Study findings shed new light on abatacept's impact on type 1 diabetes progression

Seattle, Washington Mar 16, 2023 (Issuewire.com) - Findings from the TrialNet Abatacept Prevention Study, published online March 15 by Diabetes Care, provide important new information about how abatacept impacts type 1 diabetes progression, which will inform future research.

The Abatacept Prevention Study opened in 2013 and enrolled 212 participants between the ages of 6 and 45 who were at increased risk for type 1 diabetes. All participants had two or more diabetes-related autoantibodies and normal glucose tolerance (Stage 1). Risk was identified by TrialNet screening, which detects the autoantibodies that signal the disease in its earliest stages, often years before symptoms appear.

The study found that while abatacept impacted immune response and preserved insulin production during the one-year treatment period, it did not meet the study goal of delaying progression to abnormal glucose tolerance (Stage 2) or clinical diagnosis (Stage 3). The group treated with abatacept maintained beta cell function better than the placebo group at 12 months. However, 12 months after treatment ended, beta cell function was the same for both groups. The early effect was not sustained.

"Every study gives us critical information that moves us one step closer to our ultimate goal: a future without type 1 diabetes," said Bill Russell, MD, TrialNet Abatacept Study Chair at Vanderbilt University in Nashville, TN. "This study helped us learn more about how abatacept works and its impact on disease progression."

In the treatment phase of the study, participants received 14 intravenous (IV) infusions over one year—three in the first month, then monthly for 11 months. Assigned randomly by computer, half of the participants got the study drug; the other half got a placebo infusion (looks the same as the study drug but is inactive). Neither researchers nor participants knew who was in which group until the end of the study. After the first year, participants visited a TrialNet site twice a year for monitoring until the study ended.

In an earlier TrialNet study for people newly diagnosed with type 1 diabetes (Stage 3), participants were treated with abatacept for two years. At the end of two years, those treated with abatacept had 59% better insulin production and a 9.6-month average delay in progression of insulin loss compared to those who received the placebo. That difference extended out to three years.

"Comparing findings from both studies provides important new information and direction for future research," said Dr. Russell.

Studying abatacept in both Stage 1 and Stage 3 opens the door to additional research asking: Would continued treatment make a difference? Would starting abatacept in Stage 2 be more effective? Could combining abatacept with another therapy prolong its impact?

Abatacept (CTLA-4 Ig) changes the way immune cells communicate. Marketed as Orencia®, abatacept is currently approved by the FDA for use in children as young as 6 for two types of juvenile arthritis and is also being studied for treatment of other autoimmune diseases.

TrialNet is currently planning a new study to test abatacept in combination with rituximab, another drug

that targets the immune system, in people newly diagnosed with type 1 diabetes. Expected to open for enrollment later this year, this study will be the first to test these two drugs consecutively (one after the other). Separate TrialNet studies showed each drug individually helped preserve insulin production in people newly diagnosed. By combining the two therapies, researchers expect more individuals to maintain insulin production during and possibly after treatment.

The first step for those interested in participating in TrialNet research is to get screened. TrialNet risk screening is free, quick and convenient. Those identified as being in the early stages of type 1 diabetes may be eligible for monitoring and clinical studies to try to change the course of the disease. To learn more, contact info@trialnet.org or visit www.trialnet.org.

About TrialNet

The largest clinical trial network ever assembled to change the course of type 1 diabetes, TrialNet (NCT00097292) is funded by the National Institutes of Health (NIH), primarily through the Special Statutory Funding Program for Type 1 Diabetes. TrialNet research was instrumental in the FDA's recent approval of the first drug to delay type 1 diabetes in people at risk. TrialNet conducted the clinical study that discovered teplizumab could delay type 1 diabetes for 2+ years. In addition, TrialNet data collected from more than 225,000 relatives of people with type 1 diabetes over the past 20 years led to the development of the stages of type 1 diabetes, making it possible to identify who will develop type 1 diabetes and move prevention research forward. Learn more at www.trialnet.org.

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