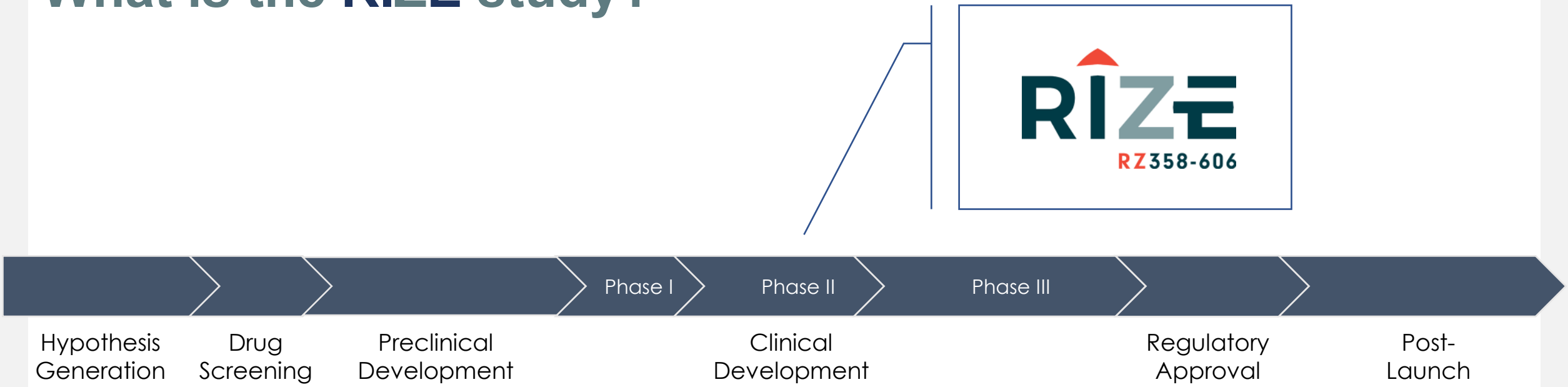
RÎZE

RZ358-606

What is the RIZE study?

