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Time needed to complete: 1h 23m

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(866) 423-7849

Emerging PH Therapies: How Will They Impact Treatment Strategies?

Announcer:
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Dr. Preston:
Hello, I'm Dr. Ioana Preston, the Director for the PH Center at Tufts Medical Center in Boston, Massachusetts. Thank you for joining us today. I have the pleasure of being accompanied by doctors Oksana Shlobin from Inova Fairfax, and Dr. Rich Channick from UCLA, both long-term experts in pulmonary hypertension. Thank you for joining me.

So let's talk about emerging therapies in PAH. For the past 25 years, the clinical research in PAH has been extremely active, and we have 14 drugs on the market now that we treat our patients with. But recently, quite a high number of clinical trials have emerged, looking at novel molecules, novel delivery systems, and a combination of these.

So Rich, thinking about clinical trials such as sotatercept, ralinepag, and other that are ongoing or have recently finished, how do you see these new compounds fit into the treatment of patients with advanced PAH disease or significant disease burden?

Dr. Channick:
Yeah, thanks for that question. It's a really good question. As you said, a very exciting time in our field. I think a drug like sotatercept, it's obviously very unique because it has a novel mechanism of action. It's not ostensibly a vasodilator. And the data that's been published is very, very strong, showing the benefit of this particular agent, even in patients on multiple other therapies. So I think it's going to have a very integral role in adding on and being part of a combination now where it'll fit in, we'll have to see. But I think that, you know, there's some other studies going on looking at patients who are more severe, patients who have earlier - more earlier in the course of the disease. So I think time will tell but it will clearly be an integral part. A drug like ralinepag, which is, you know, a prostacyclin receptor agonist, but longer acting, that may give us some further benefits. But again, we'll see. We're still earlier with that particular drug to know whether it's going to be a positive outcome.

Dr. Preston:
So Oksana, not all our patients in pulmonary hypertension clinic fit the inclusion/exclusion criteria that are very strict in the clinical trials. How do you see applying these new therapies in your clinic?

Dr. Shlobin:
It's a great question. Probably, there is no easy answer. But I think, similarly to what we've done in the past with therapies that have come to market, at the beginning, you sort of you try it out, and you use it on patients that are similar to the inclusion criteria. But as you gain experience as a provider, and hopefully with more - maybe more data coming for some of the trials, so just Rich just mentioned sotatercept and other ongoing trials of different patient population, then you start to experiment a little bit. I mean, I think we've done it since the beginning of times when therapies were available, first you get experience and then you expand your patient population. It's a different mode of therapy for these anti-proliferative agents like sotatercept, the tyrosine kinase inhibitors. So I think it'll be a learning curve for all of us. But I think with time as a community, we'll figure out where things fit. And now we have each other to learn from.

Dr. Channick:
The other thing I might add to that is that, you know, this is where things like registries and sort of the post-approval thing where you really collect real-world data to see, because like you say, it's not always the same patients that are in the trials. I think we've learned a lot from some of these registries that have come out after a drug is already being used.

Dr. Preston:
And not only efficacy long-term, but side effect profiles, right? Safety. Yes.

So Rich, as a PH expert and pulmonologist, and we are three of us are pulmonologists, we all love inhaled therapies. If you look at the ongoing clinical trials in PH, many of them are testing inhaled drugs. The imatinib inhaled, the seralutinib, vardenafil inhaled. How do you see these new approaches and delivery systems for our PH patients who have a different type of dyspnea compared to asthmatics or COPD?

Dr. Channick:
Yeah, great question. I think it's a work in progress. I think obviously, the rationale is very strong. You know, you're delivering a drug directly to the distal alveoli and therefore getting into the vascular bed and maybe having a more local effect without some of the systemic effects. And certainly there's plenty of history with inhaled treprostinil showing that it has efficacy. And now, you know, we have dry powder inhaler formulation. I can say anecdotally that, you know, some people have done very well but, you know, they have issues of coughing and whatnot with a powder inhaler. So I think there's still a few sort of kinks to be ironed out with all these new drugs delivered in an inhaled route, same story. I mean, I think it's a great idea, but as with all these things, the proof is in the clinical data and the efficacy, and we'll see. I'm optimistic, certainly.

Dr. Preston:
That's great. And Oksana now inhaled treprostinil is being the first drug approved for PH-ILD. And there are currently several inhaled formulations being tested for this population. How do you see this field emerging from here on?

Dr. Shlobin:
My hope, certainly, is that the compounds that are being tested for Group 1 PH are considered for interstitial lung disease, because although inhaled treprostinil is an effective therapy, there is more to be done for those patients that have really bad quality of life and such a high mortality. And my hope is that because the mode of action of some of the newer drugs like tyrosine kinase inhibitors is different, maybe there'll be more efficacy. And due to the anti-proliferative effects, both on their vascular bed and who knows what happens to the parenchyma level, I think, as a community, all of us are looking forward to the companies trying this drugs in patients with interstitial lung disease, because there is definitely more to be done.

Dr. Preston:
It's an area that's only little tapped, right?

Dr. Shlobin:
Very, very tiny tapped.

Dr. Preston:
We have a lot of work to do.

Dr. Shlobin:
Yes, absolutely.

Dr. Preston:
Well, this is an exciting time in clinical research in pulmonary hypertension, in not only Group 1, but other groups. We are looking forward to the results of the ongoing trials. Thank you so much for joining me today, and thank the audience for tuning in, and more news to come in the near future. Thank you.

Announcer:
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