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Latest Clinical Trial Outcomes and Breakthroughs for FCS

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Dr. Taub:
This is CME on PACE-CME and ReachMD, and I'm Dr. Pam Taub. Here with me today is Dr. Daniel Gaudet.

Dr. Gaudet:
Hi Pam, good to see you.

Dr. Taub:
Great. It's nice to have you here, and I'm really interested in your perspective on the latest clinical evidence with novel treatment options for patients with FCS.

Dr. Gaudet:
Yeah, sure. There were two recent clinical trials being published, one with plozasiran, which is a small interfering RNA, whereas olezarsen, which is another one, is an antisense oligonucleotide. They both reduce hepatic production of apolipoprotein C3 and circulating triglycerides through LPL-dependent and LPL-independent mechanisms. These trials have been conducted with patients with persistent chylomicronemia, including patients with familial chylomicronemia syndrome.

The study conducted with plozasiran was called PALISADE. There were 75 subjects with persistent chylomicronemia with or without a genetic diagnosis, who were randomized to receive subcutaneous plozasiran 25 or 50 mg or placebo every 3 months for 12 months. The primary endpoint was the median percent change from baseline in the fasting TG levels at 10 months. At 10 months with plozasiran, the median change from baseline in the fasting TG level was 80% reduction, 78% with 50 mg dosage, compared to 17% in the placebo group. These results were rapidly achieved in a couple of weeks. It was well tolerated and the incidence of acute pancreatitis decreased substantially, by a little more than fivefold in the treated group versus the placebo.

In comparison, olezarsen, the conducted study was called BALANCE. There were a total of 66 patients with genetically-proven FCS, who underwent randomization; 71% of these patients had a prior history of acute pancreatitis in the previous 10 years. They were randomized in either 80 mg olezarsen, 50 mg, or placebo. The primary endpoint was TG decrease at 6 months. And at 6 months TG, well, they were significantly reduced in the 80 mg dose of olezarsen; less pronounced in the 50 mg, but after the 53 weeks of treatment, of a year of treatment, acute pancreatitis incidence was importantly reduced in the treated group versus the placebo. There were 11 episodes of acute pancreatitis in the placebo group versus 1 in each olezarsen group. And it was well tolerated as well.

Dr. Taub:
Well, that is a great summary of those trials. What is your key take away for the audience?

Dr. Gaudet:

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Well, severe hypertriglyceridemia, persistent chylomicronemia, including the familial chylomicronemia syndrome, can be treated efficiently by inhibiting APOC3. Olezarsen and plozasiran both represent effective approaches to reduce plasma TG and eventually pancreatitis risk, despite the fact that these studies were quite short in duration.

Dr. Taub:
Thank you, Daniel. Those were great insights and a great overview of the clinical trials.

Announcer:
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