



THERAPEUTICS

**Improving the Lives of Millions of
People Living with Type 1 Diabetes**

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Experienced Leadership with Decades of Life Sciences Expertise



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Living with T1D is Like Driving on a Narrow And Dangerous Road

No FDA approved oral therapy to help maintain glucose control for the 1.6M living with type 1 diabetes 

Hyperglycemia



Hypoglycemia



TOO LITTLE INSULIN

TOO MUCH INSULIN



Cadiseqliatin: A Large Opportunity in a Long-Underserved Market

1.6M

with type 1 diabetes in US

~80%

with T1D fail to achieve target A1c

24/7

management required

0

oral adjunct therapies for T1D

~ 9.4 M with T1D globally expected to grow to 17.4 M globally by 2040^{1,2}

Based on the ADA recommended target HbA_{1c} of <7.0%, exposing them to an increased risk of diabetes-related complications^{3,4} that are life-disruptive, worrisome and life threatening

Hypoglycemia is often the major limiting factor in the glycemic management of T1D and T2D⁵

Which may involve multiple daily insulin injections, wearing of an infusion device, frequent blood glucose monitoring, carb counting and dose titration, exercise and diet management, fear of hypoglycemia...^{1,6}

Since the discovery of insulin in 1921, no oral therapy to treat T1D has been approved by the US FDA

1: Breakthrough T1D website. Last accessed on April 30th, 2025. 2: Mahase E. Type 1 diabetes: Global prevalence is set to double by 2040, study estimates. BMJ. 2022 Sep 22;378:o2289. doi: 10.1136/bmj.o2289. PMID: 36137610. 3. 1.Akturk HK, et al., T1D Exchange Quality Improvement Collaborative; Factors Associated With Improved A1C Among Adults With Type 1 Diabetes in the United States. Clin Diabetes 2 January 2023; 41 (1): 76–80. <https://doi.org/10.2337/cd22-0067>; 4: Diabetes Control and Complications Trial (DCCT): results of feasibility study. The DCCT Research Group. Diabetes Care. 1987 Jan-Feb;10(1):1-19. doi: 10.2337/diacare.10.1.1. PMID: 2882967. 5: ADA Standard of Care 2025. 6 Breakthrough T1D Canada website. Last accessed on April 30th, 2025.

Cadiseagliatin: Potential to be First Oral Adjunct Therapy for T1D

Targets High Unmet Needs in T1D

Derisked by Ph1 and Ph2 Data

In Late-Stage Development

1.6 M Americans live with T1D

- 80% of whom fail to achieve target blood glucose control with current SOC^{1,2}
- **Hypoglycemia** is often the major barrier to glycemic control³

Dosed in 500+ subjects to date⁴

- Positive impact on hypoglycemia and HbA_{1c}⁵
- FDA clinical hold resolved, ADME chromatographic signal found to be experimental artifact
- Topline Phase 3 data expected 2H2026

