UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): August 5, 2024

REZOLUTE, INC.
(Exact Name of Registrant as Specified in Charter)

Nevada	**001-39683**	**27-3440894**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

275 Shoreline Drive, Suite 500, Redwood City, CA 94065
(Address of Principal Executive Offices, and Zip Code)

650-206-4507
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 communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communication 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
Common Stock, par value $0.001 per share	**RZLT**	**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 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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 August 5, 2024, Rezolute, Inc. (the "Company") issued a press release announcing clearance by the U.S. Food and Drug Administration for its Investigational New Drug application for RZ358 (ersodetug) to treat hypoglycemia in patients with tumor hyperinsulinism. Additionally on August 5, 2024, the Company made available an updated Corporate Presentation on the Investor Relations page of its website, which will be used at investor and other meetings. A copy of the press release and Corporate Presentation are attached hereto as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibits 99.1and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated August 5, 2024
99.2	August 2024 Corporate Presentation, dated August 5, 2024
104	Cover Page Interactive Data File (formatted as inline XBRL)

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.

REZOLUTE, INC.

DATE: August 5, 2024

By: */s/Nevan Charles Elam*
Nevan Charles Elam
Chief Executive Officer

Rezolute Announces FDA Clearance of IND Application for Phase 3 Registrational Study of RZ358 for Treatment of Hypoglycemia Due to Tumor Hyperinsulinism

Second rare disease program with RZ358 in Phase 3 development

Follows successful treatment of multiple patients with tumor hyperinsulinism under the Company's Expanded Access Program

REDWOOD CITY, Calif., August 5, 2024 – Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a late-stage biopharmaceutical company committed to developing novel, transformative therapies for serious rare diseases, today announced that it received U.S. Food and Drug Administration (FDA) clearance for its Investigational New Drug (IND) application for RZ358 (ersodetug) to treat hypoglycemia in patients with tumor hyperinsulinism (HI). The Company is initiating start-up activities for the study which will be primarily conducted in the U.S. and patient enrollment is planned to commence in the first half of 2025. Ersodetug is also being studied in an ongoing global, pivotal, Phase 3 clinical trial in patients with congenital HI. Topline data from that study is expected in mid-2025.

"Hypoglycemia associated with tumor HI requires treatment to prevent serious adverse outcomes and to improve patients' daily function and quality of life, including enabling them to receive tumor directed therapies," said Brian Roberts, M.D., Chief Medical Officer at Rezolute. "We are encouraged by the substantial real-world benefit we've witnessed in tumor HI patients who have previously received ersodetug in our Expanded Access Program, coupled with the safety and efficacy demonstrated in clinical studies in patients with congenital HI, a similar condition. We believe that the clearance of our IND for this Phase 3 study reflects FDA's recognition of the potential for ersodetug to address this serious unmet need and we are excited to be moving one step closer to a potential universal treatment for hypoglycemia caused by all forms of HI."

The Phase 3 registrational study is a double-blind, randomized, placebo-controlled trial of 24 participants who have inadequately controlled hypoglycemia because of tumor HI. Eligible participants will be randomized in 1:1 fashion (12 per treatment arm) to receive ersodetug 9 mg/kg per week or matched placebo, as an add-on to standard of care. Up to 24 additional participants may be enrolled into an open-label arm, in participants whose hypoglycemia is being managed by IV glucose in a hospital setting. Following a 6-week pivotal treatment period, all participants may receive ersodetug in open-label extension. The primary endpoint is the change in Level 2 (moderate) and Level 3 (severe) hypoglycemia events by self-monitored blood glucose. Additional endpoints include overall hypoglycemia events, time in hypoglycemia by continuous glucose monitor, patient reported quality of life, hospitalizations, and change in glucose requirements (for open-label hospitalized participants).

Ersodetug is a fully human monoclonal antibody that binds to an allosteric site on the insulin receptor at target tissues such as liver, fat and muscle. Ersodetug counteracts excess insulin receptor activation caused by insulin and related hormones thereby correcting hypoglycemia. Ersodetug has the potential to be universally effective at treating hypoglycemia caused by any form of HI, including congenital or acquired forms.

