

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(D) OF  
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (date of earliest event reported): **January 6, 2023**

**vTv Therapeutics Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-37524**  
(Commission File No.)

**47-3916571**  
(IRS Employer  
Identification No.)

**3980 Premier Drive, Suite 310**  
**High Point, NC**  
(Address of principal executive offices)

**27265**  
(Zip Code)

**(336) 841-0300**  
(Registrant's telephone number, including area code)

**NOT APPLICABLE**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, par value \$0.01 per share	VTVT	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure**

On January 6, 2023, vTv Therapeutics Inc. (the “Company”) posted an updated investor presentation to its website at <https://ir.vtvtherapeutics.com>. A copy of the investor presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed subject to the requirements of amended Item 10 of Regulation S-K, nor shall it be deemed incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">vTv Therapeutics’ Investor Presentation dated January 2023</a>

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

**VTV THERAPEUTICS INC.**

By: /s/ Paul J. Sekhri  
Name: Paul J. Sekhri  
Title: Chief Executive Officer

Dated: January 6, 2023

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NASDAQ: VTVT

# Improving the Lives of Millions of Patients with Type 1 Diabetes

Non-Confidential

vTv Therapeutics

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THE STATEMENTS MADE IN THIS PRESENTATION MAY INCLUDE FORWARD-LOOKING STATEMENTS REGARDING (I) DIABETES MARKET AND OTHER MARKETS, (II) THE DEVELOPMENT, CLINICAL TRIAL PROCESS, REGULATORY APPROVAL PROCESS AND ATTRIBUTES OF INVESTIGATIONAL AND MARKETED PRODUCTS TO TREAT THESE DISEASES AND OTHER CONDITIONS, AND (III) THE FUTURE OPERATIONS, FUND-RAISING ACTIVITIES, EXPENDITURES OPPORTUNITIES, AND FINANCIAL PERFORMANCE OF VTV THERAPEUTICS INC.

THESE FORWARD-LOOKING STATEMENTS ARE ONLY ESTIMATES BASED UPON THE INFORMATION AVAILABLE TO VTV THERAPEUTICS INC. (OR THE PARTY PREPARING SUCH FORWARD-LOOKING STATEMENTS) AS OF THE DATE OF THIS PRESENTATION. THE FORWARD-LOOKING STATEMENTS INCLUDED HEREIN INVOLVE KNOWN AND UNKNOWN RISKS AND UNCERTAINTIES AND OTHER IMPORTANT FACTORS SUCH THAT ACTUAL FUTURE OPERATIONS OPPORTUNITIES, PRODUCT DEVELOPMENT PROCESSES AND OUTCOMES, CLINICAL TRIAL PROCESSES AND OUTCOMES, REGULATORY APPROVAL PROCESSES AND OUTCOMES, ECONOMIC PERFORMANCE OF PRODUCTS, FUND-RAISING ACTIVITIES AND FINANCIAL PERFORMANCE MAY DIFFER MATERIALLY FROM THOSE SET FORTH IN OR IMPLIED IN THESE FORWARD-LOOKING STATEMENTS. THESE RISKS, UNCERTAINTIES, AND OTHER FACTORS, WHICH MAY NOT BE WITHIN OUR CONTROL, ARE DISCUSSED IN MORE DETAIL IN OUR QUARTERLY AND ANNUAL REPORTS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION, INCLUDING, WITHOUT LIMITATION, UNDER THE CAPTIONS, "RISK FACTORS," "CAUTIONARY NOTES REGARDING FORWARD-LOOKING STATEMENTS" AND "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS." THEREFORE, YOU SHOULD READ THIS PRESENTATION IN CONJUNCTION WITH SUCH MEANINGFUL CAUTIONARY STATEMENTS.

UNDUE RELIANCE SHOULD NOT BE PLACED ON FORWARD-LOOKING STATEMENTS, WHICH SPEAK ONLY AS OF THE DATE HEREOF. EXCEPT AS REQUIRED BY LAW, WE EXPRESSLY DISCLAIM ANY RESPONSIBILITY TO PUBLICLY UPDATE OR REVISE OUR FORWARD-LOOKING STATEMENTS, WHETHER AS A RESULT OF NEW INFORMATION, FUTURE EVENTS OR OTHERWISE. ALL FORWARD-LOOKING STATEMENTS CONTAINED HEREIN ARE QUALIFIED IN THEIR ENTIRETY BY THE FOREGOING CAUTIONARY STATEMENTS.

THIS PRESENTATION IS BEING PROVIDED TO YOU FOR INFORMATION PURPOSES ONLY. THIS PRESENTATION DOES NOT CONSTITUTE AN OFFER OF SALE OF (OR THE SOLICITATION OF AN OFFER TO BUY) ANY SECURITIES OF VTV THERAPEUTICS INC. OR ANY OF ITS SUBSIDIARIES.