FDA Breakthrough Designation

- Treatment of T1D

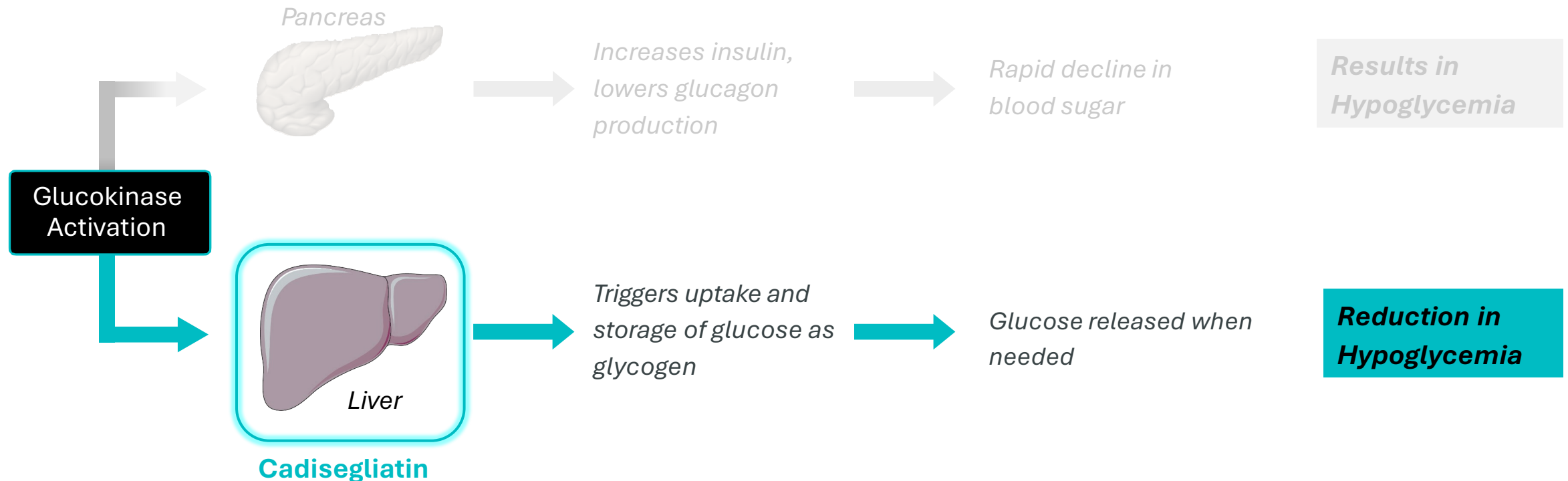
Intellectual Property

- Global portfolio of patents issued and pending provide protection through 2041

1: Akturk HK, et al., T1D Exchange Quality Improvement Collaborative; Factors Associated With Improved A1C Among Adults With Type 1 Diabetes in the United States. Clin Diabetes; 2: Breakthrough T1D. Type 1 diabetes incidence and prevalence. Breakthrough T1D. <https://www.breakthrought1d.org/t1d-basics/incidence-prevalence/>. Accessed April 16, 2025. 3: American Diabetes Association Standards of Care in Diabetes – 2023; 4: Internal studies – data on file; 5: Klein KR et al. The SimpliciT1 study: a randomized, double-blind, placebo-controlled phase 1b/2 adaptive study of TTP399, a hepatoselective glucokinase activator, for adjunctive treatment of type 1 diabetes. Diabetes Care. 2021 Apr 1;44(4):960-8

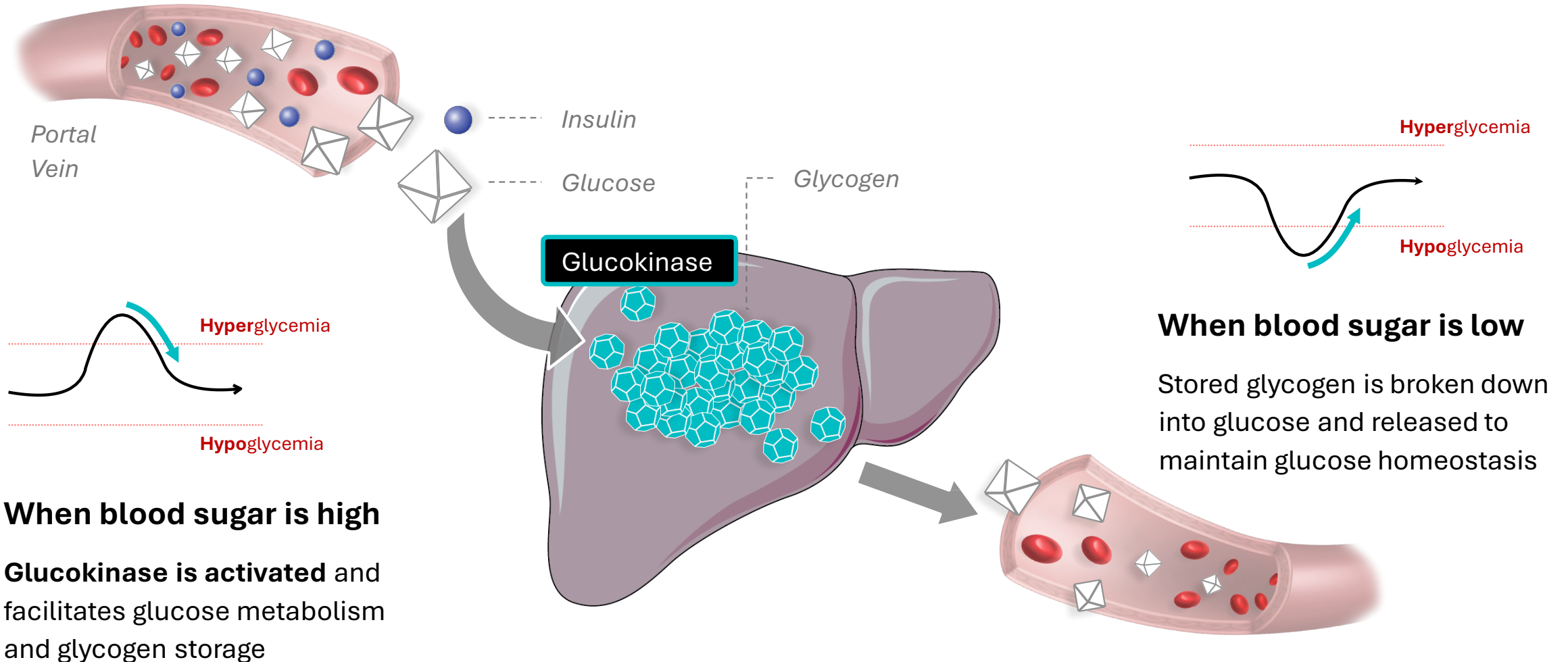
Cadiseagliatin: Liver-Selective Glucokinase Activator that Preserves GK-GKRP Interaction

- Glucokinase acts as a glucose sensor and regulates glucose metabolism in the liver and pancreas
- *Cadiseagliatin is designed to only interact with the glucokinase in the liver*