About Tumor Hyperinsulinism (HI)

Tumor HI is a rare disease that may be caused by two distinct types of tumors: islet cell tumors (ICTs) and non-islet cell tumors (NICTs), both of which lead to hypoglycemia as a result of excessive activation of the insulin receptor. Insulinomas are the most common type of ICT and may cause hypoglycemia by stimulating the over production of insulin. A variety of different NICTs, particularly hepatocellular carcinoma, can cause hypoglycemia by producing and secreting insulin-like paraneoplastic substances such as IGF-2 that bind to and activate the insulin receptor. With high morbidity and mortality rates within tumor HI, there remains a significant unmet need for new therapies directed at hypoglycemia treatment. Ersodetug has shown real-world benefit in patients with insulinoma and preclinical studies have shown that ersodetug can similarly blunt IGF-2 and insulin-mediated insulin-receptor signaling.

About Rezolute, Inc.

Rezolute is a late-stage rare disease company focused on significantly improving outcomes for individuals with hypoglycemia caused by HI. The Company's antibody therapy, ersodetug, is designed to treat all forms of HI and has shown substantial benefit in clinical trials and real-world use for the treatment of congenital HI and tumor HI.

Forward-Looking Statements

Any statements in this press release about the Company's future expectations, plans and prospects, including statements regarding the public offering, constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about the Company's strategy, future operations and future expectations and plans and prospects for the Company, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. These forward-looking statements include statements about the RZ358 Expanded Access Program, the Investigational New Drug (IND) application for RZ358, the ability of the U.S. Ersodetug to become an effective treatment for congenital hyperinsulinism, the effectiveness or future effectiveness of the U.S. Ersodetug to become an effective treatment for congenital hyperinsulinism, and statements regarding clinical trial timelines for RZ358. These forward-looking statements are based on information currently available to the Company and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to market and other financial conditions, the potential completion of the public offering, satisfaction of customary closing conditions related to the public offering and other factors discussed in the "Risk Factors" section contained in the preliminary prospectus supplement and the reports that the Company files with the SEC. Any forward-looking statements represent the Company's views only as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. While the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by law.

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508-272-6717

LHA Investor Relations
Tirth T. Patel
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212-201-6614

Exhibit 99.2

REZOLUTE

Late-stage Rare Disease Company Treating Hyperinsulinism

Corporate Presentation

NASDAQ: RZLT

Forward Looking Statements

This presentation, like many written and oral communications presented by Rezolute and our authorized officers, may contain certain forward-looking statements regarding our prospective performance and strategies within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are including this statement for purposes of said safe harbor provisions. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, and expectations of Rezolute, are generally identified by use of words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "prove," "potential," "seek," "strive," "try," or future or conditional verbs such as "predict," "could," "may," "likely," "should," "will," "would," or similar expressions. These Forward-Looking statements include, but are not limited to, statements regarding the sunRIZE clinical study, the RIZE study, the Investigational New Drug (IND) application for RZ358 (Ersodetug), the ability of RZ358 to become an effective treatment, the effectiveness or future effectiveness of RZ358 as a treatment, statements regarding clinical trial timelines for the treatment. Our ability to predict results or the actual effects of our plans or strategies is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Except as required by applicable law or regulation, Rezolute undertakes no obligation to update these forward-looking statements to reflect events or circumstances that occur after the date on which such statements were made. Important factors that may cause such a difference include any other factors discussed in our filings with the SEC, including the Risk Factors contained in the Rezolute's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, which are available at the SEC's website at www.sec.gov. You are urged to consider these factors carefully in evaluating the forward-looking statements in this release and are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement. This presentation shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

Rare Disease Company Treating Hyperinsulinism

RZ358 (ersodetug) is a fully human monoclonal antibody designed to treat hypoglycemia caused by all forms of hyperinsulinism (HI)

Two rare disease Phase 3 programs evaluating ersodetug to treat hypoglycemia in congenital HI and tumor HI