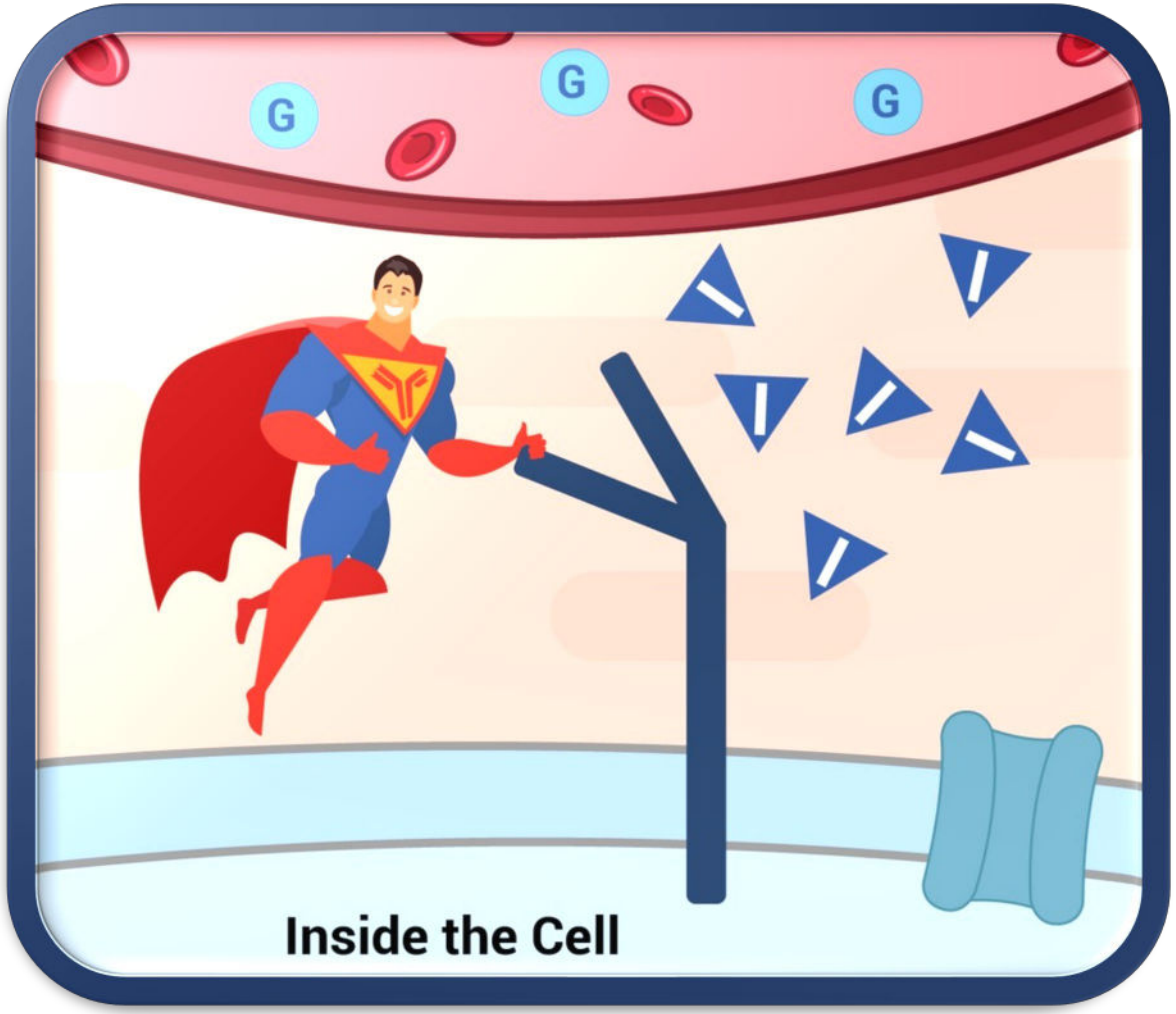


The RIZE Study is a Phase 2b clinical study of RZ358.

- RZ358 has been studied in patients with congenital HI before
- Define the best dose of RZ358 for treating HI
- Show RZ358 is safe and effective to treat HI in younger age groups

What is RZ358? How does RZ358 work?

- Scientists wanting to help children with HI made a very specific molecule, called RZ358, that is unlike any other treatment available.
- Designed to decrease insulin's messages to the cells in the body through action at the insulin receptor.
- RZ358 follows insulin to the cells and like a superhero with strong muscles RZ358 grabs a hold of the insulin receptor so insulin cannot send its message to the cell to take glucose from the bloodstream.
- When the insulin levels are lower, RZ358 can also loosen its grip on the insulin receptor and allow the right amount of glucose to go into the cells in the body.



RZ358 is a new, first of its kind treatment specifically developed to treat congenital hyperinsulinism. It works by decreasing the effect of insulin in the body to help keep blood sugars in a safe range.

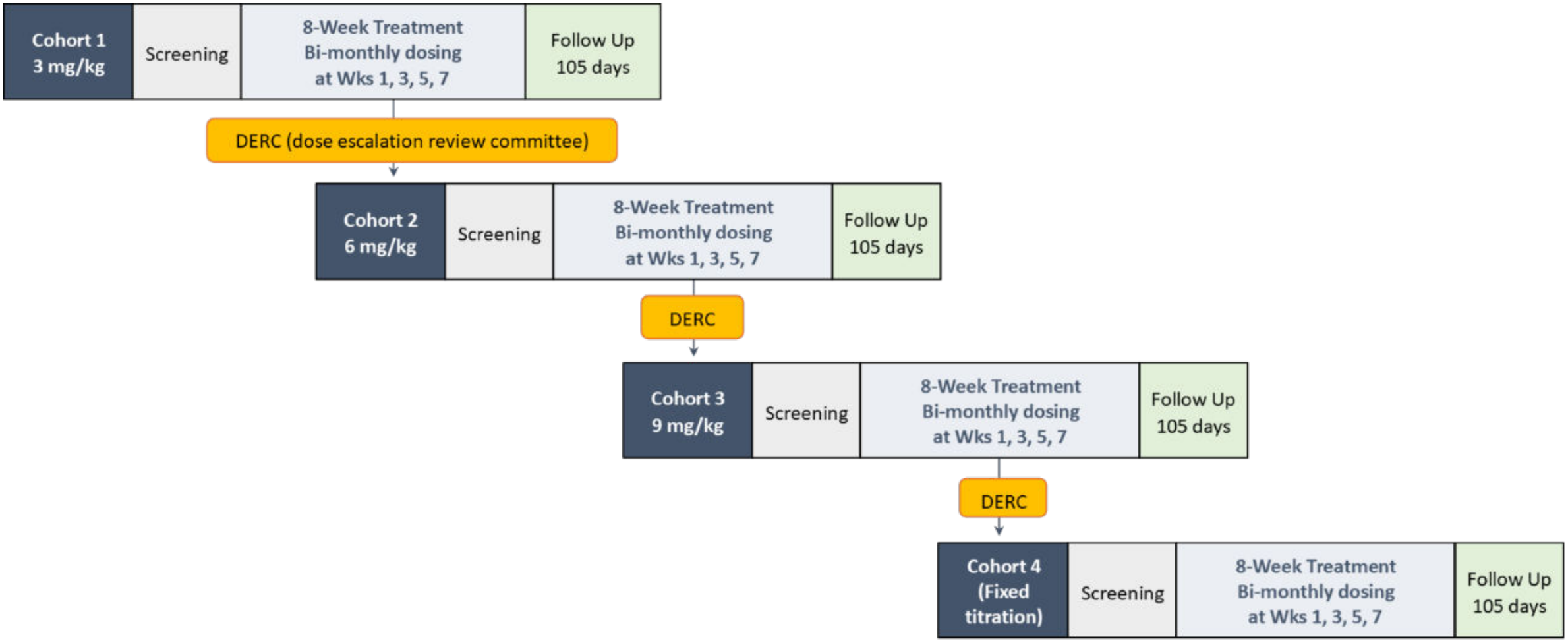
Those eligible for the RZ358 RIZE study include:

2-45 years old (12-45 years old in the US & Russia) diagnosed with CHI who are still having regular hypoglycemia (at least several times per week) based on continuous glucose monitoring (CGM) and self-monitored blood glucose (SMBG) values.