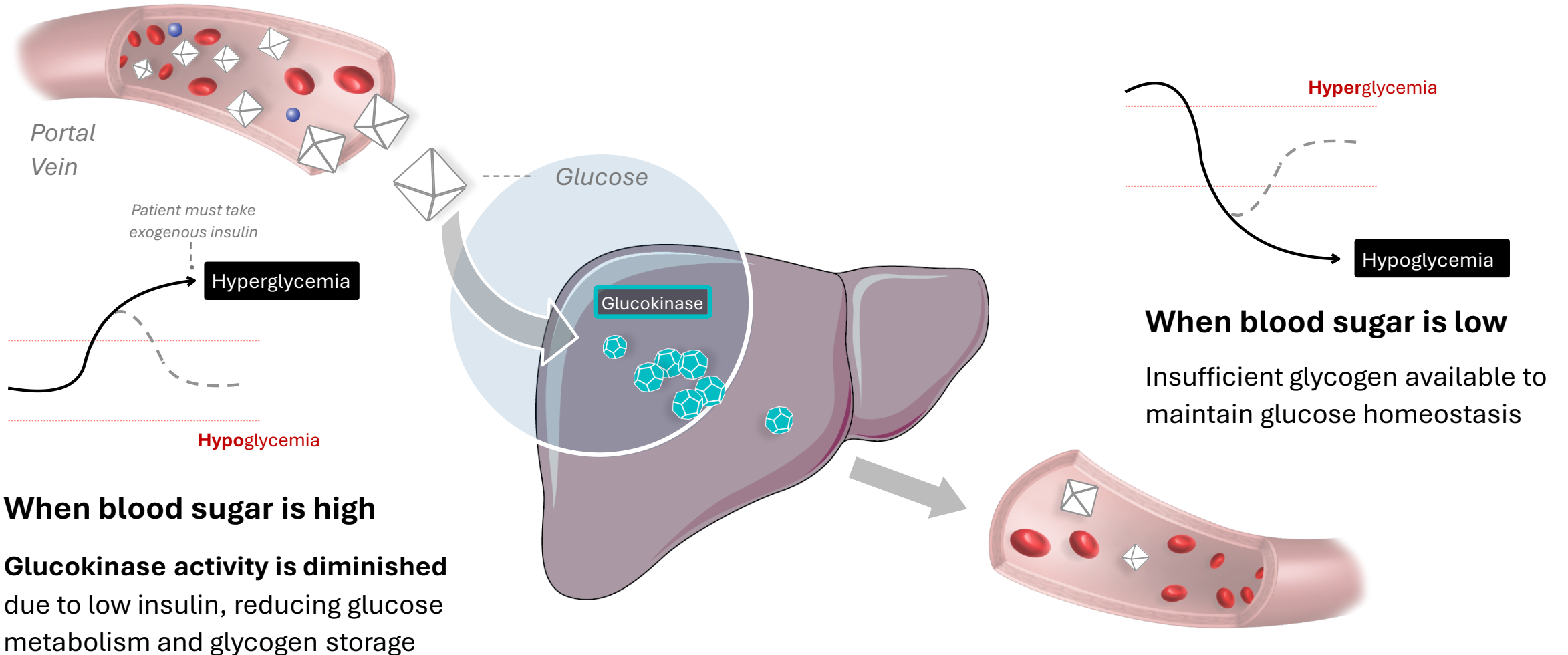
In People who do not Live with Type 1 Diabetes:

Glucokinase and insulin play essential roles in the liver to maintain glucose homeostasis including the storage of glycogen



In People who Live with Type 1 Diabetes:

Low insulin in the portal vein decreases glucokinase activity in the liver, hindering the metabolism of glucose and storage of glycogen