BY ACCEPTING THIS PRESENTATION, YOU ACKNOWLEDGE AND AGREE THAT (I) YOU WILL NOT RELY ON THIS PRESENTATION FOR MAKING ANY INVESTMENT DECISION WITH RESPECT TO ANY SECURITIES OF VTV THERAPEUTICS INC. OR ANY OF ITS SUBSIDIARIES, AND (II) ANY INVESTMENT DECISION MADE BY YOU WITH RESPECT TO ANY SUCH SECURITIES WILL BE BASED SOLELY ON AN OFFERING DOCUMENT RELATING TO SUCH SECURITIES (IF ANY), INCLUDING THE INFORMATION INCORPORATED BY REFERENCE THEREIN.

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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

					
<b>Paul Sekhri</b> President & CEO	<b>Carmen Valcarce, PhD*</b> Chief Scientific Officer	<b>Steven Tuch</b> CFO	<b>Rich Nelson</b> Head of Corp Dev	<b>Jumana Ihbais*</b> Chief Quality Officer	<b>Jon Isaacsohn, MD</b> 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



**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



**Robert Rizza, MD**  
Emeritus Professor of Medicine  
Division of Endocrinology, Diabetes,  
Metabolism & Nutrition



**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

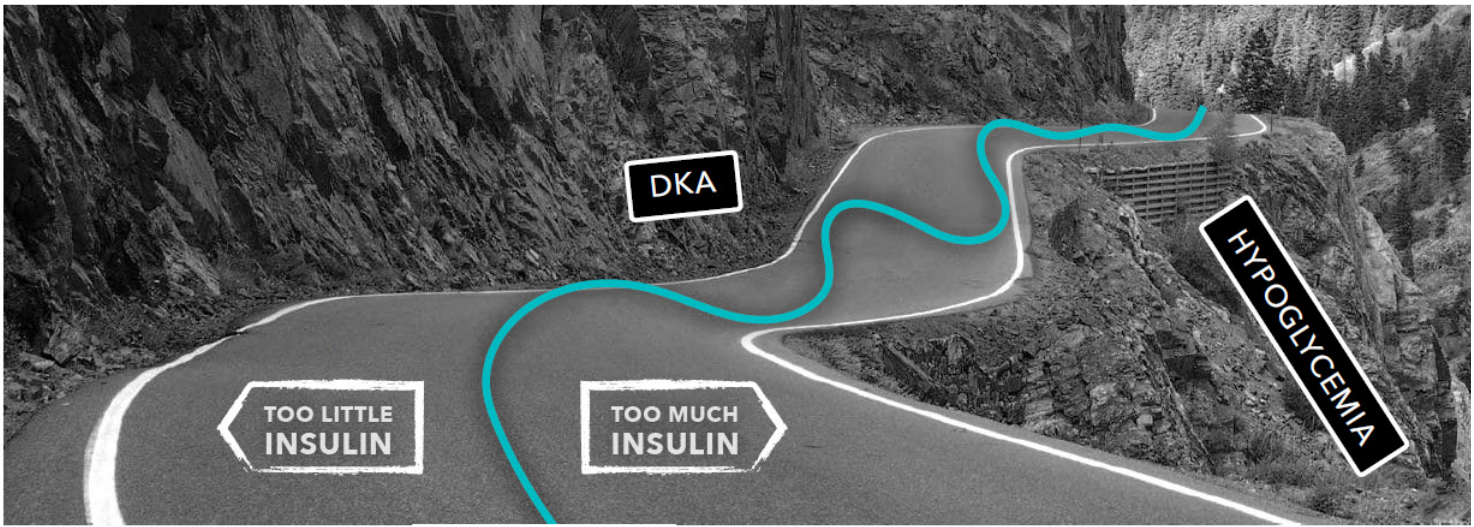




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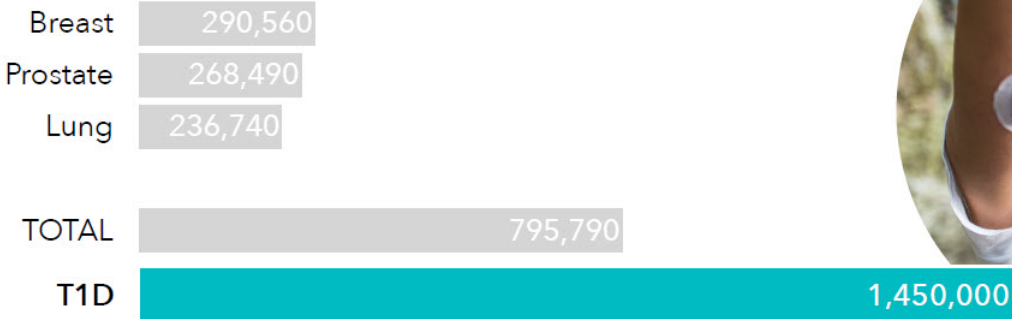
## Living with T1D is Like Driving Too Fast on a Dangerous Road

~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)

