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PRODUCT DEVELOPMENT

Hua's diabetes therapy may be first to show clinical remission

BY STEPHEN HANSEN, ASSOCIATE EDITOR

Data from a small study has shown that Hua's dorzagliatin may be the first new mechanism to induce clinical remission in a majority of early stage Type II diabetes patients by restoring the glucose-sensing ability of beta cells.

The DREAM trial is an observational study that enrolled 69 Type II diabetes patients who had achieved their target of HbA1c levels below 7% while participating in the Phase III SEED study of GSK activator dorzagliatin from Hua Medicine Ltd. (HKEX:2552). Despite not receiving any therapy during DREAM beyond diet and exercise, 65.2% of the patients maintained clinical remission from Type II diabetes at week 52.

Hua EVP and CFO George Lin told BioCentury that the mean baseline HbA1c at the start of DREAM was 6.6% vs. 6.9% at week 52.

On Aug. 30, the American Diabetes Association (ADA) published guidance defining clinical remission as an HbA1c $\leq 6.5\%$ with a minimum duration of three months.

Lin said the DREAM study defined clinical remission as a maintenance of normal or near-normal HbA1c levels. Using the ADA definition, Lin said 52% of patients in DREAM were in clinical remission at 52 weeks.

As patients in the trial were on average just one year on from their initial diagnosis and treatment-naïve before enrollment in the SEED study, Lin said the data support the case for treating Type II diabetes patients early to give them a chance at clinical remission.

"You want to give patients a chance to get back to a normal level," Lin told BioCentury. "The whole idea is you're trying to get early intervention in a progressive, degenerative disease. So if you know what causes that degeneration, and you can stop, augment

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and restore more glucose sensors so you have more beta cell function, then that's great.”

Other than a small study of high-dose, intensive insulin therapy, no other therapeutic had previously demonstrated an ability to induce clinical remission in Type II diabetes, Lin said. Bariatric surgery has been shown to induce clinical remission of Type II diabetes in 50-60% of patients across various studies.

He said the impetus for the DREAM study was an observation at the end of Phase II testing for the GCK activator that showed some patients who

achieved their HbA1c goals maintained low glucose levels after stopping therapy. He added that DREAM is still following patients to see how long the clinical remissions last.

Dorzagliatin works by modulating a glucose sensor that controls key functions dysregulated in Type II diabetes, such as insulin and glucagon secretion by the pancreas, and glycogen storage by the liver. Hua previously reported positive Phase III data for the molecule, which is under review in China.

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