs. 6%), hypocalcemia (7% vs. 0.2%), and paresthesia (6% vs. 1%).

In clinical trials of patients with secondary HPT comparing Sensipar® to placebo, the most commonly reported side effects were nausea (31% vs. 19%), vomiting (27% vs. 15%), and diarrhea (21% vs. 20%).

Please visit parsabivhcp.com and sensiparhcp.com for the Parsabiv and Sensipar full prescribing information. This Medical Industry Feature was sponsored by Amgen. To learn more about Amgen, please visit amgen.com. And, if you missed any part of this discussion, please visit (Reachmd.com/Parsabiv). This is ReachMD. Be Part of the Knowledge.