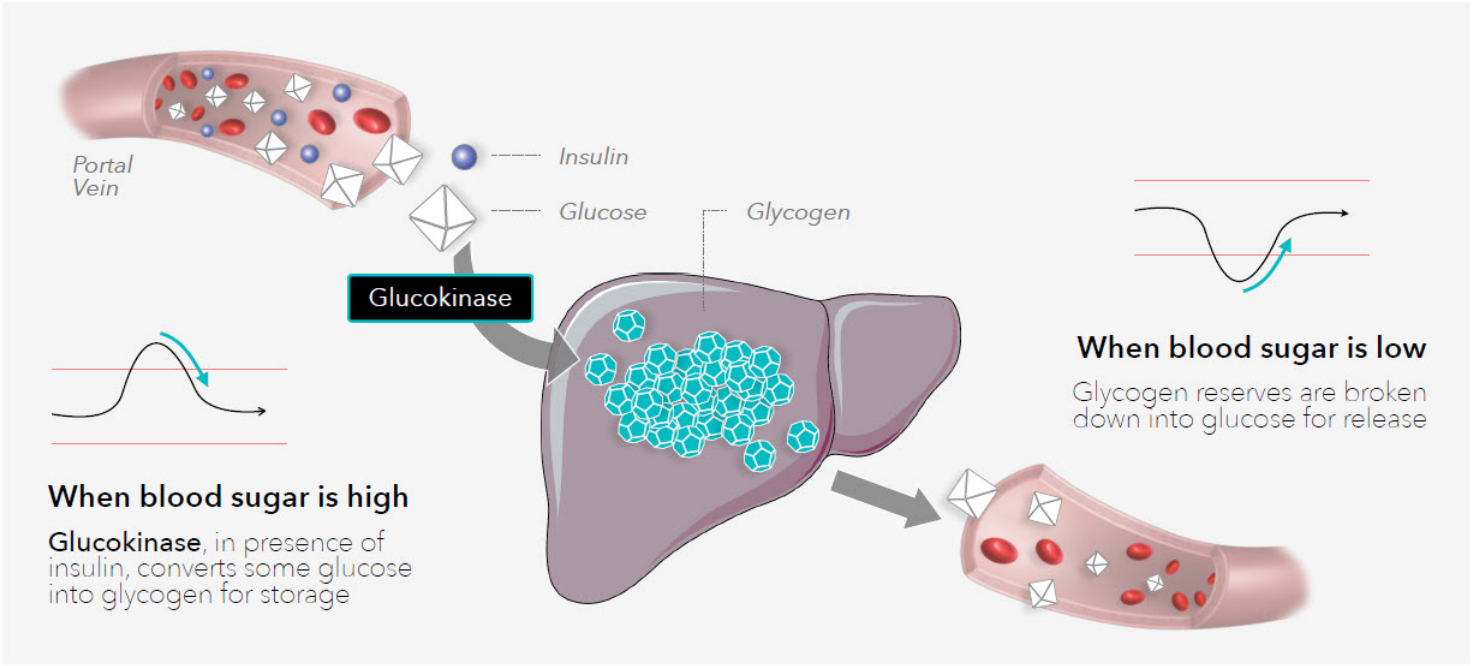
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## **TTP399: A First-Ever Oral Therapeutic for Type 1 Diabetes**

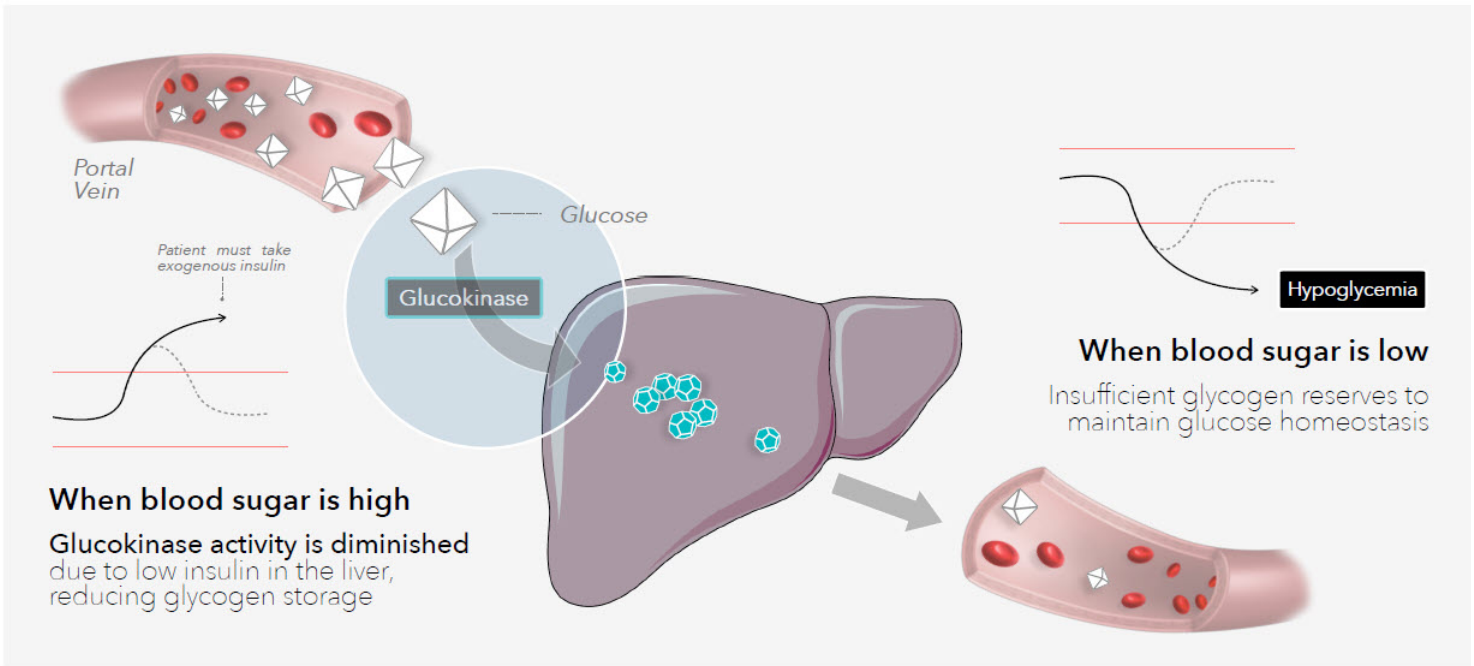
A Liver-Selective Glucokinase Activator that:

