

Improving the Lives of Millions of Patients with Type 1 Diabetes

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vTv has Developed a Breakthrough Oral Therapeutic for Type 1 Diabetes



Over 8M patients worldwide have no oral therapies to aid in the complex, lifelong challenge of managing Type 1 Diabetes (T1D).

vTv's TTP399 is a Phase 3-ready drug intended to work in concert with insulin to reduce dangerous low blood sugar events (hypoglycemia), and improve overall glycemic control and long term health outcomes.

FDA Breakthrough Therapy Designation: Q2 2021

New Leadership Builds upon Decades of Scientific & Clinical Expertise



Paul Sekhri
President & CEO



Carmen Valcarce, PhD*
Chief Scientific Officer



Steven Tuch
CFO



Rich Nelson
Head of Corp Dev



Jumana Ihbais*
Chief Quality Officer



Jon Isaacsohn, MD
Chairman



Border denotes new
addition in last 18 months

* Scientific & clinical team has an average
tenure of >15 years with vTv

Distinguished SAB Continues to Support Development of TTP399



John Buse, MD, PhD

Verne S. Caviness Distinguished Professor
Director, Diabetes Center
Director, NC Translational & Clinical Sciences Institute



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL



G. Alexander "Zan" Fleming, MD

Founder & Executive Chairman, Kinexum
Former FDA Supervisory Physician for Diabetes



Justin Gregory, MD, MSci

Asst. Professor of Pediatrics
Pediatric Endocrinology



Gary Koch, PhD

Professor, Department of Biostatistics
Director, Biometric Consulting Laboratory



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL



Robert Rizza, MD

Emeritus Professor of Medicine
Division of Endocrinology, Diabetes,
Metabolism & Nutrition



MAYO CLINIC COLLEGE
OF MEDICINE AND SCIENCE



Jay Skyler, MD, MACP, FRCP

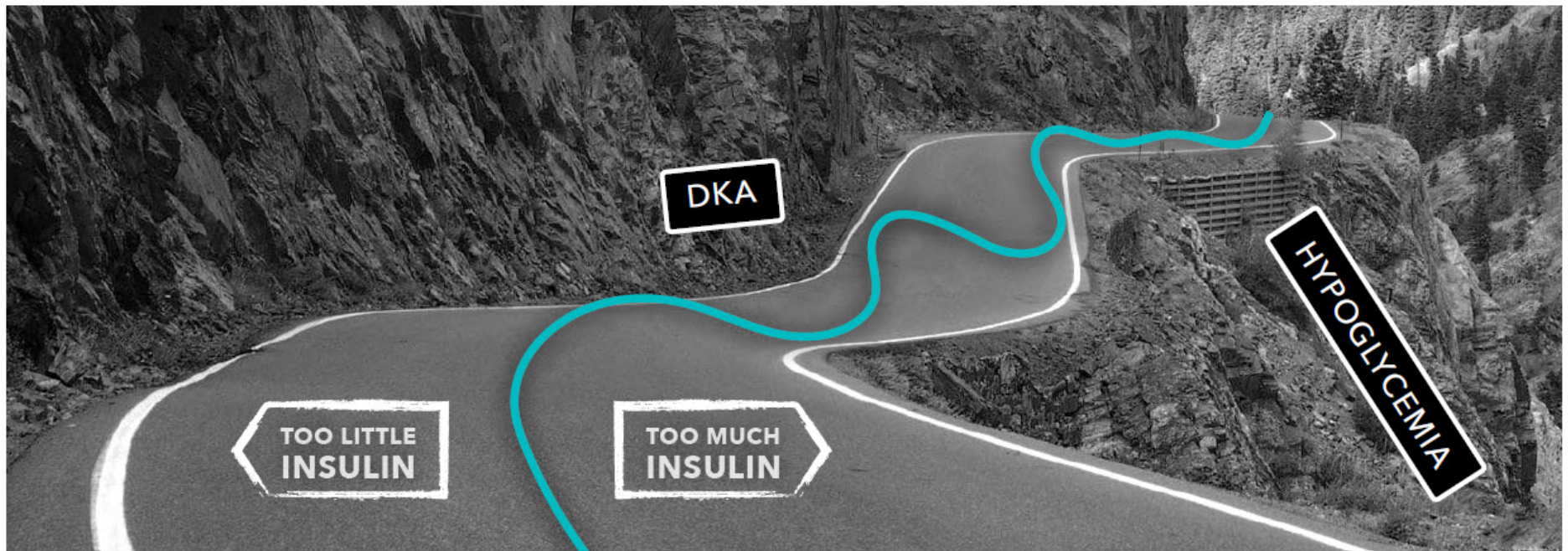
Professor of Medicine, Pediatrics, & Psychology
Division of Endocrinology, Diabetes, & Metabolism
Deputy Director for Clinical Research & Academic
Programs, Diabetes Research Institute



MILLER SCHOOL
of MEDICINE

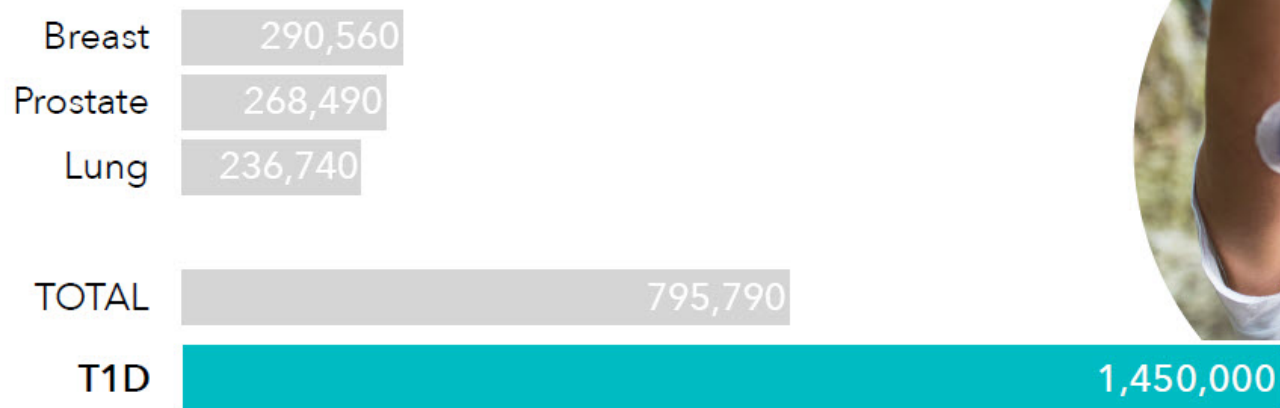
Living with T1D is Like Driving Too Fast on a Dangerous Road