Compelling real-world evidence of patient benefit under the Company's Expanded Access Program

Each program is a potential >$1B+ market opportunity with additional upside with market expansion

Seasoned management team with demonstrated success from early development through commercialization

Management Team

Nevan Charles Elam
Founder & Chief Executive Officer

Brian Roberts
Chief Medical Officer

Daron Evans
Chief Financial Officer

Susan Stewart
Chief Regulatory Officer

Michael Deperro
SVP, Corporate Development

Two Phase 3 Rare Disease Indications Targeting Hyperinsulinism

Program	Target	IND-Enabling	Phase 1	Phase 2	Phase 3	Next Milestone	Milestone Expected
RZ358 (ersodetug)	Congenital Hyperinsulinism (cHI)					Topline data	Mid-2025
RZ358 (ersodetug)	Tumor Hyperinsulinism (tHI)					Patient enrollment in Phase 3 study	1H 2025
RZ402	Diabetic Macular Edema (DME)					Available for partnering	N/A

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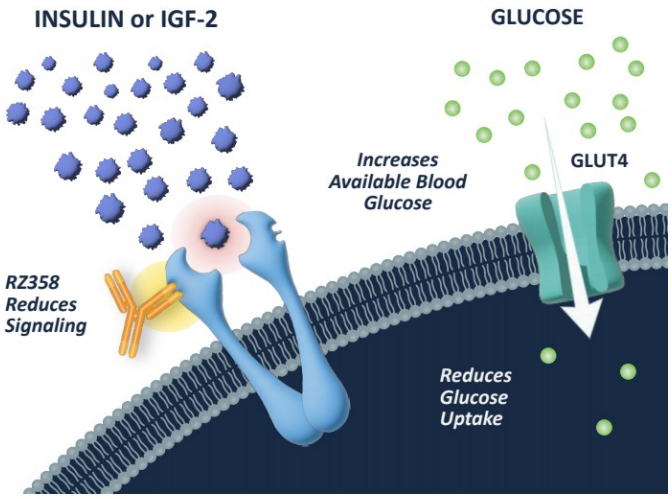
Ersodetug

Treatment for Hyperinsulinism (HI)

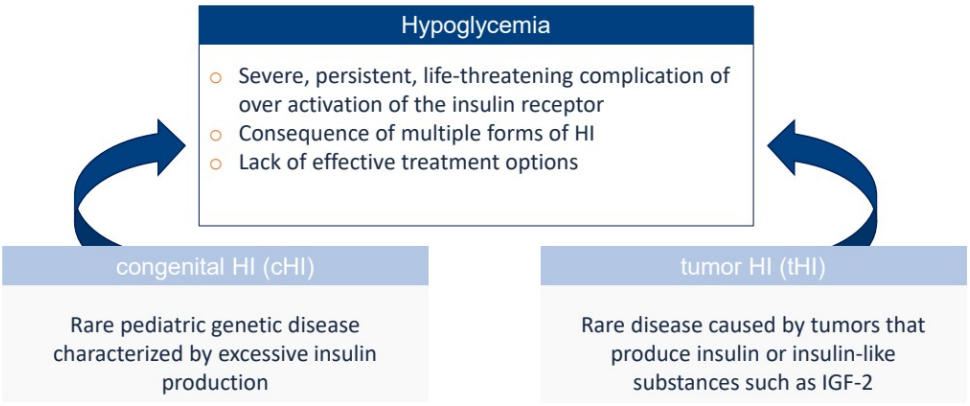
Antibody Designed to Treat All Forms of HI

- Ersodetug allosterically binds to the insulin receptor to modulate the signaling effect of insulin and IGF-2 to maintain glucose values in a healthy range
- Novel mechanism operates downstream to counteract excess insulin receptor activation
- Administered by IV infusion every 2 to 4 weeks



GLUT4: glucose transporter type 4.