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

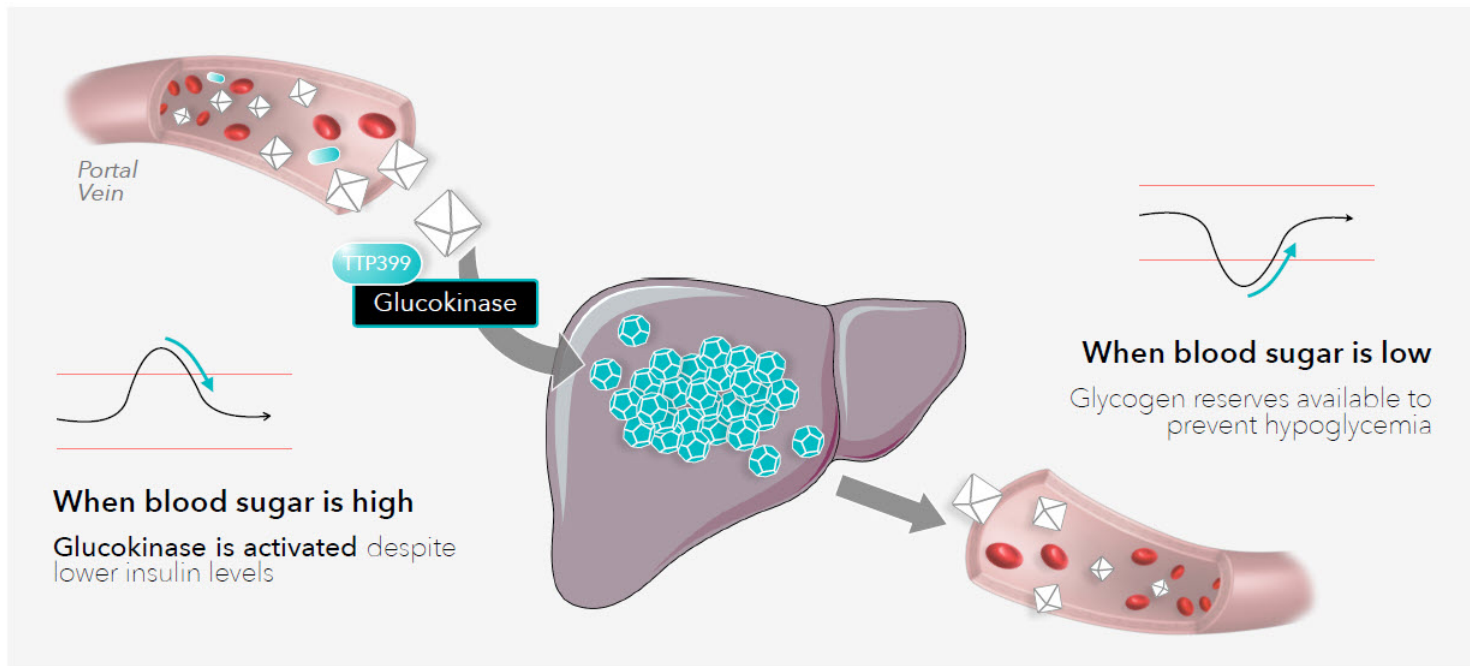
# In Healthy Patients, the Liver Acts as a Reservoir for Glucose