~80% of patients fail to achieve good blood glucose control. Fear of hypoglycemia is so intense that many accept high blood glucose, risking long-term health consequences and diabetic ketoacidosis (DKA).



More People in the U.S. are Living with T1D than are Diagnosed Annually with Breast, Prostate and Lung Cancer Combined

U.S. Estimated New Cancer Cases vs. U.S. Type 1 Diabetes Patients



20% of Patients are Under 20 Years Old

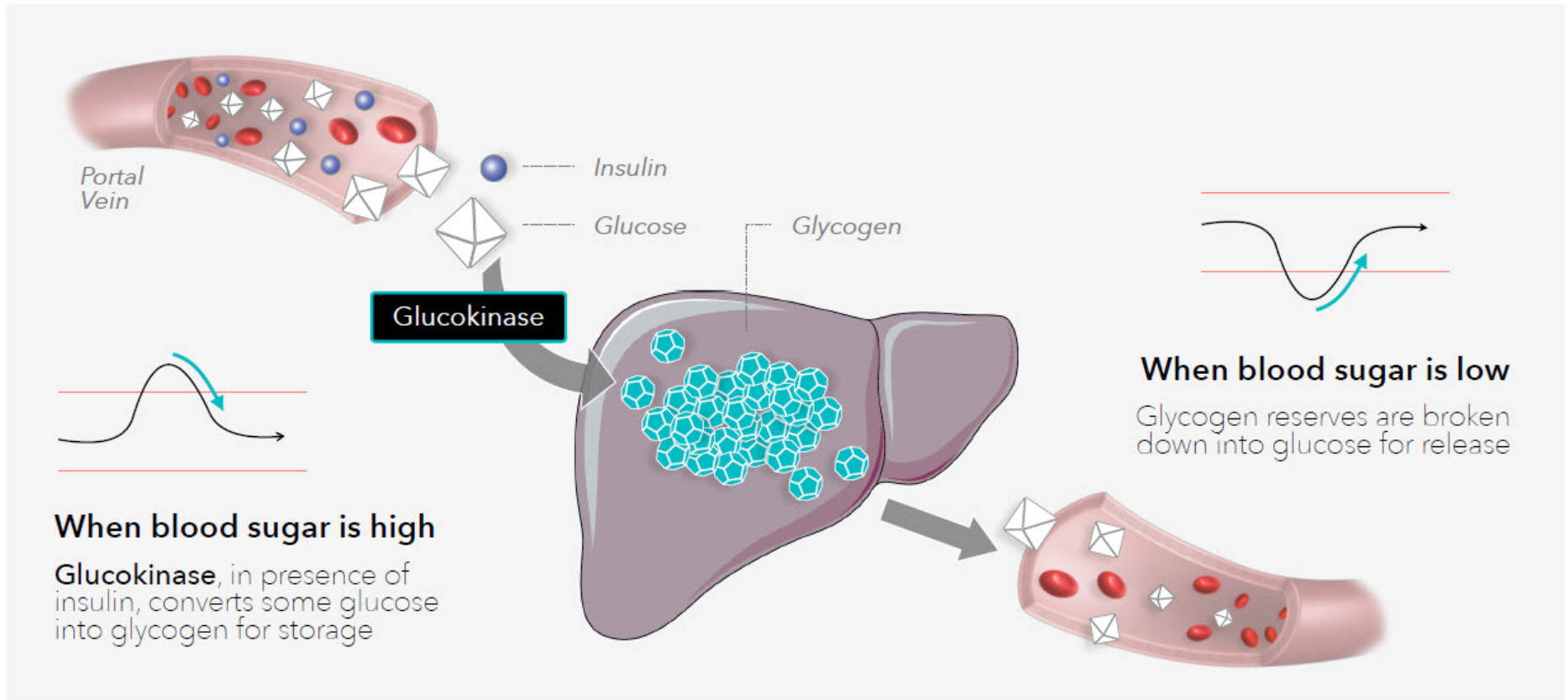
*Sources: Cancer Statistics, 2022 (American Cancer Society);
National Diabetes Statistics Report, 2020 (CDC)*