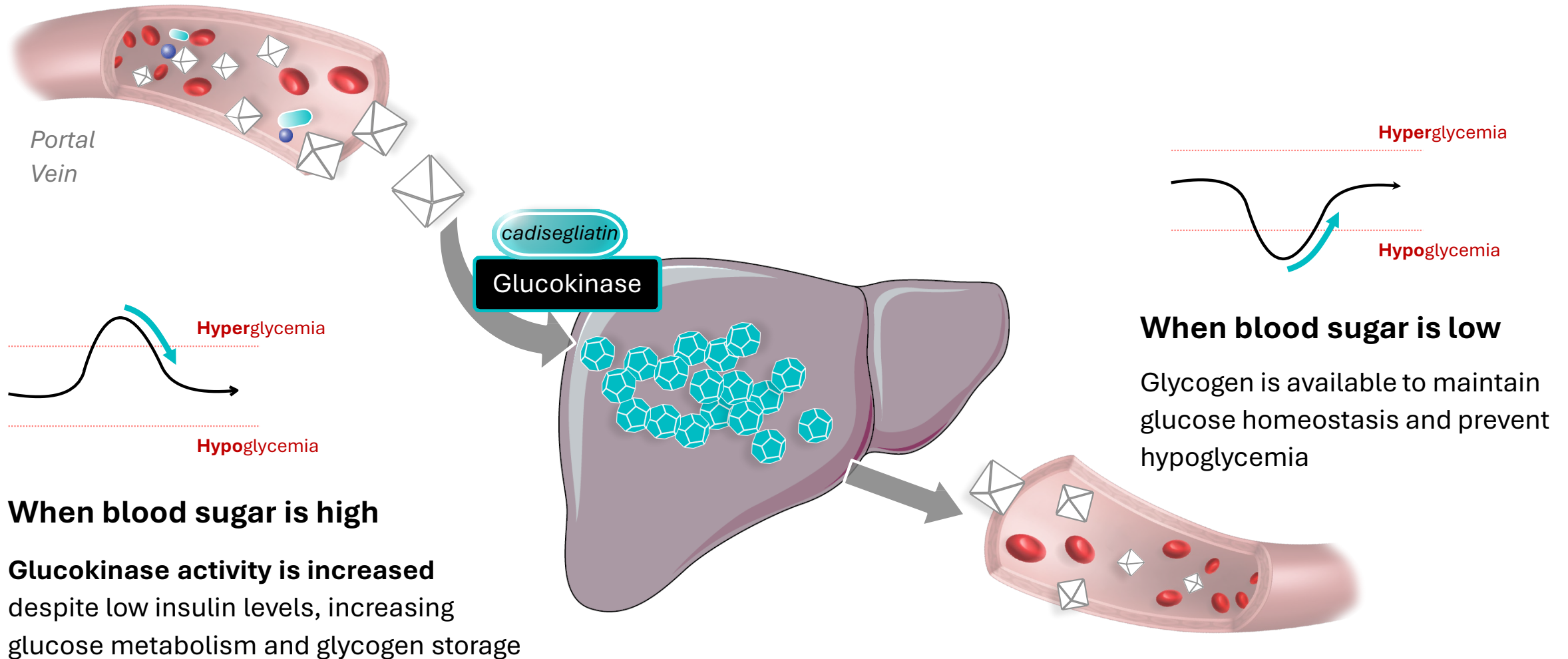


When blood sugar is high

Glucokinase activity is diminished due to low insulin, reducing glucose metabolism and glycogen storage

Cadisegliatin, a Glucokinase Activator, Restores Glucose Metabolism in the Liver

Glucokinase activation by cadisegliatin in the liver lowers blood glucose, improves glucose homeostasis and glycogen storage



Clinical Data for Cadisegliatin in T1D and T2D

AGATA Phase 2 Study in T2D¹

Reduction of HbA_{1c} by 0.9% vs. metformin ($p < 0.01$)

No difference to metformin with regards to hypoglycemia or hyperlipidemia over 6 months

N = 190; US Study

SimpliciT1 Phase 2 Study in T1D²

50% fewer symptomatic hypoglycemic episodes ($p < 0.04$) and no ketoacidosis

Reduction of HbA_{1c} by 0.36% vs. insulin alone ($p < 0.001$)

40% of cadisegliatin treated patients had **reductions of total daily insulin dose and HbA_{1c} (by 0.41%) vs. insulin alone**

N = 100; US Study

Insulin Withdrawal Study in T1D³

No increased risk of ketoacidosis vs. insulin alone

Despite short treatment for only 7-10 days:

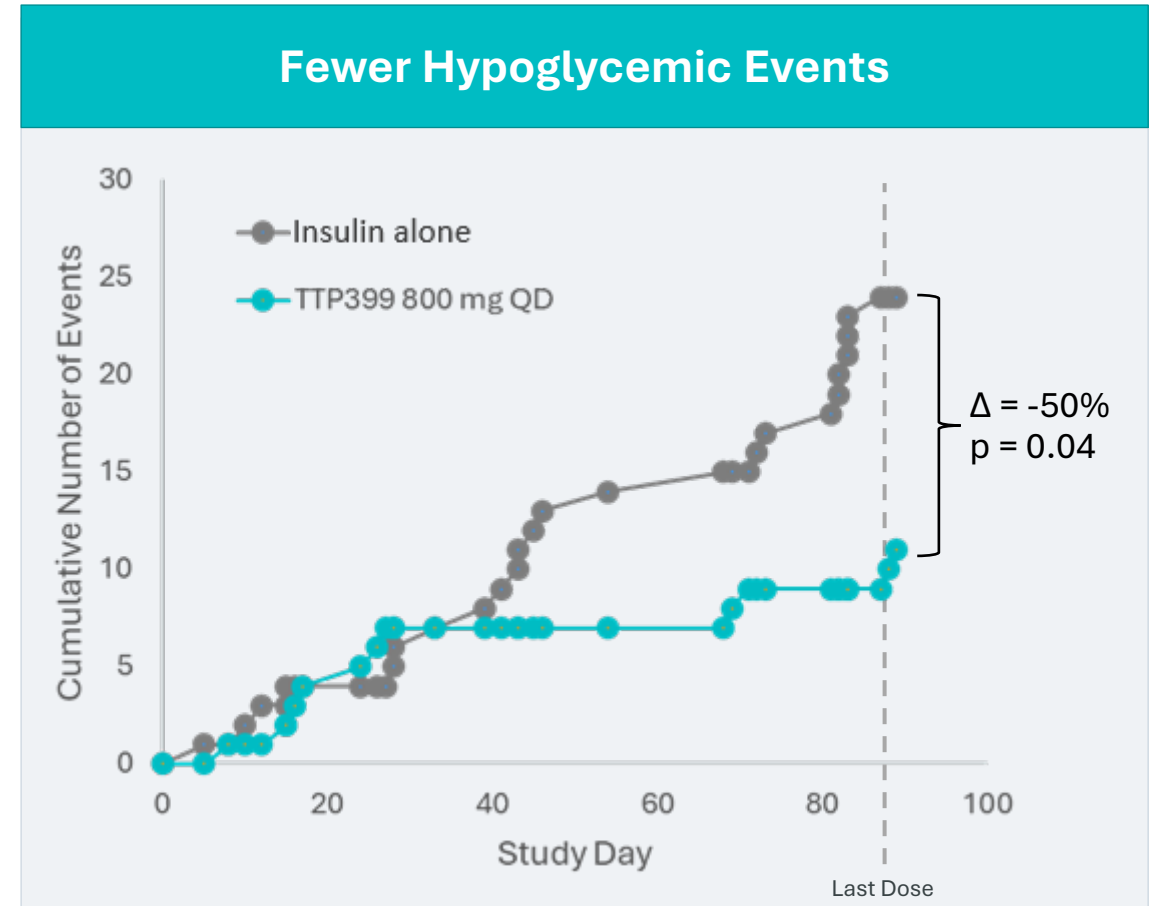
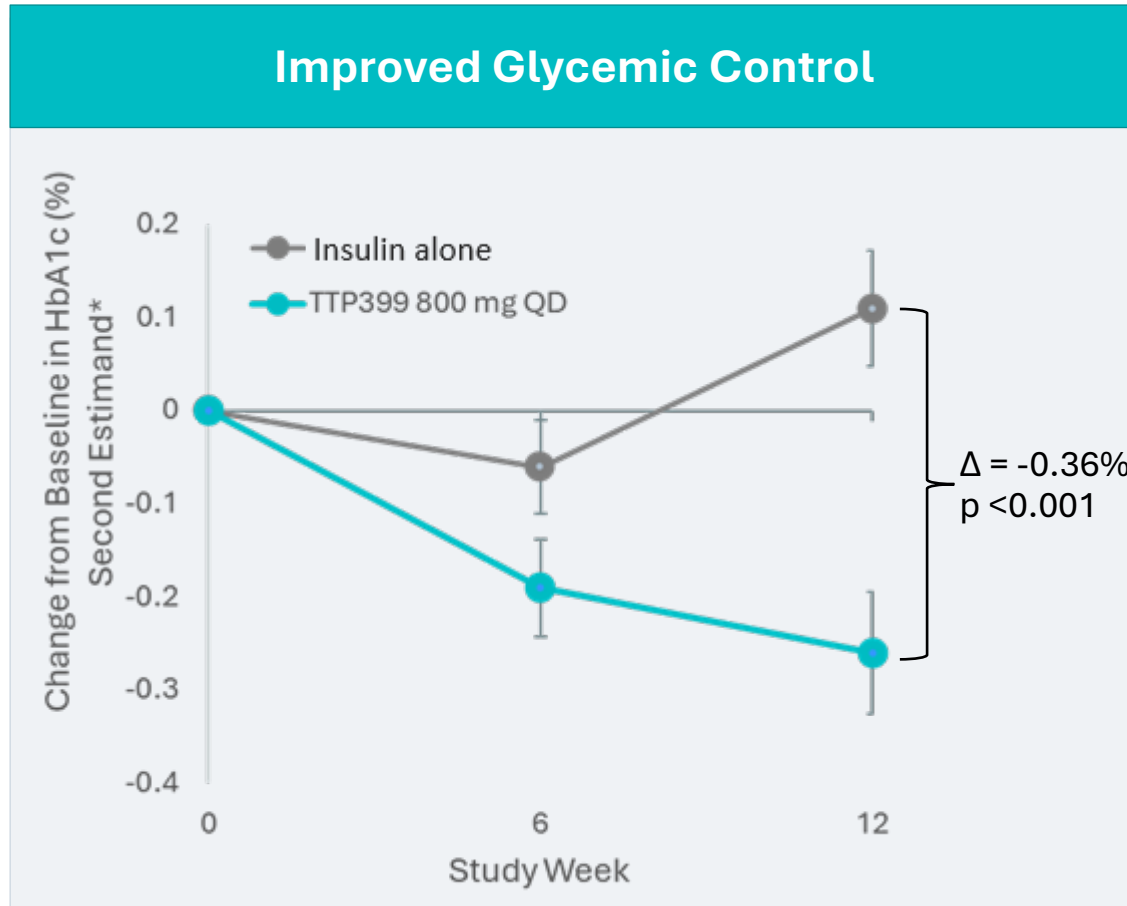
- **Improved fasting plasma glucose levels**
- **Fewer hypoglycemic events**