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

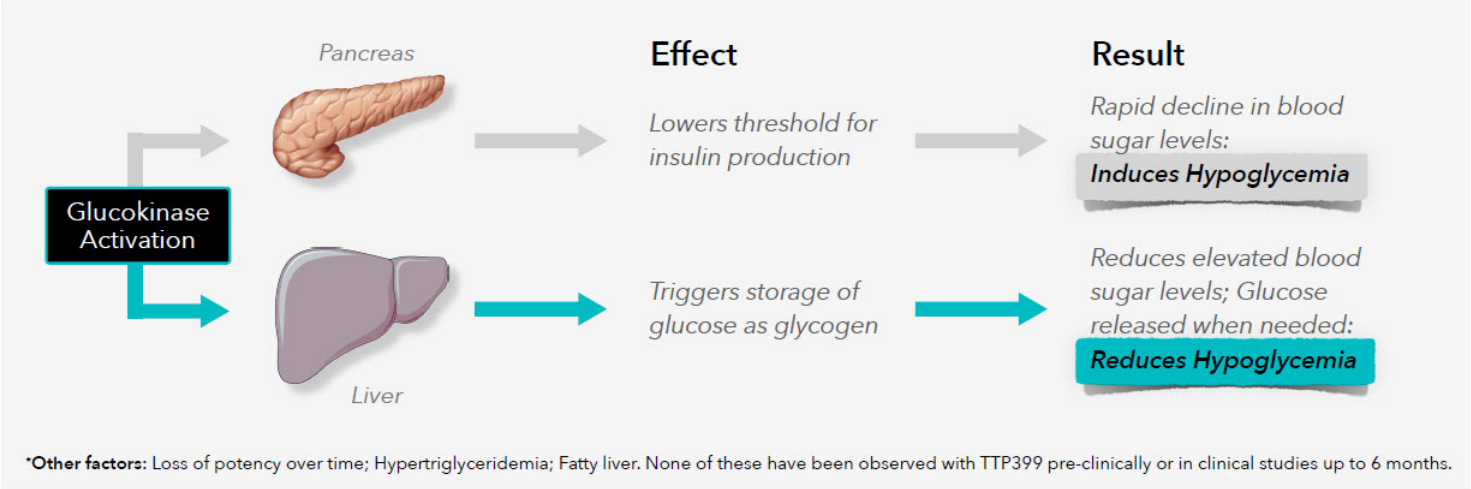


# TTP399 Reactivates Innate Glucose-Regulating Capacity of the Liver

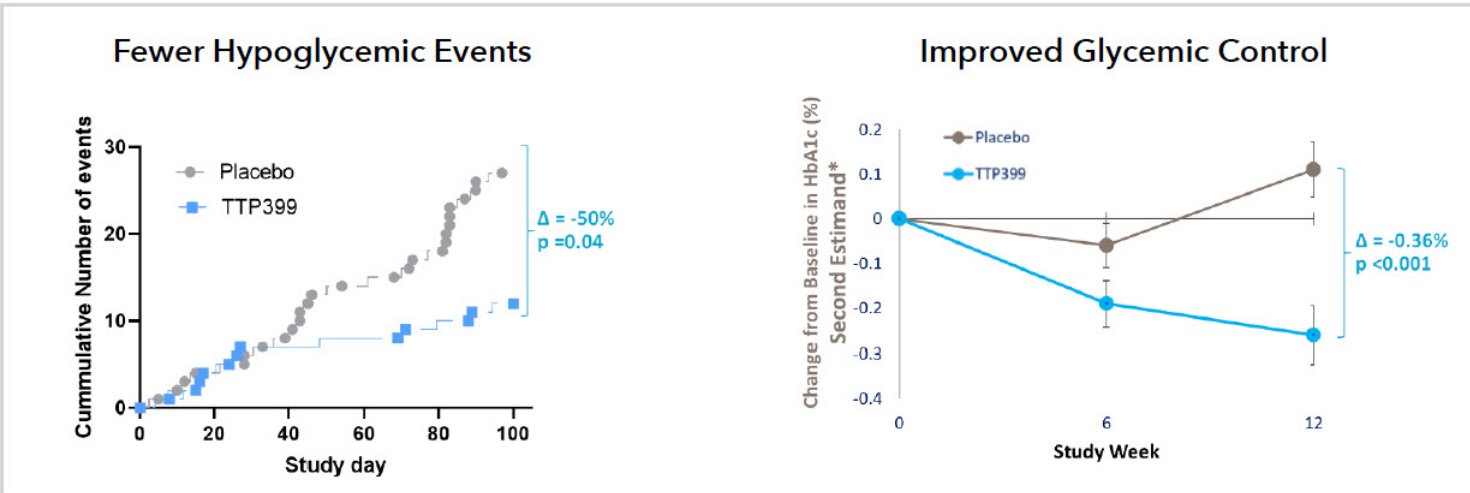


# TTP399 is the First Liver-Selective Glucokinase Activator to Reach Phase 3

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



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



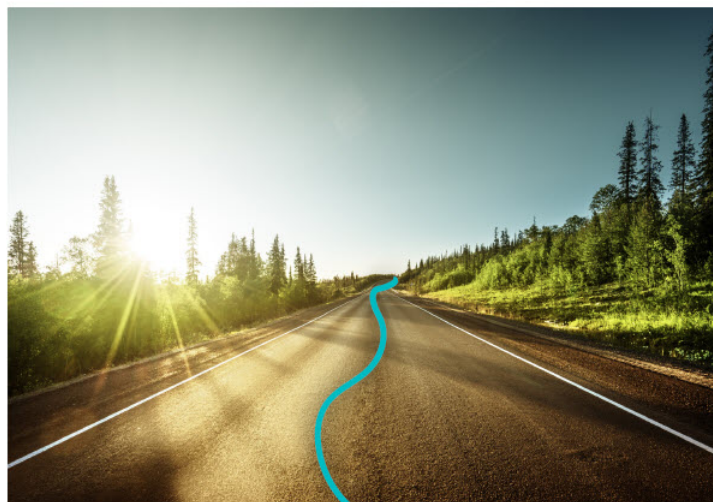