TTP399: A First-Ever Oral Therapeutic for Type 1 Diabetes

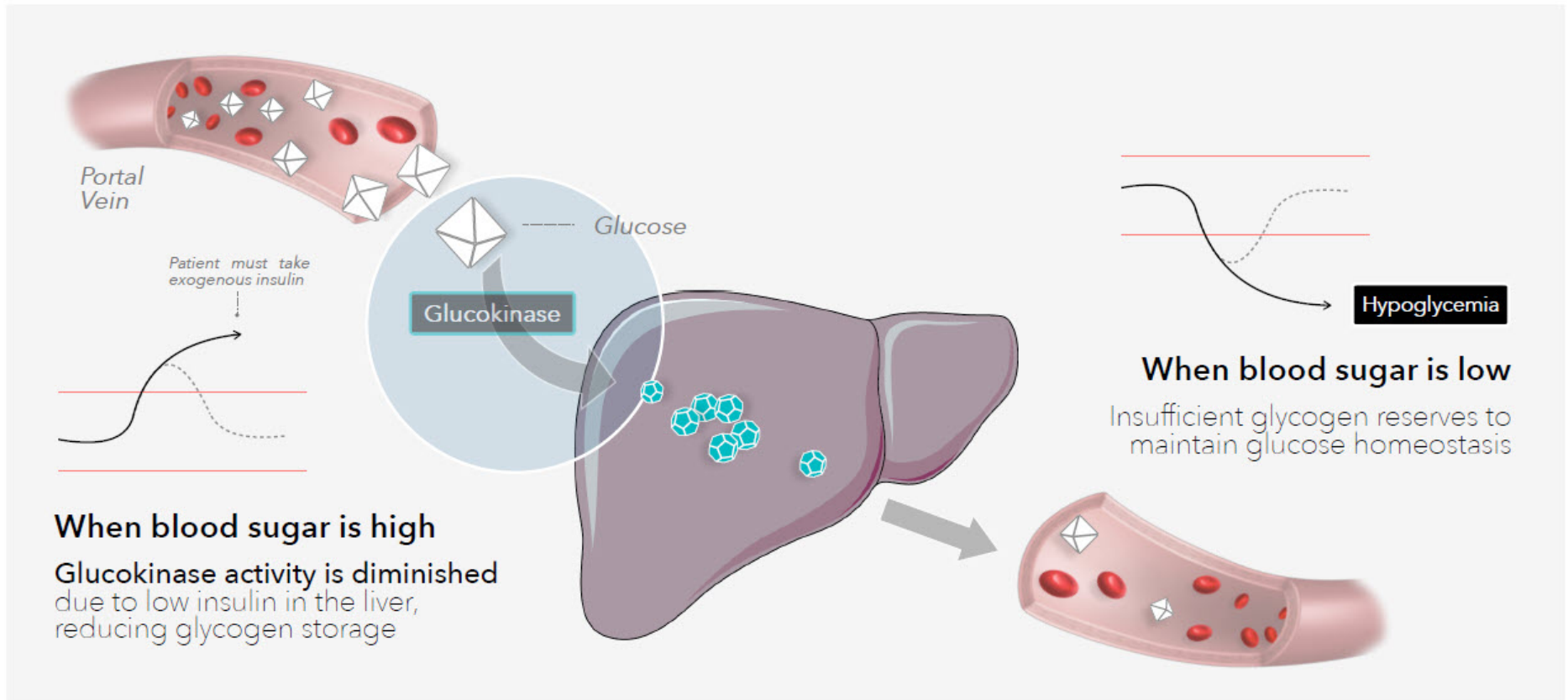
A Liver-Selective Glucokinase Activator that:

- 1) Reduces the Risk of Hypoglycemia**
- 2) Improves Glycemic Control**

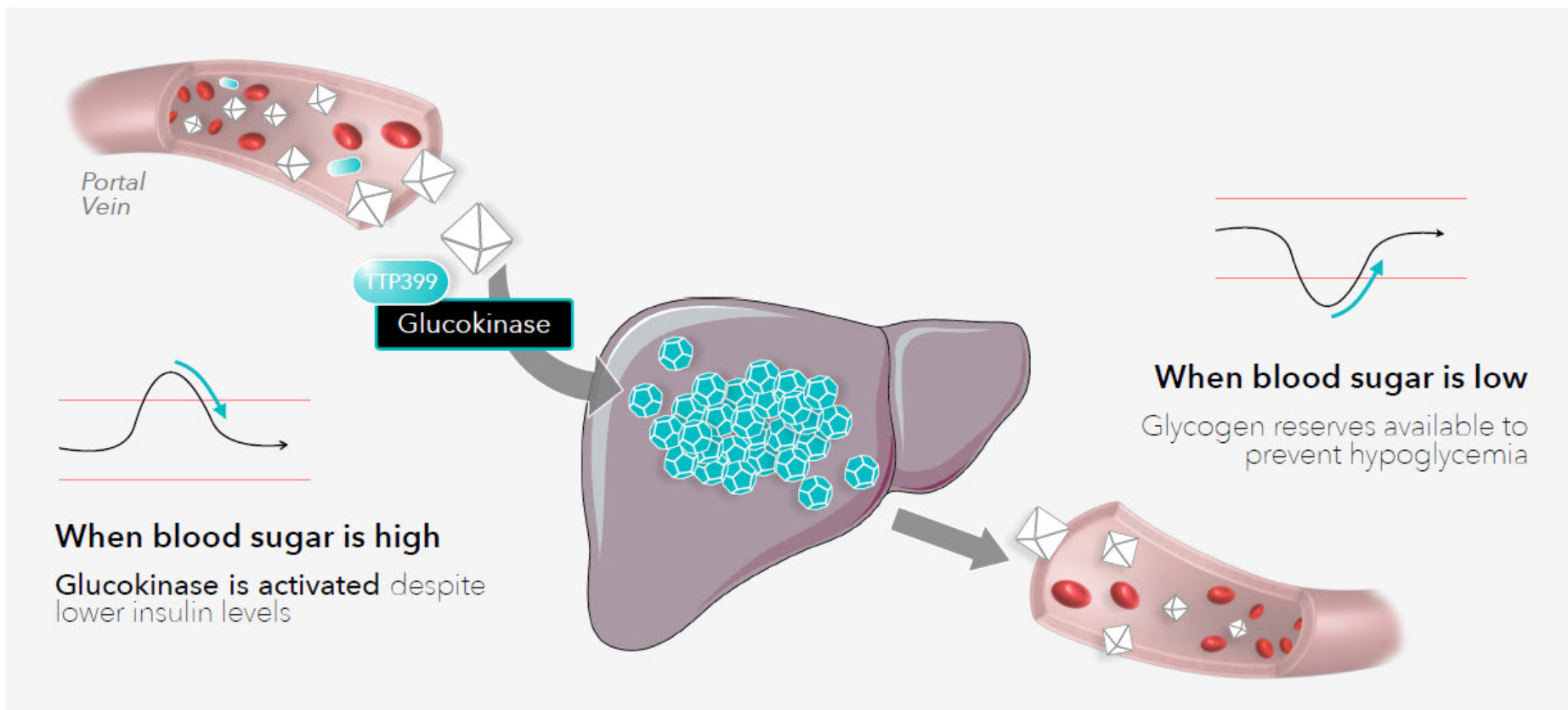
In Healthy Patients, the Liver Acts as a Reservoir for Glucose