N = 23; US Study

1: Vella A, et al. Targeting hepatic glucokinase to treat diabetes with TTP399, a hepatoselective glucokinase activator. Science translational medicine. 2019 Jan 16;11(475):eaau3441; 2: Klein KR et al. The SimpliciT1 study: a randomized, double-blind, placebo-controlled phase 1b/2 adaptive study of TTP399, a hepatoselective glucokinase activator, for adjunctive treatment of type 1 diabetes. Diabetes Care. 2021 Apr 1;44(4):960-8; 3: Klein KR et al. Impact of the hepatoselective glucokinase activator TTP399 on ketoacidosis during insulin withdrawal in people with type 1 diabetes. Diabetes Obes Metab. 2022, Aug;24(8):1439-1447. doi:10.1111/dom.14697

Cadiseigliatin Significantly Reduced Hypoglycemia and HbA1c v. Insulin Alone¹

SimpliciT1 Phase 2 Trial in patients with T1D



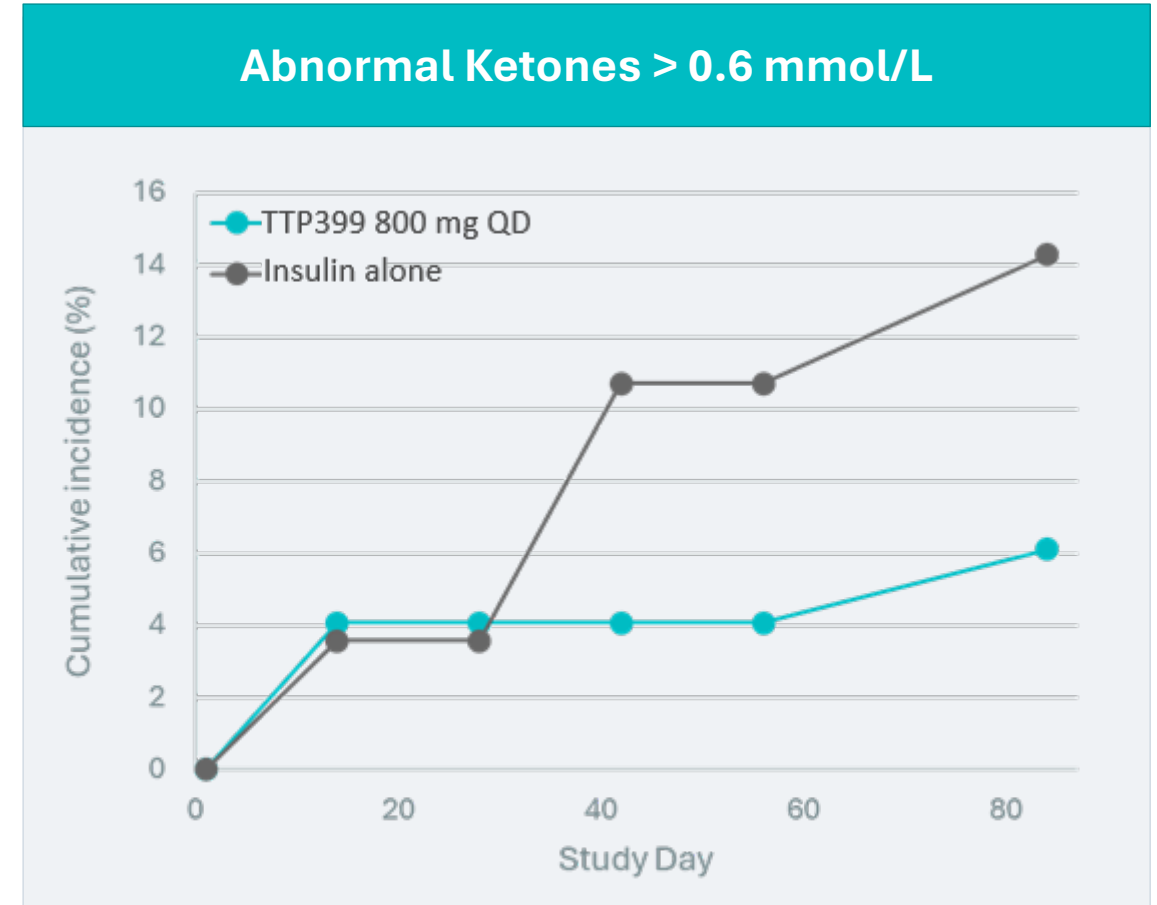
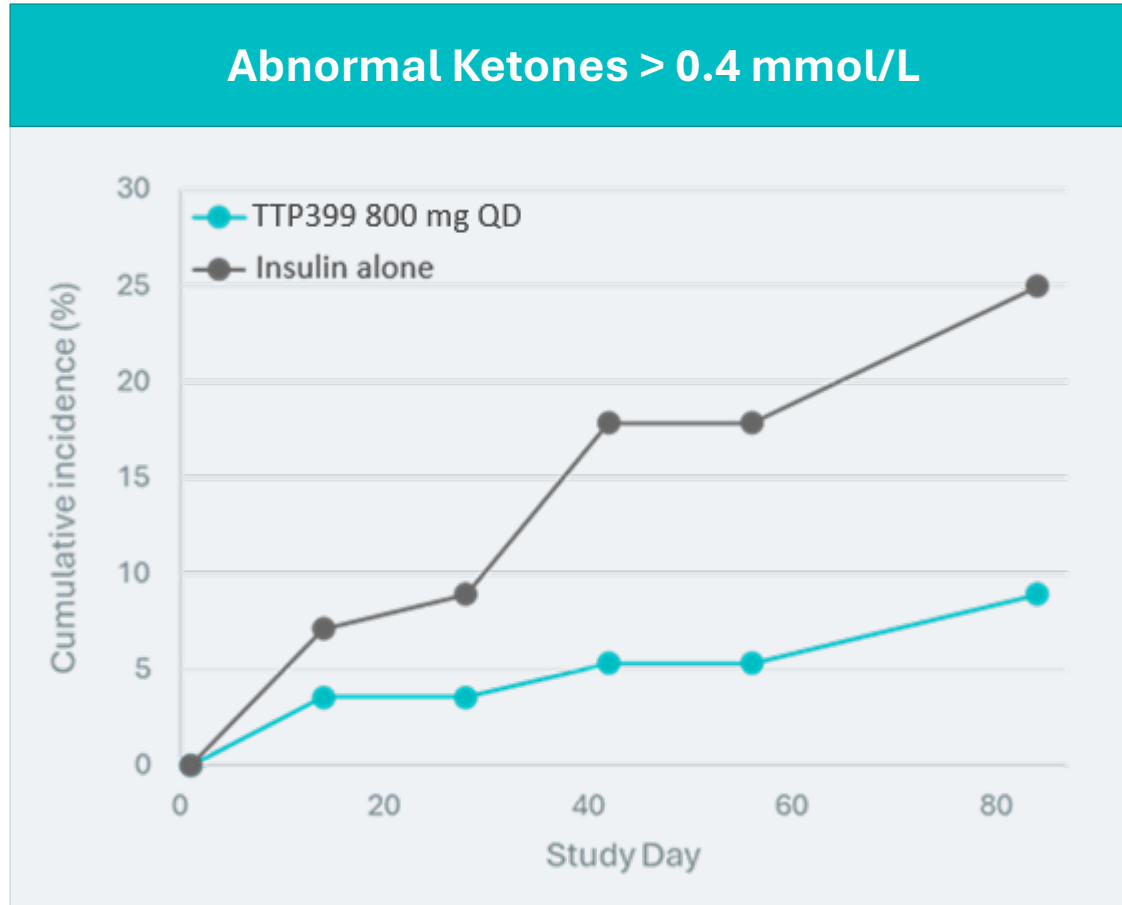
Randomized, Double-Blind, Placebo (insulin alone) Controlled 2-Part Study of ~100 patients.