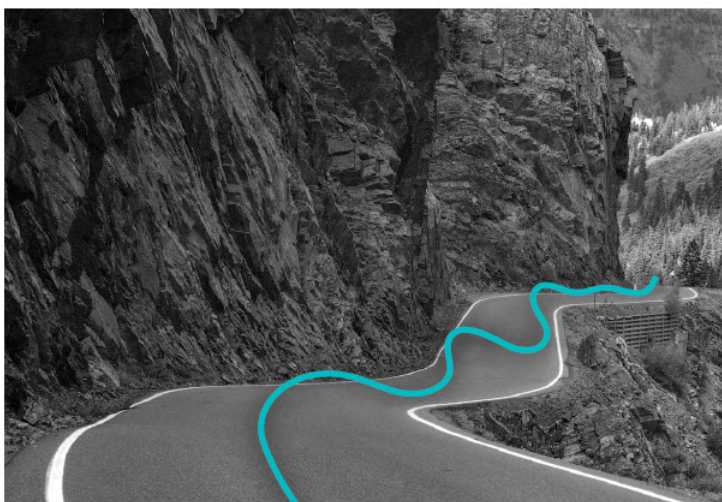
Randomized, Double-Blind, Placebo Controlled 2-Part Study of ~100 patients. A total of 46 patients in the treatment groups received 800mg daily of TTP399.

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

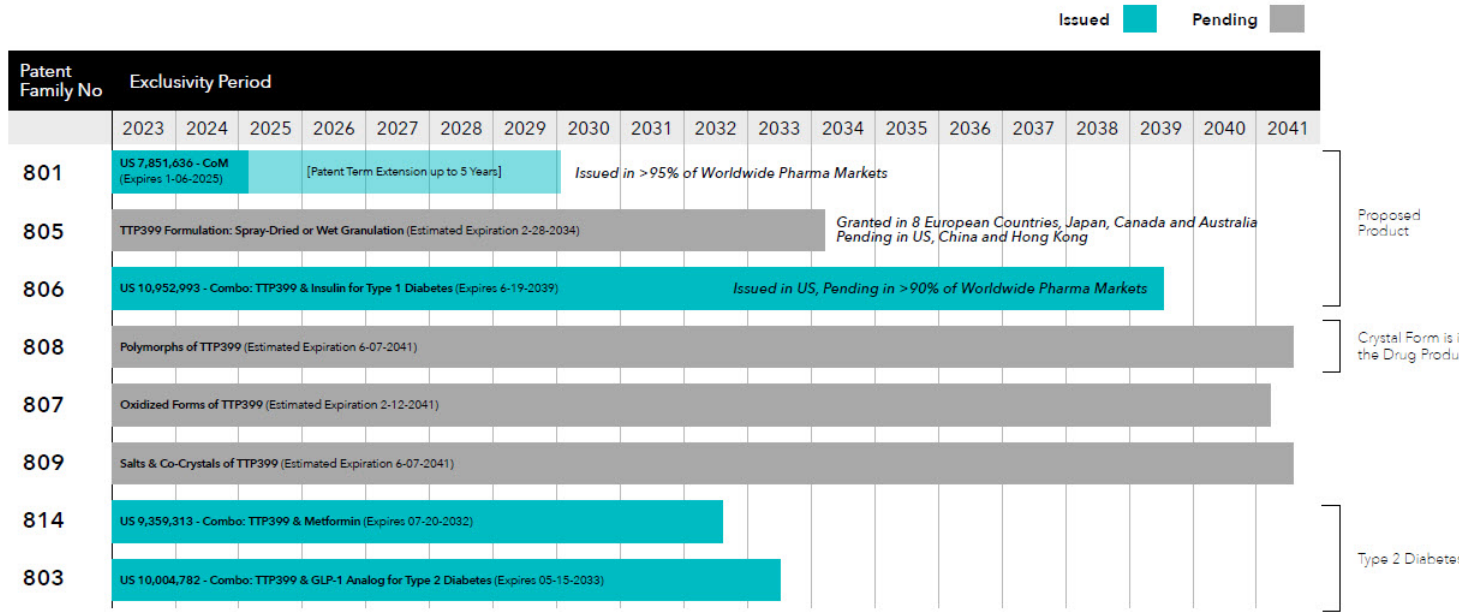


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# We Have the Opportunity to Ease the Burden of Managing T1D and Improve the Lives of Patients Living with Type 1 Diabetes