With Type 1 Diabetes, Glucokinase Activity in the Liver is Impaired

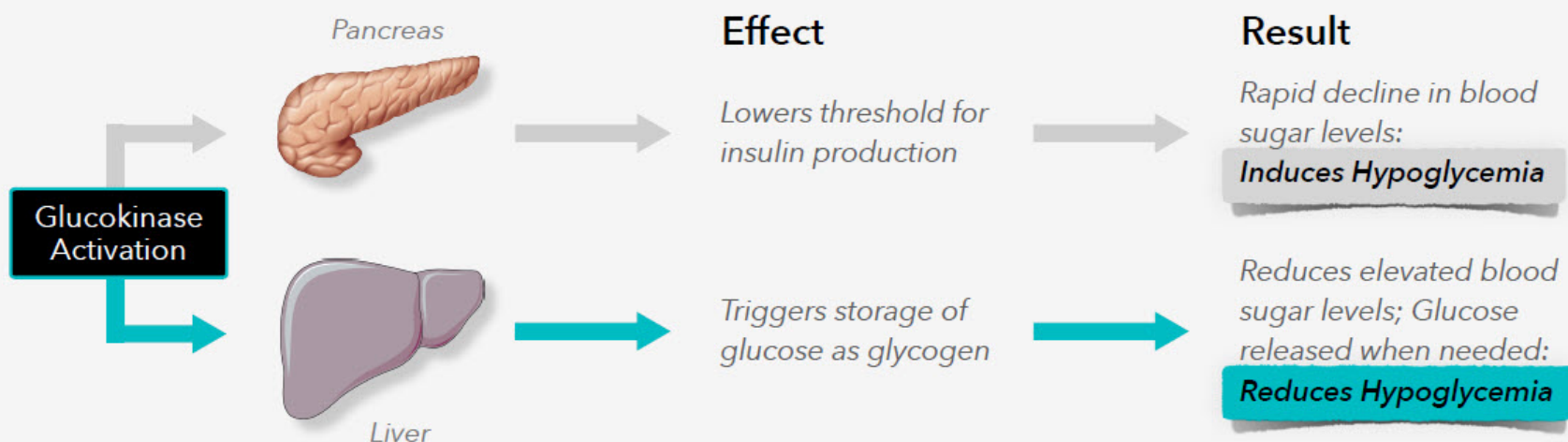


TTP399 Reactivates Innate Glucose-Regulating Capacity of the Liver



TTP399 is the First Liver-Selective Glucokinase Activator to Reach Phase 3

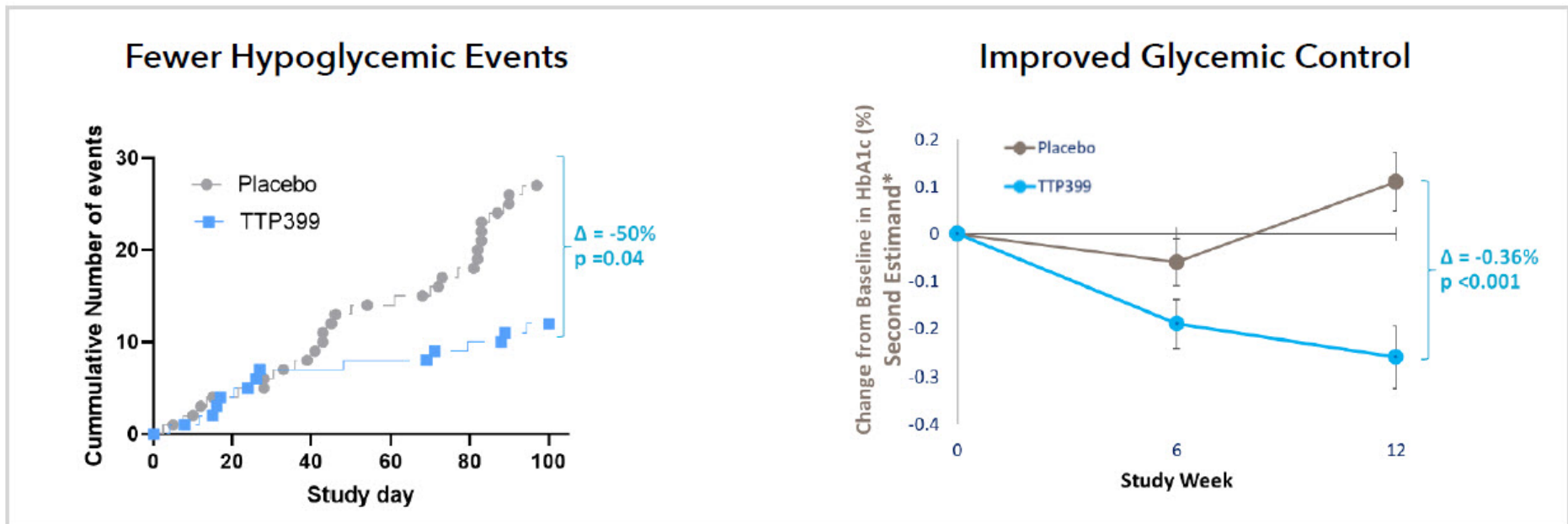
Glucokinase is present in both pancreatic β -cells & the liver.
Past efforts to target have failed due to an increase in hypoglycemic events among other issues*



*Other factors: Loss of potency over time; Hypertriglyceridemia; Fatty liver. None of these have been observed with TTP399 pre-clinically or in clinical studies up to 6 months.

