NEUROENDOCRINE CANCER FOUNDATION

Dr. Halfdanarson on ITM's COMPETE Trial at 2025 ENETS

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Lisa Yen 00:00
I'm Lisa Yen, Director of Programs and Outreach for the Neuroendocrine Cancer Foundation, and I'm here in Krakow Poland with Dr Thor Haldanarson at the European Neuroendocrine Tumor Society Congress. And Dr Thor, thank you for joining me. I know we've been listening to some amazing research and trials. What is one of the highlights for you?

Dr. Thor Halfdanarson 00:20
So, this has you really got an interesting conference. So, I think the, one of the highlights has to be what I think is the first phase 3 clinical trial, initially presented at ENETS, which is the **COMPETE** trial of lutetium 177 **DOTATOC**. So, this is not the usual PRRT which is lutetium 177 dotatate, also known as Lutathera. This is DOTATOC. So, a similar PRRT to the regular Lutetitum in patients who mostly had received previous therapy and were mostly grade 2. They were randomized to four cycles of lutetium 177 DOTATOC every three months, so also a little different from the Lutathera, versus everolimus or Afinitor as you may know best. And this trial show without any doubt that the PRRT is more effective. Can't say this came as a surprise. We've known what everolimus does for years. It's an effective drug, but it's not quite as effective as PRRT is, and now we had direct comparison. 300 patients. Today, I think, is probably my key takeaway. There have been a lot of other interesting studies presented. There was a smaller study of PRRT versus sunitinib for pancreatic neuroendocrine tumors called **OCLURANDOM (NCT02230176**) that also showed improvement in what we call progression free survival in patients receiving PRRT. We've known these data. They were presented two years ago, but this is due to more mature, longer follow up. So exciting times for radioligand and in patients with NETs.

Lisa Yen 02:03
Yeah, really exciting. So you're saying that that trial, the COMPETE trial, showed that PRRT is more effective than everolimus.

Dr. Thor Halfdanarson 02:12
it is in terms of improving what's called **progression free survival**. Keep in mind, progression free survival is really the time from starting the treatment until the tumors grow. So, what they do is they had about 100 patients receive everolimus, about 200 patients receive PRRT, and then they just start the

clock, and then they see, how long can they go, on average, until the tumors grow? And they follow certain criteria: what like growth, but what constitutes growth? Of all of these, these strict criteria, and they showed that the PRRT literally had a longer Progression Free Survival, what is more effective. What we don't really know yet is the overall survival. Will people necessarily live longer? I'm not sure if they do, as long as you ultimately get PRRT. So, I'm not saying it's wrong to start with everolimus, but if you asked me, So, what would be the most effective, or more effective of those two, everolimus or PRRT? Well, in terms of progression free survival, I would have to say PRRT, because that's what data just showed today.

Lisa Yen 03:17
Yeah, so progression free survival, meaning a longer vacation, per se, without having to worry about going to the next treatment.

Dr. Thor Halfdanarson 03:26
Yeah, exactly, and four treatments, three months apart. So that, I think, is worth some

Lisa Yen 03:32
Yeah, so patients want that the longer vacations, longer time, without having to worry about the next treatment, they also want to live well. So, what did it show in terms of that?

Dr. Thor Halfdanarson 03:41
So, we still don't have the full quality of blight, but tons. But we saw from the other studies on the OPA random that the quality of life was actually better, at least some aspects of quality of life in the patients taking or getting PRT compared to those who got sunitinib. So, I think we'll have to wait for the final publication. These are better data, but I'm eagerly waiting for the final report where I can really look into the quality of life that data. I'm hoping there will be some patient reported outcomes as well.

Lisa Yen 04:10
Yeah, yeah. Okay, so we're waiting for that data of what about side effects?

Dr. Thor Halfdanarson 04:14
Side that's nothing new. So, all of these are side effects we knew from from from PRRT can lower your blood counts. Severe side effects like leukemia and myelodyspastic syndrome, thankfully, are really uncommon, so no more common than we previously have seen. Everolimus is a well-known side effect profile. So, nothing new, no new safety signals. So both drugs, I think, performed as expected to put side effects, but one was superior to the other with with progressing visual.

Lisa Yen 04:49
Yeah, okay. So key takeaway that you want it, you want the patients to know

Dr. Thor Halfdanarson 04:53
from that. So key takeaway would be from this trial is that the PRRT seems to be more effective than the everolimus in terms of progressing-free survival, but everolimos is still a good option. So will it ultimately matter if you get PRRT first and everolimus later, or sunitinib or caba=ozantinib or what have

we? I think as long as all of our patients get all of our available effective options, well, that's really what we should do.

Lisa Yen 05:18
Thank you, Dr Thor, for sharing your thoughts about this trial, and thank you for being here and for all you do on behalf of the net patient community.

05:25
Likewise. Thank you very much. We could not do it without you.