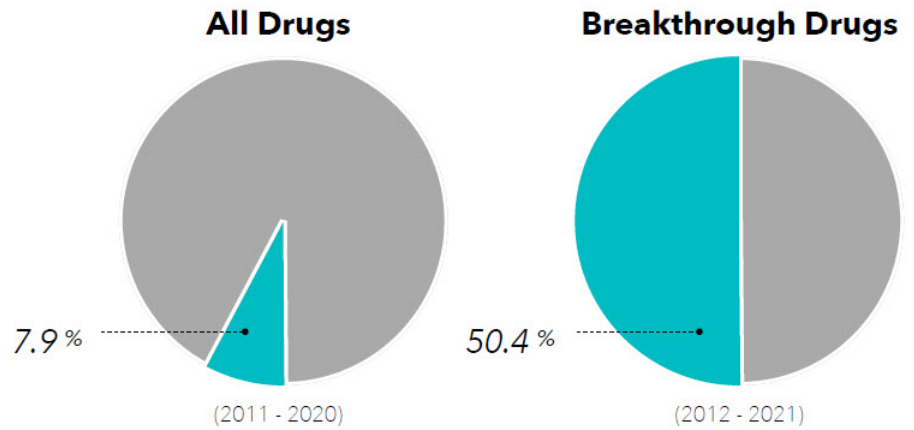
# Strong IP Protection through 2039



# 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)

**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

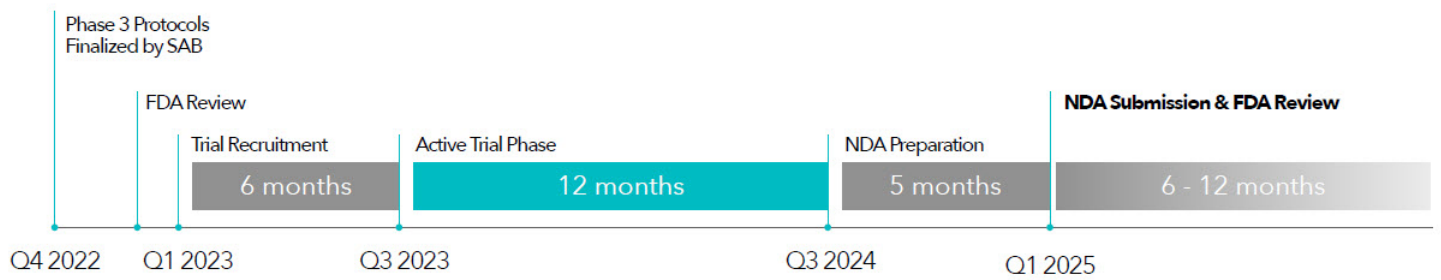


**ENDPOINTS**

**Primary:** Change in Hemoglobin A1C  
**Secondary:** Frequency of Hypoglycemia









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## NDA Submission Expected by 1H 2025



EU EMA submission expected to follow US FDA submission.

# Additional Pipeline Creates Further Upside

PRODUCT	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	PARTNERS + REGIONS
<b>TTP399</b> GK Activator	Type 1 Diabetes				
	Type 2 Diabetes				
<b>TTP273</b> Oral GLP-1R Agonist	Cystic Fibrosis-Related Diabetes				 Cystic Fibrosis Foundation
	Type II Diabetes				 Hudsons Medicine Asia (excl. Japan)
<b>HPP737</b> PDE4 Inhibitor	SAD/MAD Completed				
	Psoriasis				 NEWSQARA Asia (excl. Japan)
	COPD				 NEWSQARA Asia (excl. Japan)
	Atopic Dermatitis				 NEWSQARA Asia (excl. Japan)
<b>HPP593</b> PPAR-δ Agonist	Primary Mitochondrial Myopathy				 Reneo Worldwide
<b>Azeliragon</b> RAGE Antagonist	Pancreatic Cancer				 CANTEX Worldwide
<b>HPP971</b> Nrf2/Bach1 Modulator	Renal Diseases				 Anteris Bio Worldwide
<b>HPP3033</b> Nrf2/Bach1 Modulator	Undisclosed				
<b>TTP-RA</b> RAGE Antagonist	Type 1 Diabetes Prevention				

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# Investors, Partners, and Board



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:

<b>Jon Isaacsohn, MD</b> Chairman	<b>Paul Sekhri</b> President & CEO	<b>Rich Nelson</b> EVP Corp. Dev.	<b>Keith Harris, PhD</b> Director	<b>John Fry</b> Director
<b>Chandresh Harjivan, MD</b> Director	<b>Fahed Al Marzooqi, MD</b> Director	<b>Howard Weiner, MD</b> Director	<b>Hersh Kozlov</b> Director	

# Appendix



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## **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*