Hypoglycemia as a Result of HI



Ersodetug has shown substantial benefit in studies and real-world use for treatment of cHI and tHI

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Congenital HI

Disease Background

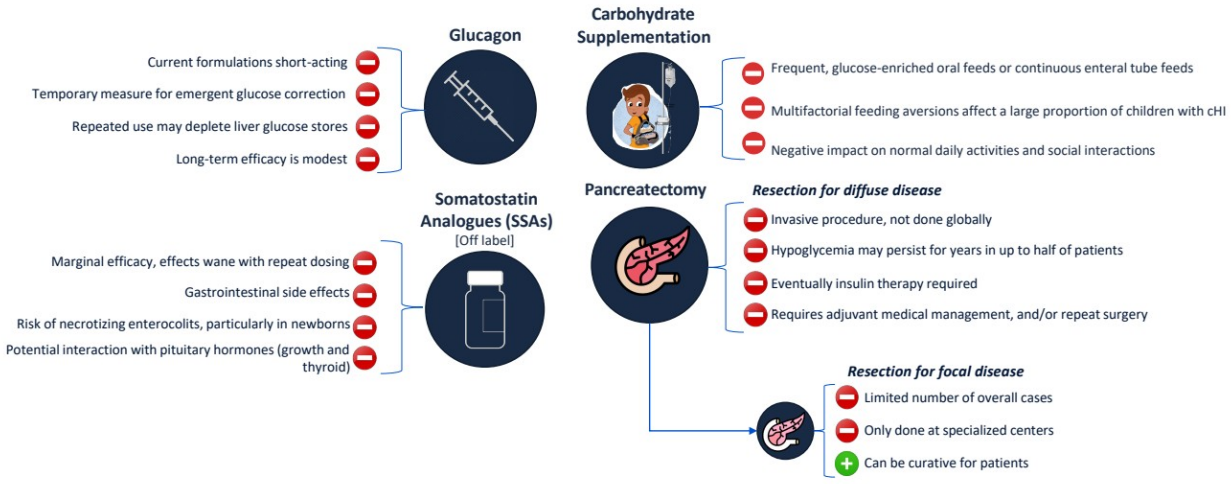
- **~2000 individuals in the U.S. that would be candidates to use ersodetug**
  - 1 in 28,000 live births in the US
  - 25 years of treatment required on average
  - ~3500 cases in the US
  - Often presents within first month of life
- **Most common cause of persistent hypoglycemia in infants and children**
- **Symptoms often not recognized until life-threatening**
- **Risk of coma, death, and other serious complications**
- **50% of children have neurological deficiencies**
- **No therapy has been developed and approved for chronic treatment**

Standard of Care for HI is Inadequate

- **Diazoxide (DZ) is the current standard of care and only approved treatment for hypoglycemia caused by HI**
- **50% of patients do not respond to DZ**
- **May experience frequent and serious adverse reactions**
  - FDA black box for pulmonary hypertension
- **Patients report[1] intolerable side effects and would welcome an alternative treatment option**
  - Increased body hair (85%)
  - Loss of appetite (36%)
  - Swelling (25%)
  - Stomach pain/upset stomach (23%)
  - Facial changes (22%)

Source: 1) HI Global Registry 2022 Annual Report: 165 patients surveyed, 134 have taken DZ.

Other Available Treatment Options are Suboptimal



Phase 2b RIZE Study Results

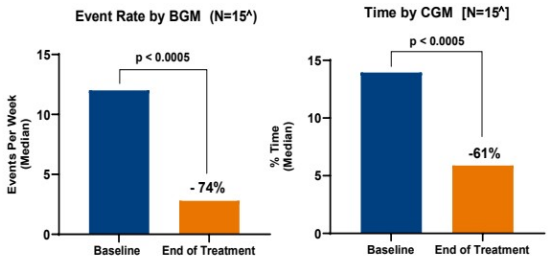
- **23 participants**
  - Average age ~6.5 (16 participants were between 2-6 years of age)
  - Diverse group across gender and genetics
- **~20% average daily time in hypoglycemia and 13 hypoglycemia events per week at baseline**
  - Participants were on SOC
- **Generally safe and well-tolerated**
  - No adverse drug reactions
  - No study terminations
  - No clinically-significant hyperglycemia or hyperglycemia AEs
- **Study exceeded expectations for glucose correction:**
  - Improvement in time in hypoglycemia and overall events of up to ~90% at top doses
  - Nearly universal response rate at the top dose
- **Predictable and dose-dependent pharmacokinetics**

SOC: standard of care. AEs: adverse events.

