Diasome's HDV-Insulin demonstrates substantial Level 2 hypoglycemia reductions in setting of increased insulin use

The OPTI-1 trial shows increasing liver-targeted bolus insulin restores liver physiology allowing subjects to decrease Level 2 hypoglycemia by 50% at nighttime

CLEVELAND, OH, UNITED STATES , June 2, 2022 /EINPresswire.com/ -- Diasome Pharmaceuticals, Inc., a life sciences company focused on the development of novel therapies for the treatment of diabetes and other metabolic conditions, announced today the publication of a Phase 2b dose optimization study ("OPTI-1") in Diabetes, Obesity, and Metabolism that details the clinical outcomes of its lead asset, a liver targeted insulin called HDV-Insulin.

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>
> *Ruth Weinstock, MD, PhD*

Diasome's Hepatocyte Directed Vesicle™ technology (HDV-Insulin) is a novel excipient that binds to insulin molecules and targets insulin directly to liver hepatocytes, enabling the liver to store and release glucose. By insulinizing the liver, the body's own glucose control center allows people with diabetes to achieve liver glucose uptake, which in turn enables the liver to release that glucose during times of fasting, exercise, and sleeping to prevent hypoglycemia.

The OPTI-1 trial was designed to compare the effect of HDV-Insulin (insulin lispro) on improved bolus (rapid-acting mealtime insulin) to basal (long-acting insulin) ratios and on hypoglycemia endpoints over a 3-month treatment period following a 3-month Standard of Care (SOC) run-in period. This trial enrolled 58 adults with Type 1 diabetes, and the mean HbA1C at the study start was 6.9%.

During the run-in period, all participants were optimized on SOC bolus insulin and basal insulin regimens, and all participants utilized real-time, unblinded continuous glucose monitoring (CGM) devices throughout both the run-in period and the subsequent HDV-Insulin 90-day treatment period. On Day 91 of the study, participants switched their bolus insulin to HDV-Insulin and simultaneously reduced their optimized basal insulin dosing by either 10% or 40%. These basal reduction rates were designed to enable participants to better control blood sugar with

increased rapid-acting mealtime HDV-Insulin dosing compared to their prior SOC optimized insulin ratio.

Key findings from the published trial results include the following:

- At the end of the 90-day SOC run-in period, subjects in the -40% basal reduction group (mean A1C = 6.6%) experienced 1.1 nighttime Level 2 hypoglycemic events per week. At the end of the 90-day HDV-Insulin treatment period, the number of nighttime Level 2 hypoglycemic events per week was 50% lower.

- In the -40% basal reduction group, the bolus to basal insulin ratio increased by 30%, p-value 0.02, indicating a durable ability for participants to safely increase their mealtime insulin dosing while simultaneously reducing nighttime Level 2 events.

- By the end of the 90-day HDV™ treatment period, both bolus and basal dosing increased in both treatment groups, resulting in a total insulin dose increase of ~7%.

- HDV™ showed no liver toxicity, and despite increased insulin use, participants on HDV did not show increased weight gain.

Ruth Weinstock, MD, PhD, the lead author and one of the clinical investigators, said: "Hypoglycemia is our biggest challenge to achieving better glycemic control in persons with type 1 diabetes. The results from the OPTI-1 study demonstrate that insulinizing the liver at mealtime, as is done with HDV-insulin, can be an exciting and efficacious strategy to reduce hypoglycemia, especially at nighttime."

"The results from OPTI-1 further build our confidence and understanding that HDV-insulin decreases Level 2 hypoglycemic events across the A1C spectrum and shows that liver targeting of mealtime insulin is a superior strategy to improve overall glycemic control in persons with type 1 diabetes. Our focus for restoring normal physiology by targeting insulin to the liver at mealtime demonstrates a therapeutic breakthrough that the field has long required and is an exciting prospect for insulin-requiring patients" said Marc Penn, MD, PhD, Chief Medical Officer of Diasome.

W. Blair Geho, MD, PhD, Diasome's Chief Scientific Officer, concluded by stating, "In comparison to the level of control achieved during the 90-day standard of care run-in period, the addition of HDV to insulin lispro during the next 90-day period provided patients with a substantial reduction in both CGM-measured Level 2 hypoglycemia and participant recorded hypoglycemia. The ability to do this in the context of increased mealtime and total insulin dosing strongly supports our strategy to use HDV's liver targeting to convert the insulins used every day around the world from hypoglycemia causing to hypoglycemia preventing."

For further information, please visit: www. Diasome.com

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