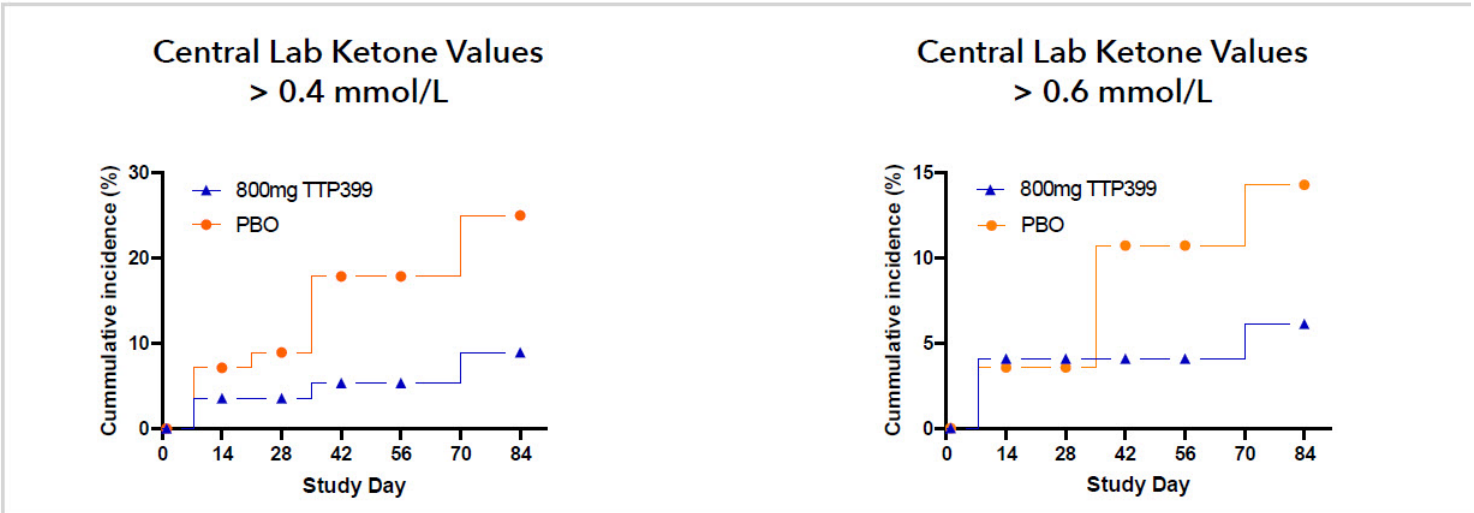
**560 Subjects have Received One or More Doses of TTP399**

## **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

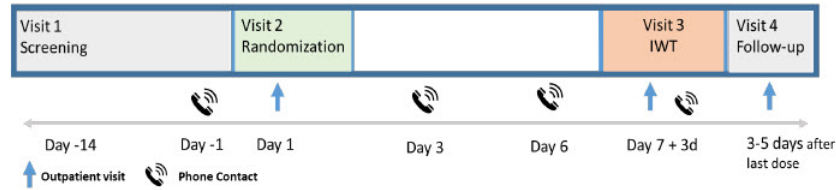
**Participants:** 23 adults with T1D on insulin pumps

**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 ( $\beta$ -hydroxybutyrate) will be collected for 10h

Study design similar to clinical studies using SGLT2 inhibitors<sup>1,2</sup>

Results from similar preclinical study using TTP355<sup>3</sup>  
Decreased ketones in plasma after insulin withdrawal with liver-selective GKA compared to placebo

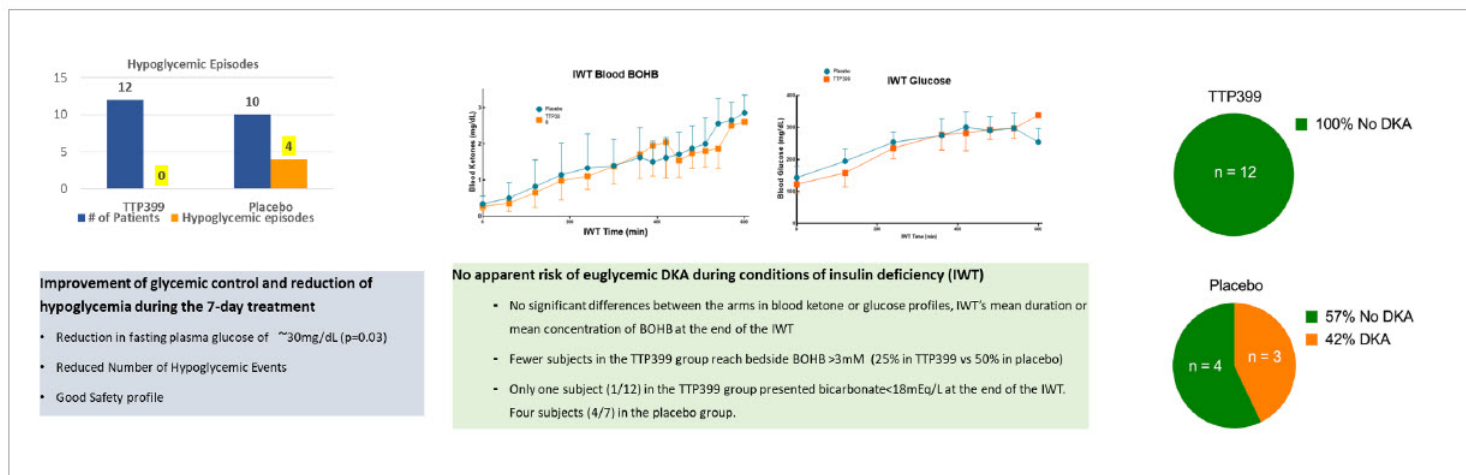


(1) Herring et al, Diabetes Care 2020 <https://doi.org/10.2337/dc19-2579>

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

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



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