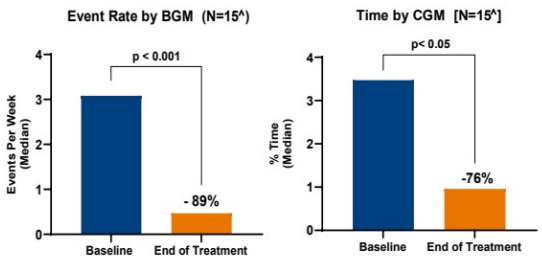
Substantial Improvement in All Hypoglycemia Metrics

Improvement in time in hypoglycemia and overall events of ~75% and up to ~90% at top doses

Hypoglycemia (<70 mg/dL)



Severe Hypoglycemia (<50 mg/dL)

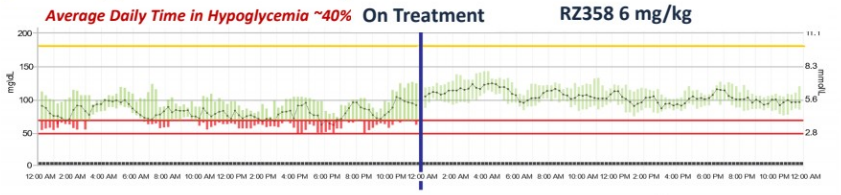


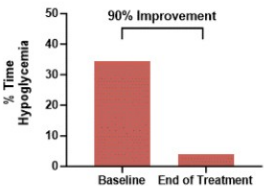
Pooled 6 and 9 mg/kg dose levels representative of Phase 3 population and dosing

BGM: blood glucose monitoring. CGM: continuous glucose monitoring. One 9 mg/kg participant excluded from analyses for stopping background therapy while on study; two others wore CGM incorrectly which impacted efficacy by CGM but were included in analyses.

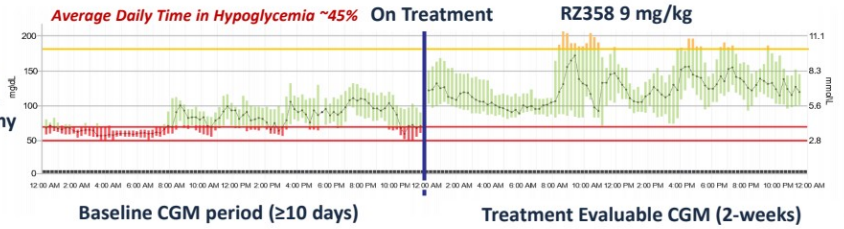
Compelling Patient Responses

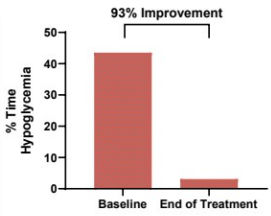
2-Year-Old on SSA





6-Year-Old; Failed meds, pancreatectomy





Nearly universal patient response rate (>50% hypoglycemia correction) observed at mid and top doses

SSA: Somatostatin Analog. CGM: continuous glucose monitoring.