Our Phase II Trial Demonstrated Statistically & Clinically Significant Efficacy & Safety

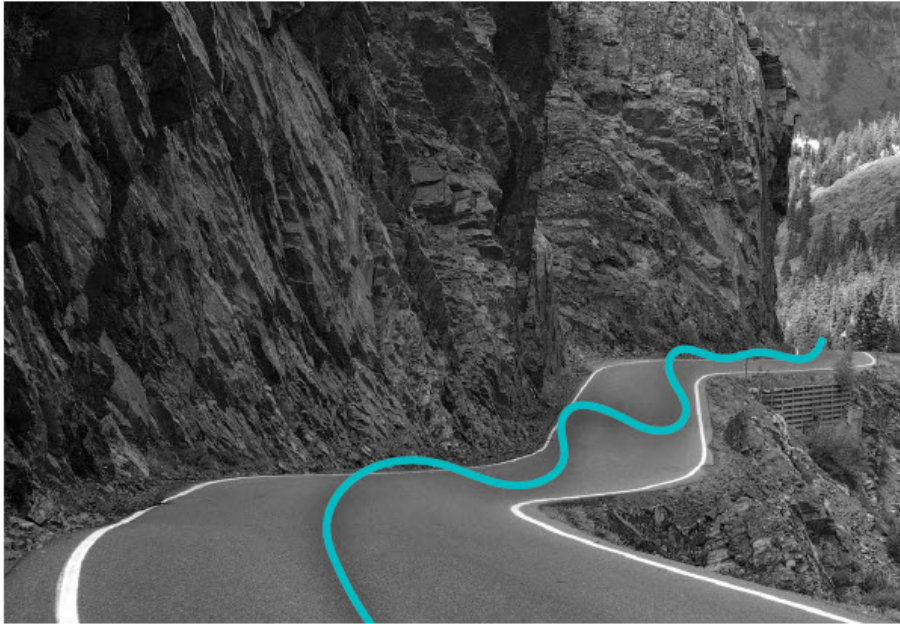
Trials sponsored in part by:
JDRF IMPROVING
LIVES.
CURING
TYPE 1
DIABETES.



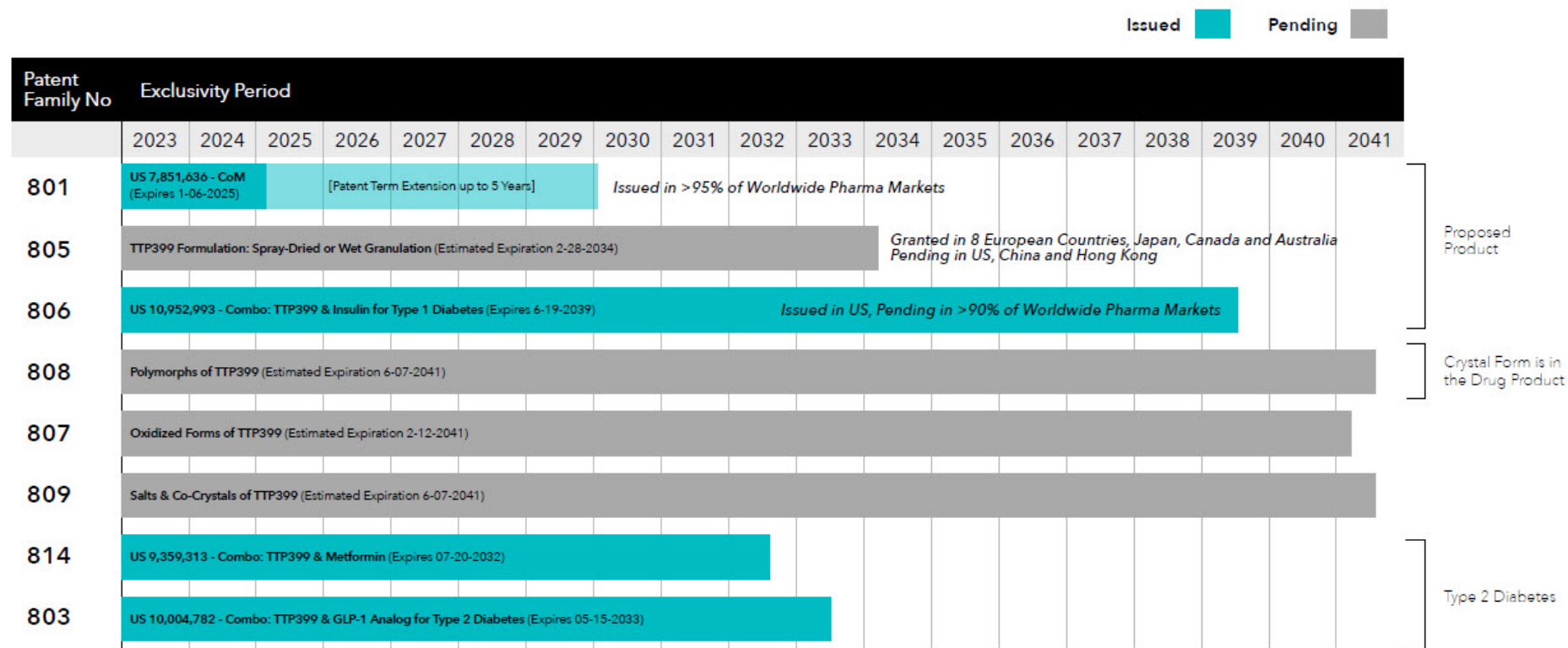
Randomized, Double-Blind, Placebo Controlled 2-Part Study of ~100 patients. A total of 46 patients in the treatment groups received 800mg daily of TTP399.

