Redefining
Oral Biologics

September 2021

Rani
THERAPEUTICS

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Corporate Summary

- Converting injectable biologics into pills
- **$56BN+ initial market opportunity**[1] targeting multiple markets across multiple diseases
- 5 internal development programs
  - Initiation of at least two Phase 1 trials expected in 2022; Repeat-dose study expected in 2022
- Octreotide Phase 1 completed supporting platform safety, tolerability and bioavailability
- Established IP portfolio with 270+ patents filed and 160+ issued/allowed as of 3/24/21

[1]Includes all indications for TNFα inhibitors. Estimated cumulative addressable market for key identified pipeline candidates (octreotide, TNFα antibody, insulin, GLP-1, parathyroid hormone and human growth hormone) per third-party market analyses

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Patients Prefer Pills

88%

of RA patients would prefer a daily pill to a bi-weekly injection of Humira

38%

of diabetics miss **4+** injections per week

Frost & Sullivan research report commissioned by Rani

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"Patients initiating treatment with glucagon-like peptide-1 receptor agonists (GLP-1RAs) **had a 71% higher discontinuation rate** in the first 6 months compared with those initiating saxagliptin (oral DPP-4 therapy)"[1]

"The most commonly reported **barrier to maintaining injectable medication was injection concerns** (42%) such as aversion to needles, pain, or needle size."[1]

"The majority of patients (79%) would **prefer a twice-daily oral tablet than an injection** or IV infusion (for rheumatoid arthritis)"[2]

"**Optimal adherence differed significantly** between oral and injectable (93% vs 76%, p< 0.001)"[3]

Sources:

[1] https://www.sciencedirect.com/science/article/pii/S0149291816303757#bib12

[2] https://www.valueinhealthjournal.com/article/S1098-3015(13)03426-8/pdf

[3] https://onlinelibrary.ectrims-congress.eu/ectrims/2017/ACTRIMS-ECTRIMS2017/199728/jonathan.roux.adherence.to.oral.versus.injectable.disease-modifying.therapies.html#:~:text=Mean%20MPR%20was%20higher%20for,%25%2C%20p%3C%200.001).

Rani's Technology

Rani’s Development Approach

- **Designed for Minimal Discomfort**
  No small intestine pain receptors
- **Absorption similar to injections**
  Upon Deployment
- **Agnostic to payload**
  Designed to accommodate peptides, proteins and antibodies
- **Strong patent position**
  Covering both the platform and drugs in combination with the platform
- **Scalable design**
  For low cost, high volume manufacturing

The RaniPill capsule is similar in size to a fish oil or calcium pill

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Development Pipeline

	INDICATION(S)	FORMULATION	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT EXPECTED MILESTONE
CORE PROGRAMS							
RT-101	**NETs / Acromegaly***	**Octreotide**					Repeat Dose Platform Study in 2022
RT-105	**Psoriatic Arthritis**	**Anti TNF-α Antibody**					Initiate Phase 1 in 2023***
RT-102	**Osteoporosis**	**PTH-OP**					Initiate Phase 1 in 2022***
RT-109**	**GH Deficiency**	**hGH**					Initiate Phase 1 in 2022***
RT-110	**Hypo-parathyroidism**	**PTH-Hypo**					Initiate Phase 1 in 2023***
COLLABORATION OPPORTUNITIES							
RT-103	**T2 Diabetes**	**GLP-1 Mimetic**					
RT-106	**T2 Diabetes**	**Basal Insulin**					

RT-XXX refers to the RaniPill capsule containing a biologic in a proprietary Rani formulation
* Each of these indications will require separate trials
** CCHN will have limited opportunity to negotiate for rights within China
***To follow submission and clearance of IND

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Preclinical & Clinical Experience

Preclinical & Clinical Experience

- **Preclinical – 10 molecules** assessed
  - 4 antibodies, 5 peptides, 1 large protein
  - Awake dogs, anesthetized juvenile pigs
  - Single and repeat-dose studies
    - No serious adverse events observed to date
    - High bioavailability, comparable to parenteral injections