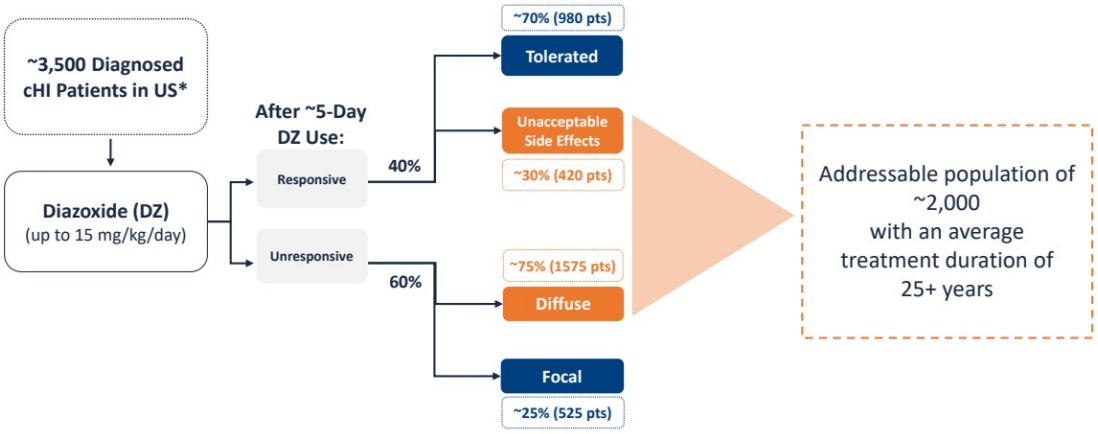
Phase 3: The sunRIZE Study

- **Multi-center, double-blind, randomized, controlled, safety and efficacy registrational study**
- **Patient population (n=56)**
  - Ages 3 months and above who have not achieved adequate glycemic control with standard of care medical management
- **Primary endpoint: change in average hypoglycemia events per week**
  - Secondary endpoints include change in average daily percent time in hypoglycemia, change in severe hypoglycemia events and time, time in a target glucose range, and symptomatic hypoglycemia events
- **Pivotal treatment arms**
  - ~48 participants ages 1 year and above randomized in double blind, placebo-controlled fashion
  - Three bi-weekly loading doses, then 4 monthly doses over a total 6-month treatment period
    - 5 mg/kg (+ SOC) (n = 16)
    - 10 mg/kg (+ SOC) (n = 16)
    - Placebo (SOC only) (n = 16)
  - Open label treatment arm: ~8 participants ages 3 months to 1 year
  - Eligible participants may continue in a long-term extension study following pivotal treatment
- **Topline results expected mid-2025**

SOC: standard of care.

Immediately Addressable U.S. Market

Diagnosis and Treatment Pathway Illustrates that ~2,000 Individuals are Addressable



HI: hyperinsulinism. DZ: Diazoxide. DZR: Diazoxide Responsive. DZNR: Diazoxide Non-Responsive (kATP channel defect). *Similar numbers in EU

Addressable Worldwide Market

- **~10K individuals in primary markets**
  - 1 in 28,000 live births and up to 1 in 2,500 live births in certain populations due to consanguinity
  - In addressable patient population, disease persists for more than 25 years on average
- **At Launch >50% of the market is addressable**
  - <50% of patients are adequately managed by standard of care
  - Growing percentage of patients on standard of care experience unacceptable side effects
- **Rapid patient identification and concentrated prescriber base enables accelerated adoption**
  - 60% of patients are diagnosed within 1 month of presentation
  - 80% of patients are managed at centers of excellence that are participating the Phase 3 clinical trial
- **Regulatory Designations: Orphan, Pediatric Rare Disease (FDA), PRIME (EMA), ILAP (UK)**
- **Potential for expanded indications such as tumor HI**

$1B+ market opportunity with rare disease pediatric disease drug pricing

HI: hyperinsulinism.

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Tumor HI

Disease Background

- **~1,500 immediately addressable individuals with severe, refractory hypoglycemia in the U.S.**
- **Hypoglycemia caused by two distinct tumor types:**
  - Islet Cell Tumors (ICT)
    - Excessive secretion of insulin
    - Malignant insulinomas are the most common ICTs that cause hypoglycemia
  - Non-Islet Cell Tumors (NICT)
    - Produce and secrete insulin-like substances such as IGF-2 that over-activate the insulin receptor
    - Hepatocellular carcinomas (HCC) are the most common NICTs that cause hypoglycemia
- **Significant unmet need across both tumor types**
  - Resulting hypoglycemia is often severe and may have serious adverse outcomes
  - Limited treatment options with poor efficacy and safety profiles
  - High morbidity and mortality rates
  - Can require hospitalization (often prolonged and in ICU) and interferes with patient quality of life
  - May prevent adjuvant tumor treatment

