

### Transcript Details

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### Making a Difference for Patients with sHPT

ANNOUNCER: You're listening to ReachMD. This week's Medical Industry Feature, "*Spotlight on Nephrology: Making a difference for patients with 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.

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.

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

RUSSELL: Welcome to today's program. I'm your host Dr. John Russell, and today I will be talking with experts in the fields of nephrology about the changing dynamics of nephrology care and how it affects their patients with secondary hyperparathyroidism, also known as sHPT. It's one of the particularly challenging aspects of treating adult patients with chronic kidney disease who are on hemodialysis. Joining me today is Dr. David Henner, a nephrologist from Pittsfield, Massachusetts.

HENNER: Hi, glad to be here.

RUSSELL: Also joining us on the podcast today will be Dr. Abdul Abdellatif, a nephrologist from Houston, Texas. So, Dr. Henner, nephrology patients seem to be an underserved patient population when it comes to new treatment options. What do you see happening to remedy that?

HENNER: That may seem to be the case. And while there have been very few new drugs in nephrology over the last several years,<sup>1</sup> we need to acknowledge that there are positive things happening to help our patients right now. There are a lot of great treatment options available and one of them that comes to mind is Parsabiv®. That is one drug that I can say, without hesitation, has made a difference in my practice. For years, I've wanted to manage my patients' secondary hyperparathyroidism and be able control administration of their treatment while also helping to lower and maintain their labs.

RUSSELL: Dr. Abdellatif, do you also share those sentiments?

ABDELLATIF: Absolutely. In my practice, Parsabiv® has played an important role in building treatment plans for my patients with sHPT. Unfortunately, there is data that show that despite the availability of sHPT treatments, including calcimimetics, the incidence of patients with high PTH, greater than 600, has more than doubled in the recent years.<sup>2</sup> So that tells me there is more work to do with the treatment options we have for our patients.

RUSSELL: But if calcimimetics like Parsabiv® provide hope, why do you think that has happened?

ABDELLATIF: There are countless reasons this might have happened. To me, a big problem is not monitoring labs in a timely fashion. Take a drug like Parsabiv®, for instance. Based on the label, PTH should be monitored 4 weeks after initiation or dose adjustment when maintenance dose is reached check PTH per the facility. Corrected calcium should be checked 1 week after initiation or dose adjustment and then every 4 weeks once you have found the maintenance dose.<sup>3</sup> I think another reason could be lack of proper titration because of inadequate lab checks. If you are not monitoring labs as recommended you may not be titrating as efficiently as you could if you checked their labs as directed. Titration is an

important part of monitoring patients treated with Parsabiv. I make it a point in my practice to be sure we are monitoring labs regularly and titrating as recommended. We work as a team; both my nurses and dietitians are aware of my treatment plan for our patients.

RUSSELL: That makes a lot of sense. Dr. Henner, is Parsabiv® having any effect on how you and your peers are treating sHPT and what you can do for your patients?

HENNER: Parsabiv® has had a huge impact on the way we treat our patients with secondary hyperparathyroidism. For myself, and most of my colleagues, we routinely write Parsabiv® for appropriate patients. And I see that trend continuing because we have seen good results managing secondary hyperparathyroidism with Parsabiv®-based regimens.

RUSSELL: Doctor that's good to hear. If you're just tuning in, you are listening to this week's Medical Industry Feature sponsored by Amgen. I'm your host, Dr. John Russell. We're talking about the changing landscape of patient care in sHPT. We'll be back in just a moment.

ANNOUNCER: Here's some additional important safety information for Parsabiv®. 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.

Now, back to the program.

RUSSELL: Dr. Henner, you've told us how *you* feel about Parsabiv®. What about your patients?

HENNER: Oh, I have patients that have been on Parsabiv® who have told me they are very thankful for it. Let me give you an example. I had this one patient who I had been treating for secondary hyperparathyroidism and her PTH was rather high. I suspected she was not adherent to her current therapy because she had a history of that. We eventually initiated her on Parsabiv® at the starting dose of 5 mg 3 times a week. We titrated every 4 weeks and her secondary hyperparathyroidism labs responded. That means we checked that her serum calcium was normal and continued to monitor as we adjusted the dose per the label. Her labs responded so well, in fact, after several months, her PTH was around 500, and her phosphorus and calcium levels were where I like to see them. She had to travel out of town and when she did, she looked for a dialysis center that could give her Parsabiv®. She said if they couldn't give her Parsabiv®, that was a deal breaker. That's how strongly many of my patients feel about this treatment.

RUSSELL: That's quite a statement. Dr. Henner says this is not an isolated case—and Dr. Abdellatif confirms that.