Study Details: <https://diabetesjournals.org/care/article/44/4/960/138590/The-SimpliciT1-Study-A-Randomized-Double-Blind> & <https://clinicaltrials.gov/ct2/show/NCT03335371>

We Have the Opportunity to Ease the Burden of Managing T1D and Improve the Lives of Patients Living with Type 1 Diabetes



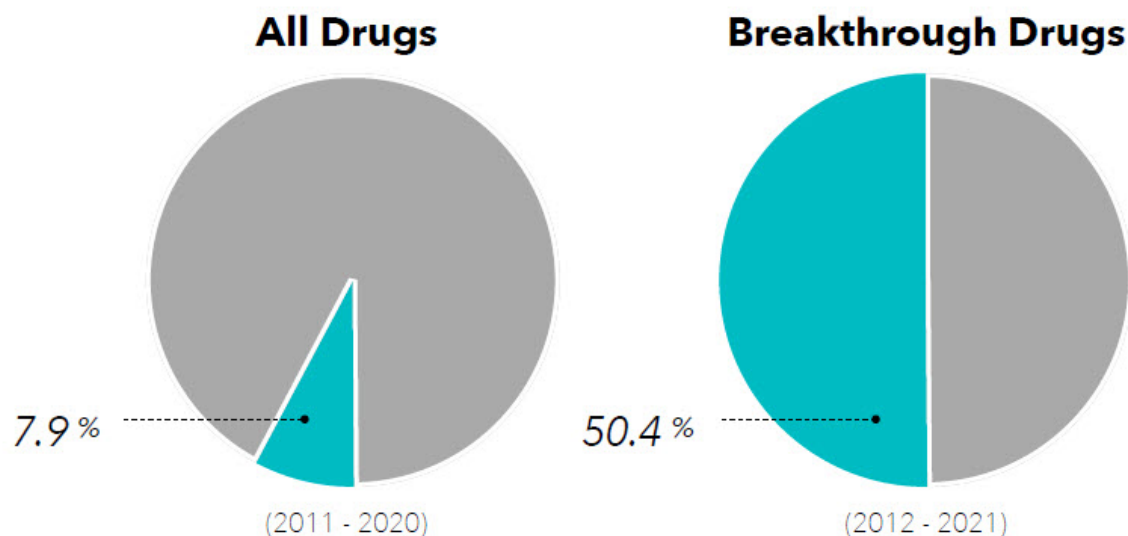
Strong IP Protection through 2039



Breakthrough Drugs: Much Higher Odds of Approval

TTP399 Breakthrough Therapy Designation: Q2 2021

Overall approval rates for
clinical-stage drugs:



"Breakthrough Therapy designation is a process designed to **expedite the development and review** of drugs that are intended to treat a serious condition and preliminary **clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy** on a clinically significant endpoint(s)."

Sources: FDA.gov; Pharma Intelligence (Q2 2021)

Phase 3 Pivotal Studies in US and EU; CRO Selected



Pivotal Study 1 - Type 1 Diabetes (US & EU, Primary Endpoint at 6 Months)

200 placebo	200 400mg TTP399, 2X Daily	200 800mg TTP399, 1X Daily	200 800mg TTP399, 2X Daily
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12 Month Study; All patients with Continuous Glucose Monitors

ENDPOINTS

Primary: Frequency of Hypoglycemia
Secondary: Change in Hemoglobin A1C

Pivotal Study 2 - Type 1 Diabetes (US & EU, Primary Endpoint at 12 Months)

200 placebo	200 400mg TTP399, 2X Daily	200 800mg TTP399, 1X Daily	200 800mg TTP399, 2X Daily
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12 Month Study; All patients with Continuous Glucose Monitors

ENDPOINTS

Primary: Frequency of Hypoglycemia
Secondary: Change in Hemoglobin A1C

Add'l Phase 2 Study - Type 2 Diabetes (Middle East, Primary Endpoint at 12 Months)

200 placebo	200 400mg TTP399, 1X Daily	200 800mg TTP399, 1X Daily
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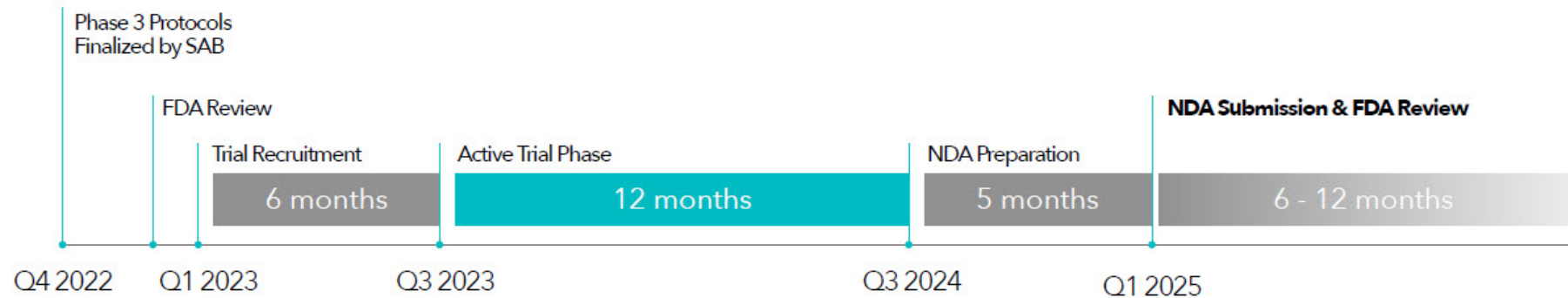