Treatment Options and Unmet Need

- **Tumor-directed therapies do not directly treat hypoglycemia**
  - Adequate hypoglycemia management is required prior to initiation of tumor-targeted therapies
- **Therapies to treat malignant insulinoma are often ineffective or poorly tolerated**
  - Diazoxide (DZ) is the only approved treatment
    - Suboptimal response rates and serious side effects
  - Somatostatin analogs (SSAs)
    - Used off-label with limited success
    - May worsen hypoglycemia in tumor HI setting
  - mTOR-inhibitors
    - Used off-label and have potentially severe side effects
- **Limited and often ineffective treatment options for hepatocellular carcinoma (HCC)**
  - Medical therapies directed at suppressing insulin secretion such as DZ and SSAs do not work in non-islet cell tumors (NICTs) where HI is caused by non-insulin substances such as IGF-2

Real-world Patient Benefit Under EAP

- **Multiple ICT patients with severe refractory hypoglycemia**
  - Hospitalized and in life-threatening or hospice-bound condition
  - Required continuous high volume/concentration intravenous dextrose or nutritional infusion
  - Tumor-directed therapies (e.g., embolization, radiotherapy, chemotherapy) deferred because of hypoglycemia
  - Physician-requested use of ersodetug
- **Administration of ersodetug resulted in:**
  - Substantial hypoglycemia improvement with no significant side effects
  - Discontinuation of intravenous dextrose
  - Discharge from in-patient to out-patient care
  - Resumption of tumor-directed therapies

Joslin Diabetes Center | HARVARD MEDICAL SCHOOL AFFILIATE

BRIGHAM HEALTH
BRIGHAM AND WOMEN'S HOSPITAL

Stanford MEDICINE

MOFFITT CANCER CENTER

Hôpital Cochin Port-Royal AP-HP

OHSU

EAP: Expanded Access Program. Sources: n engl j med 389;8 Aug24,2023 - https://www.nejm.org/doi/full/10.1056/NEJMc2307576?query=TOC&cid=NEJM+eToc%2C+August+24%2C+2023+DM2279684_NEJM_Non_Subscriber&bid=1754093795