- **Clinical – 3 molecules** assessed**, 5 human clinical studies** in healthy volunteers
  - RaniPill™ platform-only study
  - Phase I study with RaniPill and biologic (octreotide)
  - 3 studies simulating Rani delivery via Endoscopic intrajejunal injections
  - 2 peptides,1 antibody
    - No serious adverse events observed to date
    - High bioavailability, comparable to injections

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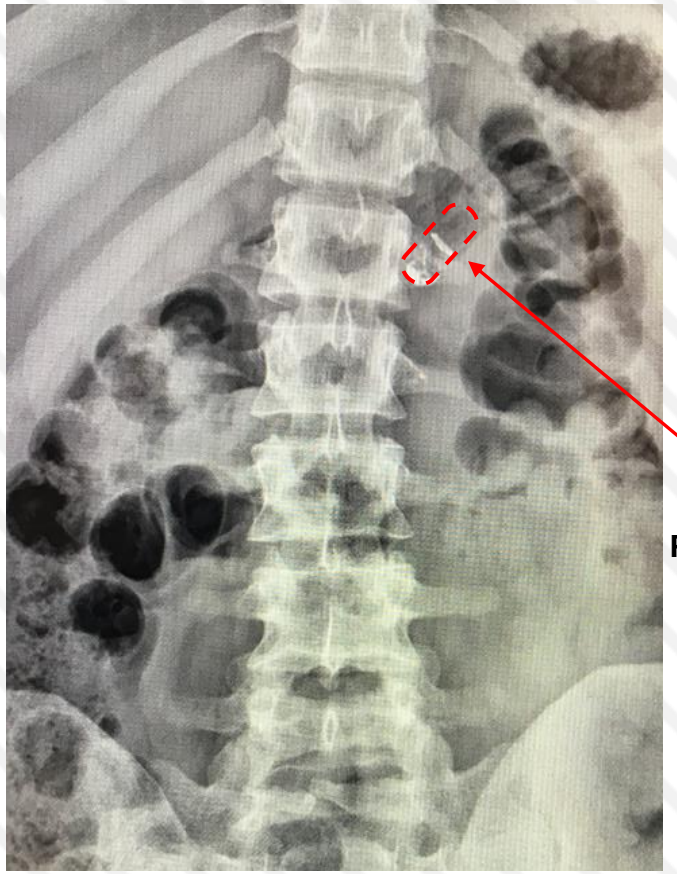
Safety and Tolerability Study of RaniPill Platform in Humans

- Study conducted in 2018
- RaniPill device tracked by X-ray imaging
- RaniPill device without a needle in fasted and fed groups
  - N=10 per group
- No food effect observed on device functionality
- RaniPill was well-tolerated by all subjects
- No serious adverse events were reported
- Met all safety endpoints
  - Ability to swallow
  - No sensation upon deployment
  - Ability to pass capsule remnants

X-Ray Image of Intact RaniPill



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RaniPill Repeat Administration Canine Study

Study Overview

***Objective*:**
Evaluate safety and tolerability of once-daily 7 day repeat oral administration of the RaniPill capsule

***Animal Model*:**
Male and female beagles naïve to all drugs

***Study Groups*:**
Test Group:
Orally administered RaniPill capsule, containing octreotide, once a day for 7 days, followed by a 7 day wash-out period; n = 8 (4 males, 4 females)
Control Group:
Orally administered enteric coated size 000 capsule, containing sugar once a day for 7 days, followed by a 7 day wash-out period; n = 4 (2 males, 2 females)

Histopathology

Animals necropsied at end of the study:
Postmortem examination (excluding brain) was performed in 12 dogs (Test = 8, Control = 4) on Day 14 ± 1

Samples of small intestine from each animal (duodenum n = 1, jejunum n = 3, ileum n = 1) were collected for histopathological evaluation

Histological evaluation included an assessment and semi-quantitative scoring of lesions such as inflammation, hemorrhage, necrosis and fibrosis/fibroplasia