12 Month Study; Type 2 Diabetes Patients on Insulin with No Continuous Glucose Monitoring

ENDPOINTS

Primary: Change in Hemoglobin A1C
Secondary: Frequency of Hypoglycemia

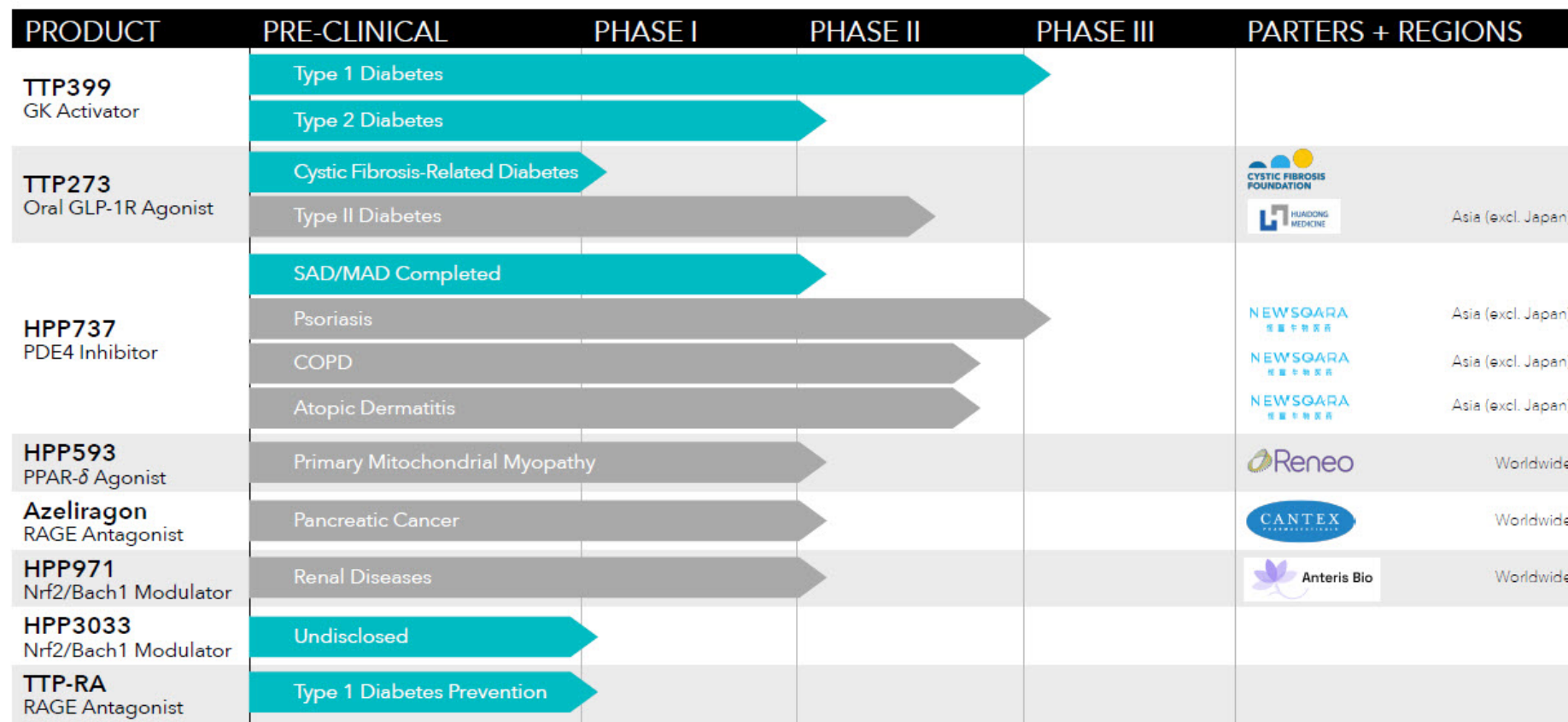
NDA Submission Expected by 1H 2025



EU EMA submission expected to follow US FDA submission.

Additional Pipeline Creates Further Upside

vTv 
Partner 



Investors, Partners, and Board



MACANDREWS
&FORBES
HOLDINGS INC.

Majority stakeholder; holding company owned by Ronald Perelman. Has supported the company since inception.



Announced \$10M investment at \$2.41 / share in July 2022. As part of the transaction, Jon Isaacsohn, MD, CEO of CinRX and former CMO of Teva Pharmaceuticals joined as Chairman and is helping oversee Phase III trials.



Announced \$25M investment at \$2.41 / share in June 2022. G42 has additionally agreed to solely fund a Middle East trial.

Current Board:

Jon Isaacsohn, MD
Chairman

Paul Sekhri
President & CEO

Rich Nelson
EVP Corp. Dev.

Keith Harris, PhD
Director

John Fry
Director

Chandresh Harjivan, MD
Director

Fahed Al Marzooqi, MD
Director

Howard Weiner, MD
Director

Hersh Kozlov
Director



Appendix

Safety: TTP399 Tested in 13 Clinical Trials with Over 560 Subjects Dosed

11 Clinical Studies in Healthy Volunteers & Type 2 Diabetes Patients

9 Phase 1 Studies
2 Phase 2 Studies

2 Clinical Studies in Type 1 Diabetes Patients

Simplici-T1 Study

Sentinel Phase - 5 Patients

Part 1 - 19 Patients

Part 2 - 85 Patients

TTP399-118 DKA Mechanistic Study

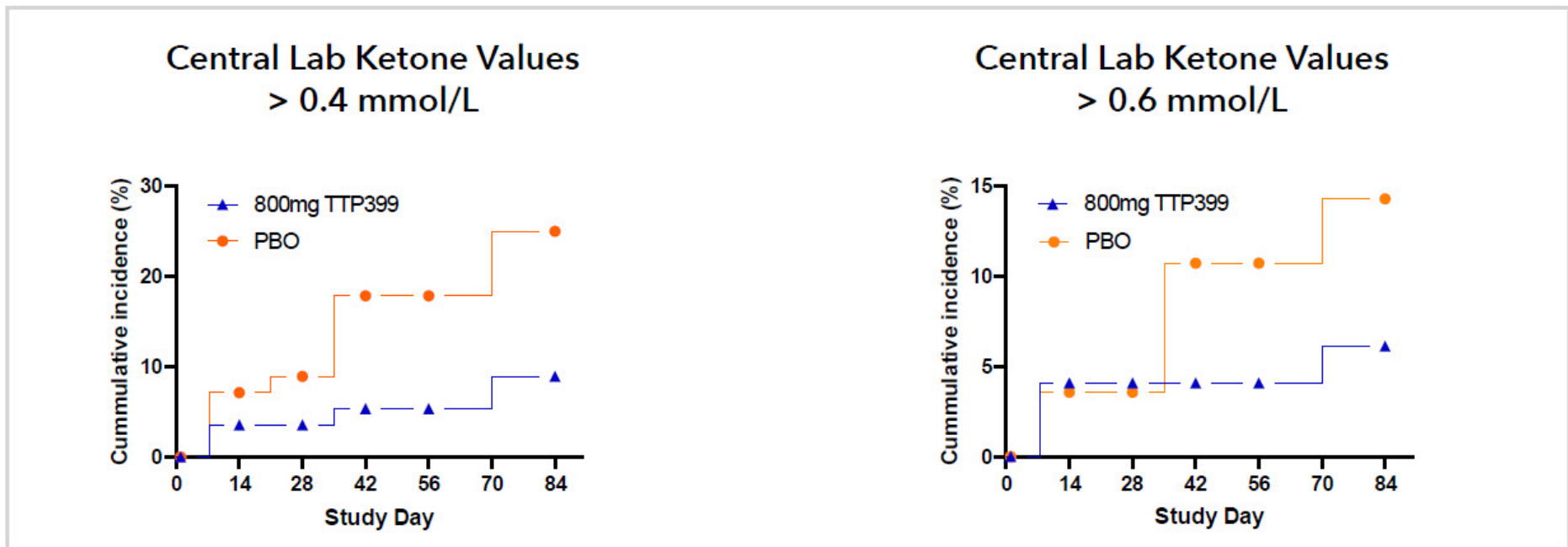
560 Subjects have Received One or More Doses of TTP399