A total of 49 patients in the treatment groups received 800mg daily of cadiseigliatin.

*This pre-specified analysis evaluated the effect on HbA1c for patients without evidence of noncompliance with prescribed treatment who did not administer notable increases of bolus insulin of three or more units. This analysis was conducted consistent with current regulatory guidance. Data shown is a meta-analysis from Part 1 and Part 2.

No Observed Increased Risk of Ketoacidosis with Cadisegliatin vs. Insulin Alone¹

SimpliciT1 Phase 2 Trial in patients with T1D



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Cadiseigliatin was Well-Tolerated Across People Living with T1D¹

Type 1 Diabetes – 3-month Phase 2 trial

Treatment Emergent and Serious Adverse Events ¹	Cadiseigliatin 800 mg (n=49)	Placebo (n=56)
Subjects with ≥1 TEAE	32 (65%)	36 (64%)
Subjects with ≥1 related TEAE	3	5
SAEs	1	1
Subjects with ALT, AST, ALP > 1.5 x UNL and/or bilirubin >2 x ULN	1 (2%)	2 (4%)
Subjects with AST or ALT >3 x ULN and bilirubin >1.5 x ULN	0	0
DKA Events	0	0
Subjects with ≥ 1 BOHB > 1 mmol/l	1 (2%)	3 (5%)

TEAE=treatment emergent adverse event; SAE=serious adverse event; ALT=alanine transaminase, AST=aspartate transaminase, ALP=alkaline phosphatase; UNL=upper limit of normal; DKA= diabetic ketoacidosis; BOHB=β-Hydroxybutyric acid

Cadisegliatin Did Not Adversely Impact Lipids in People Living with T1D¹

Type 1 Diabetes – 3-month Phase 2 Trial

Fasting Lipid Changes from Baseline in Type 1 Diabetes Patients ²	Cadisegliatin 800 mg (n=40)	Placebo (n=45)
Fasting TG (mg/dL)		
Baseline	90 (87)	90 (49)
Change from Baseline @EoS	-4.5 (82)	-2.5 (37)
Fasting HDL (mg/dL)		
Baseline	63 (19)	66 (19)
Change from Baseline @EoS	1.4 (10)	-2.6 (9)
Fasting non-HDL (=calculated LDL; mg/dL)		
Baseline	92 (22)	93 (28)
Change from Baseline @EoS	-0.8 (16)	-1.1 (30)