ABDELLATIF: One particular patient comes to mind is one of my patients, a young lady, who has been on and off dialysis for many years most recently four years on hemodialysis and her secondary hypoparathyroidism continued to get worse. Actually, her parathyroid hormone was high. Once Parsabiv® became available, she was the first patient in her dialysis unit to be initiated on the medication and we started her on 5 mg, 3 times a week at the end of her hemodialysis.

RUSSELL: How exactly do you do that?

ABDELLATIF: Oh, you give it at the end of hemodialysis session either given during rinse back or an IV push after rinse back with an appropriate saline flush. I prefer IV push after rinse back within ML of saline flush. Those are the basics—all the details are in the Parsabiv® prescribing information.<sup>3</sup>

RUSSELL: I see, thanks for clarifying that. So, anyway, back to your patient.

ABDELLATIF: Yes, so we started the patient on the 5 mg of Parsabiv IV at the end of each hemodialysis session and after her PTH came back 4 weeks later, her PTH was still elevated even though it was dropping so I adjusted the dose to 10 mg 3 times a week in the same manner and on her repeat labs in 4 weeks, her PTH was within target range of about 400-500 and we monitored the patient over the upcoming months and her level was maintained in the 300-400 range over 1 year period without any further adjustment of her dosing state on the 10 mg dose during her therapy.

RUSSELL: What was it like to be able to deliver such good news to her?

ABDELLATIF: It feels great and satisfying to deliver good news to our patients. Often, they are not use to hearing good news. That's really inspiring, and it actually draws me and my staff to look for more appropriate patients for this treatment.

RUSSELL: Turning now to Dr. Henner, I can see that you and many of your colleagues are having some success with Parsabiv®. Is this in part why you feel optimistic about the treatment of sHPT?

HENNER: It has a great deal with how I feel about the treatment of secondary hyperparathyroidism, and I am so thankful for a drug like this. I have another option to treat my patients with secondary hyperparathyroidism, and I am able to control administration, something that's really important to me.

RUSSELL: Dr. Abdellatif, do you share Dr. Henner's outlook for your patients with sHPT? What other challenges do you look forward to overcoming?

ABDELLATIF: I definitely agree with Dr. Henner. I have full confidence in using Parsabiv® for my appropriate patients with secondary hyperthyroidism and I am optimistic that I can do a lot for patients with sHPT in large part because of this regimen. Like I said before, why wait for the future when you can have a positive impact on someone's life today.

RUSSELL: Dr. Abdellatif, thanks for joining me today.

ABDELLATIF: Thank you.

RUSSELL: Dr. Henner, thanks as well.

HENNER: Thank you!

RUSSELL: Well, this has been a very helpful discussion. I want to thank Drs. Henner and Abdellatif for their time and thoughts. There is definitely a lot of positive energy surrounding the sHPT community and these doctors are a big part of it. Thanks for joining us today and look for our other programs discussing important issues in nephrology.

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

#### **Contraindication:**

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.

#### **Hypocalcemia:**

Parsabiv® lowers serum calcium and can lead to hypocalcemia, sometimes severe. Significant lowering of serum calcium can cause QT interval prolongation and ventricular arrhythmia.

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®. Closely monitor corrected serum calcium and QT interval in patients at risk on Parsabiv®.

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®. Monitor corrected serum calcium in patients with seizure disorders on Parsabiv®.

Concurrent administration of Parsabiv® with another oral calcimimetic could result in severe, life-threatening hypocalcemia. Patients switching from cinacalcet to Parsabiv® should discontinue cinacalcet for at least 7 days prior to initiating Parsabiv®. Closely monitor corrected serum calcium in patients receiving Parsabiv® 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.

#### **Worsening Heart Failure:**

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.

#### **Upper Gastrointestinal Bleeding:**

In clinical studies, 2 patients treated with Parsabiv® in 1253 patient years of exposure had upper gastrointestinal (GI) bleeding at the time of death. The exact cause of GI bleeding in these patients is unknown and there were too few cases to determine whether these cases were related to Parsabiv®.

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®. Monitor patients for worsening of common Parsabiv® GI adverse reactions and for signs and symptoms of GI bleeding and ulcerations during Parsabiv® 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%). Please visit [parsabivhcp.com](https://www.parsabivhcp.com) for the Parsabiv® full prescribing information.

This Medical Industry Feature was sponsored by Amgen. To learn more about Amgen, please visit [amgen.com](https://www.amgen.com). And, if you missed any part of this discussion, please visit ([Reachmd.com/Parsabiv](https://Reachmd.com/Parsabiv)). This is ReachMD. Be Part of the Knowledge.

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