Details about the RIZE study:

- Duration of trial participation is approximately **26 weeks**
  - **2-5** weeks of screening (before the first dose)
  - **8** weeks receiving **RZ**358 (once every 2 weeks)
  - **13** weeks of follow-up (3 follow up visits)
- **RZ**358 is given by IV infusion over 30 minutes
- Over the 8-week dosing period, four inpatient/dosing stays will be necessary (2-3 nights each, 9 nights total)
- Travel, lodging, and incidental assistance are provided to the families as needed during the 26 weeks
- Both CGM and SMBG will be monitored and recorded throughout the study treatment and follow up period
- Blood samples to assess safety and to measure the amount of **RZ**358 will be collected during the study
- Participants (or parents) will keep a daily electronic diary to record:
  - SMBG values at pre-specified timepoints
  - Any glucose events and/or rescue therapy taken

Study Design



RIZE Trial Timeline

RZ358-606

2020												2021									
Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct

Regulatory Approvals → Approved in 12 Countries

Site Activations → 16-17 Sites Targeted

Enrollment Period

In order to meet goal of trial completion by end of 2021, more countries and more sites have been added to increase patient access to the RIZE study.

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Compassionate Use / Extended Use

2021				2022				2023			
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4

Interim Option: Investigator Sponsored Trial (IST) / Compassionate Use

- ❑ Meets immediate needs of the patient
- ❑ Led by the Investigator
- ❑ RZT will provide RZ358 drug and provide regional regulatory guidance

Phase 2 RIZE Study → Phase 3 Study

- ❑ Patients who are benefitting from RZ358 have the option to continue to receive drug after participating in the RIZE study.

Definitive Option: Extension Study for Phase 2 (RIZE) and Phase 3

- ❑ Separate protocol or Appendix to Current protocol
- ❑ Start-up timeline will be driven by regulatory submissions and approvals
- ❑ Phase 2b extension database will be the same for the Phase 3 study extension

Where is the RIZE Study being conducted?

AGES 12 – 45 YR

Philadelphia, PA*
Fort Worth, TX*
Moscow, Russia

AGES 2 – 45 YR

Montreal, Canada
Manchester, UK*
London, UK*
Barcelona, Spain*
Magdeburg, Germany*
Odense, Denmark*
Sofia, Bulgaria
Varna, Bulgaria
Belgrade, Serbia
Ankara, Turkey
Diyarbakir, Turkey
Tel Hashomer, Israel
Jerusalem, Israel

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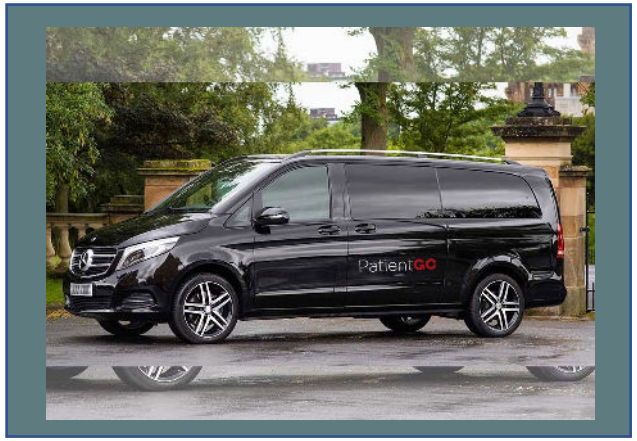
* These sites (also circled on map) are able to accept participants from other countries.

Patient Travel Services



Patient GO® Services

- GROUND TRANSPORTATION
- AIR AND RAIL TRAVEL
- OVERNIGHT ACCOMMODATION
- LONG-TERM HOUSING
- LANGUAGE SUPPORT
- REIMBURSEMENTS
- STIPEND PAYMENTS
- SITE & PATIENT DOCUMENTS
- COVID-19 SUPPORT

Interested in RIZE ?

RZ358-606

Visit https://connect.trialscope.com/studies/5837c52d-e200-4a2a-83c5-562ae1513225?pv=1 to learn more about the RIZE study and how you can take part

OR

Contact Rezolute's Director of Scientific and Patient Affairs, Davelyn Hood at davelyn@rezolutebio.com

Be sure to check out the kid-friendly RZ358 video in Rezolute's conference booth! Help us name our superhero by entering your suggestion in the booth chat!

Thank You

from the

RZ358-606

Clinical Team!

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