TG=Triglycerides; HDL=High Density Lipoprotein; LDL=Low Density Lipoprotein; EoS=End of Study; Data are Mean (SD)

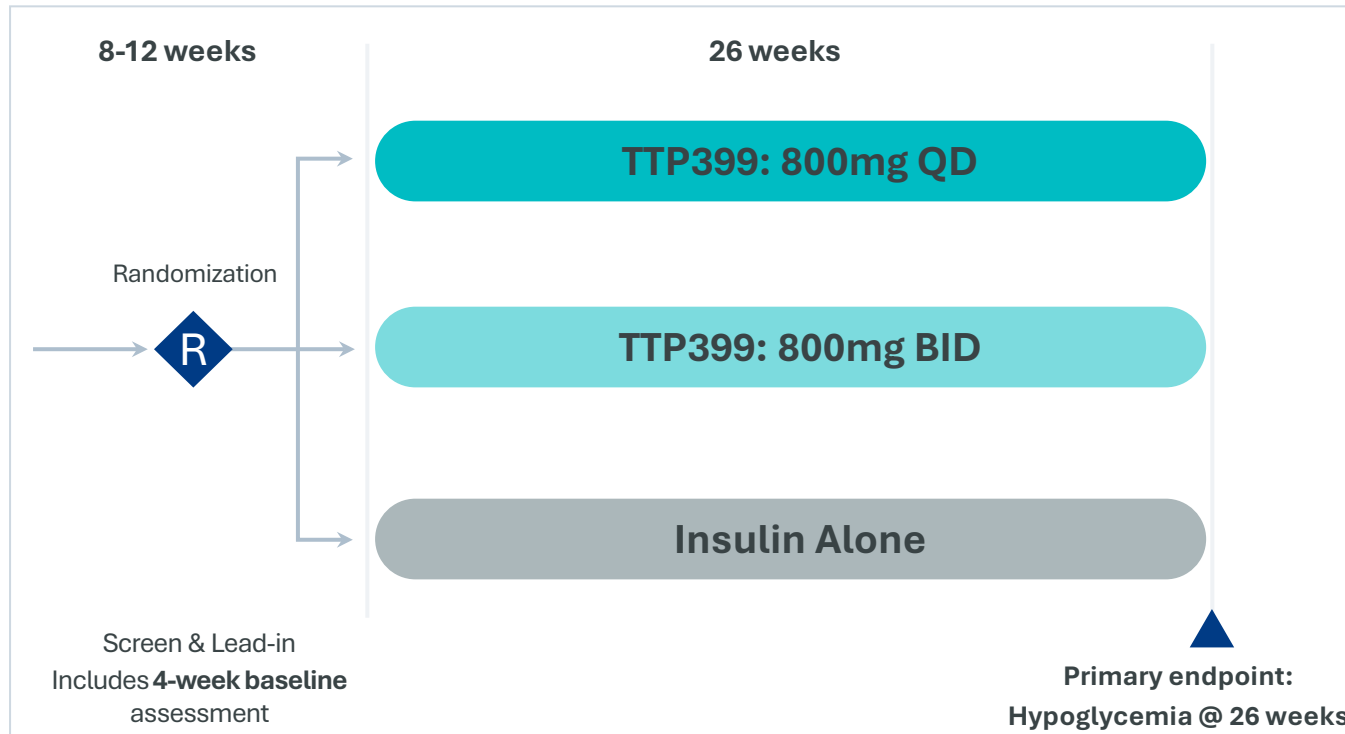
Cadiseqliatin Phase 3 CATT1 Study* – Informed by FDA Advice and Published Guidance for Endpoint Selection, Exposure and Population Criteria

CATT1 Phase 3 trial resumed 2Q2025 with topline data expected 2H2026

CATT1 Study

Target Enrollment:

- 150 subjects at
- 20-25 US sites



Primary endpoint:
Incidence of **Level 2** (based on study CGM) and **Level 3** (based on blinded clinical adjudication)
hypoglycemic events

Key secondary endpoint:
Change in Hemoglobin A_{1C}

CATT1 will use continuous glucose monitoring (CGM) to measure reduction of hypoglycemic events in accordance with the FDA draft guidance issued in 2023 on diabetes-related clinical trials**

Cadiseagliatin: Late-Stage Program with Potential to be the First Approved Oral Adjunct Therapy for T1D in the U.S.

Derisked by Phase 1 and 2 data (n>500) which showed positive impact on hypoglycemia and HbA_{1c}

Granted **Breakthrough Therapy** designation by FDA

Completed **\$51M PIPE** in February 2024 with support of healthcare-focused investors, including Breakthrough T1D Fund (f/k/a JDRF T1D Fund)

Topline Phase 3 data expected in 2H2026



Thank You