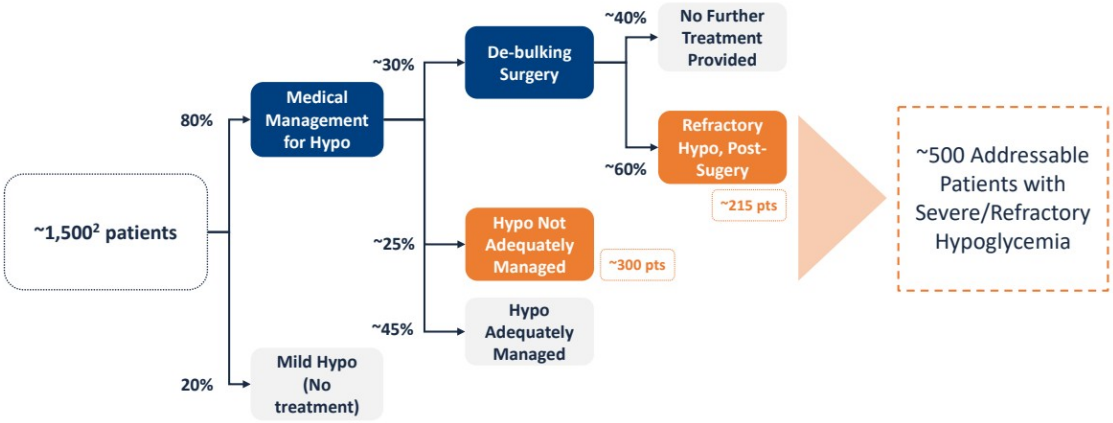
Phase 3 Study Overview

- **Multi-center, double-blind, randomized, controlled, safety and efficacy registrational study**
- **Patient population (n= up to 48)**
  - Adult ICT and NICT patients with HI who have not achieved adequate hypoglycemia control with SOC therapies
  - 24 participants in double-blind, placebo-controlled arm (to evaluate primary endpoint/hypoglycemia events)
  - Up to 24 participants in open label arm: initial 6 NICT patients and any hospitalized participants on IV glucose
- **Primary endpoint: change in average hypoglycemia events per week by self-monitored blood glucose**
  - Secondary/additional endpoints: change in average daily percent time in hypoglycemia, change in Level 1 hypoglycemia events and time, hospitalization, patient reported quality of life
  - Open-label arm to evaluate change in IV glucose requirements in hospitalized participants
- **Treatment arms and dosing regimen**
  - Once weekly administration over 6-week pivotal treatment period
    - 9 mg/kg RZ358 (+ SOC) (n = 12)
    - Matched placebo (SOC only) (n = 12)
    - 9 mg/kg RZ358 Open Label Arm (n ≤ 24)
  - Eligible participants may continue in a long-term extension study following pivotal treatment
- **IND filed and cleared: start-up activities in progress to enable patient enrollment in 1H 2025**

ICT: islet-cell tumor. NICT: non-islet cell tumor. SOC: standard of care.

Immediately Addressable U.S. ICT Market

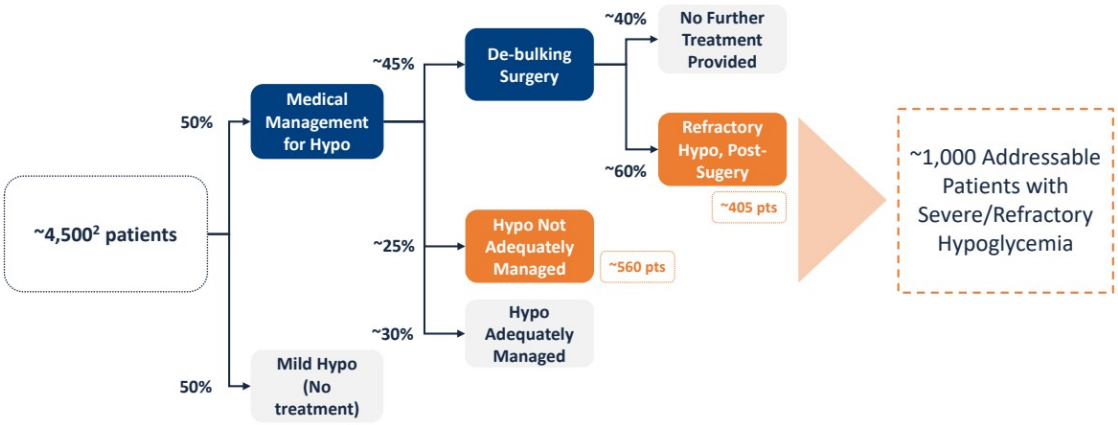
Malignant Insulinoma Hypoglycemia (Hypo) Diagnosis and Treatment Pathway[1]



ICT: islet cell tumor. Source: 1) Based on analysis of seven years of data from the Komodo Claims Assessment; 2) Approximate, average prevalence of patient with both malignant insulinoma and diagnosed hypoglycemia.

Immediately Addressable U.S. NICT Market

Hepatocellular Carcinoma + Hypoglycemia (Hypo) Diagnosis and Treatment Pathway[1]



NICT: non-islet cell tumor. Source: 1) Based on analysis of seven years of data from the Komodo Claims Assessment; 2) Approximate, average prevalence of patient with both malignant insulinoma and diagnosed hypoglycemia

Rare Disease Company Treating Hyperinsulinism

Mission-driven to improve outcomes for individuals with severe hypoglycemia caused by hyperinsulinism (HI)

RZ358 (ersodetug) is a fully human monoclonal antibody designed to treat hypoglycemia caused by all forms of HI

Compelling real-world evidence of patient benefit under the Company's Expanded Access Program

Each program has a potential >$1B+ market opportunity with upside potential

Strong Balance Sheet; cash runway through Q2 2026