TTP399 was Well Tolerated at All Doses Tested

The clinical results obtained to-date are consistent with preclinical data and the MOA of a liver-selective GKA

Safety: Cumulative Incidence of Subjects with Abnormal Ketones

BOHB > 0.4 and 0.6 mmol/L as Determined by Central Lab



Study Details: <https://diabetesjournals.org/care/article/44/4/960/138590/The-SimpliciT1-Study-A-Randomized-Double-Blind>

Safety: Mechanistic Study of DKA Risk from TTP399

Objective: Evaluate Effects of TTP399 on Ketogenesis During Insulinopenia

Trials sponsored in part by:



Study Design

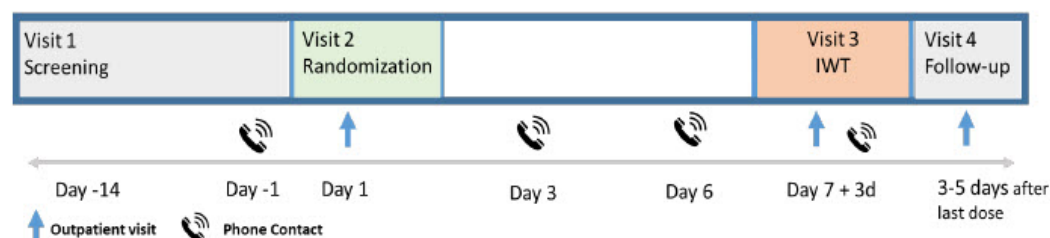
Participants: 23 adults with T1D on insulin pumps

Dosing: TTP399 800mg or placebo once daily for 7 days (randomized 1:1)

Insulin withdrawal test: on day 7, insulin pumps will be stopped and physically removed at 6 am and serial measurements of plasma glucose and ketones (β -hydroxybutyrate) will be collected for 10h

Study design similar to clinical studies using SGLT2 inhibitors^{1,2}

Results from similar preclinical study using TTP355³
Decreased ketones in plasma after insulin withdrawal with liver selective GKA compared to placebo

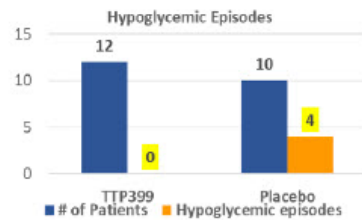


(1) Herring et al, Diabetes Care 2020 <https://doi.org/10.2337/dc19-2579>

(2) Patel et al, Diabetes Technology & Therapeutics 19:618-622, 2017 <https://doi.org/10.1089/dia.2017.0267>

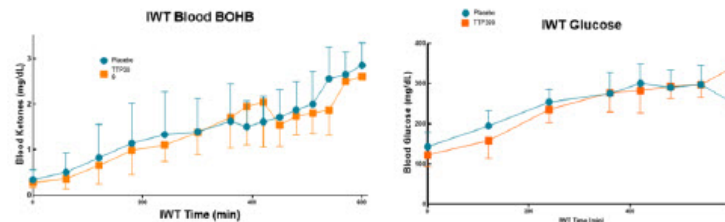
(3) https://vTvtherapeutics.com/wp-content/uploads/2020/08/GKA-Poster-Keystone-2017_01182017_final-minipigs.pdf TTP355: liver-selective GKA (first generation)

Safety: No Observed Risk of Euglycemic DKA During Conditions of Insulin Deficiency (IWT)



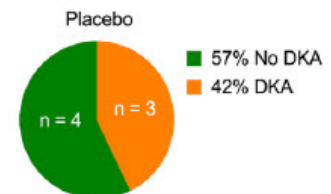
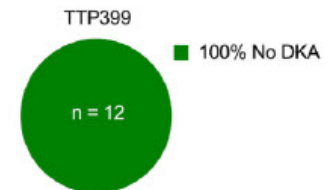
Improvement of glycemic control and reduction of hypoglycemia during the 7-day treatment

- Reduction in fasting plasma glucose of ~30mg/dL (p=0.03)
- Reduced Number of Hypoglycemic Events
- Good Safety profile



No apparent risk of euglycemic DKA during conditions of insulin deficiency (IWT)

- No significant differences between the arms in blood ketone or glucose profiles, IWT's mean duration or mean concentration of BOHB at the end of the IWT
- Fewer subjects in the TTP399 group reach bedside BOHB >3mM (25% in TTP399 vs 50% in placebo)
- Only one subject (1/12) in the TTP399 group presented bicarbonate <18mEq/L at the end of the IWT. Four subjects (4/7) in the placebo group.



Klein et al. *Diabetes Obesity and Metabolism* June 2022. <https://doi.org/10.1111/dom.14697>