Summary

The RaniPill capsules were well-tolerated in all animals

No significant gastrointestinal abnormalities were associated with oral administration of the RaniPill capsule

No clinically adverse observations were noted

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Phase I Study with the RaniPill Containing Octreotide

COMPLETED	Q4 2019
Subjects	Healthy men and women, aged 18-55 years
Design	Open label, single center (Australia)
Test Articles	RaniPill Devices: 3 versions with incremental balloon sizes, each containing 100 µg of octreotide
1 Control Arm (N=6)	IV Injection of 100 µg of octreotide (*Sandostatin*®)
3 Treatment Arms (N=52)	3 cohorts of RaniPill devices with incrementally sized balloons
Primary Endpoints	Safety and Tolerability of the RaniPill capsule
Secondary Endpoint	Bioavailability of octreotide delivered via the RaniPill capsule

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Phase I Primary Endpoints: Safety and Tolerability

- Octreotide-RP capsule was well-tolerated by all subjects
- No subject had difficulty swallowing the capsule
- Capsule remnants passed out in all subjects
- No serious adverse events noted in the study

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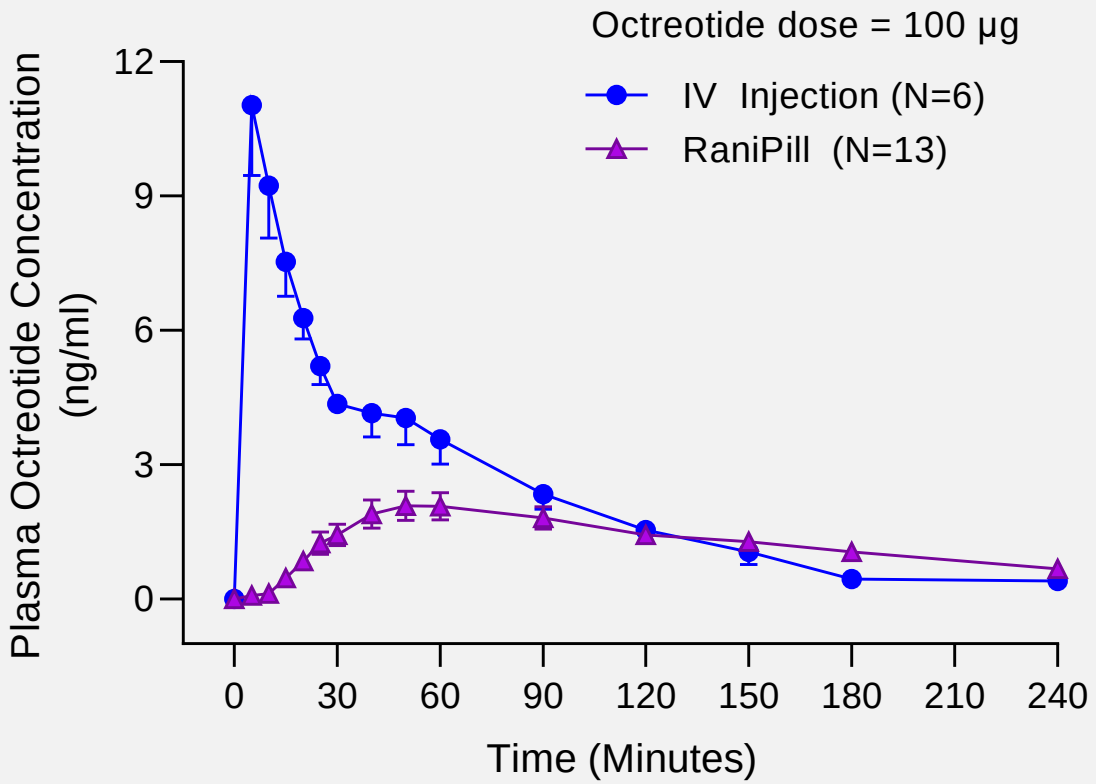
Pharmacokinetic Data: RT-101 Phase I Study



Bioavailability = 65%

RaniPill delivered Octreotide

with high bioavailability

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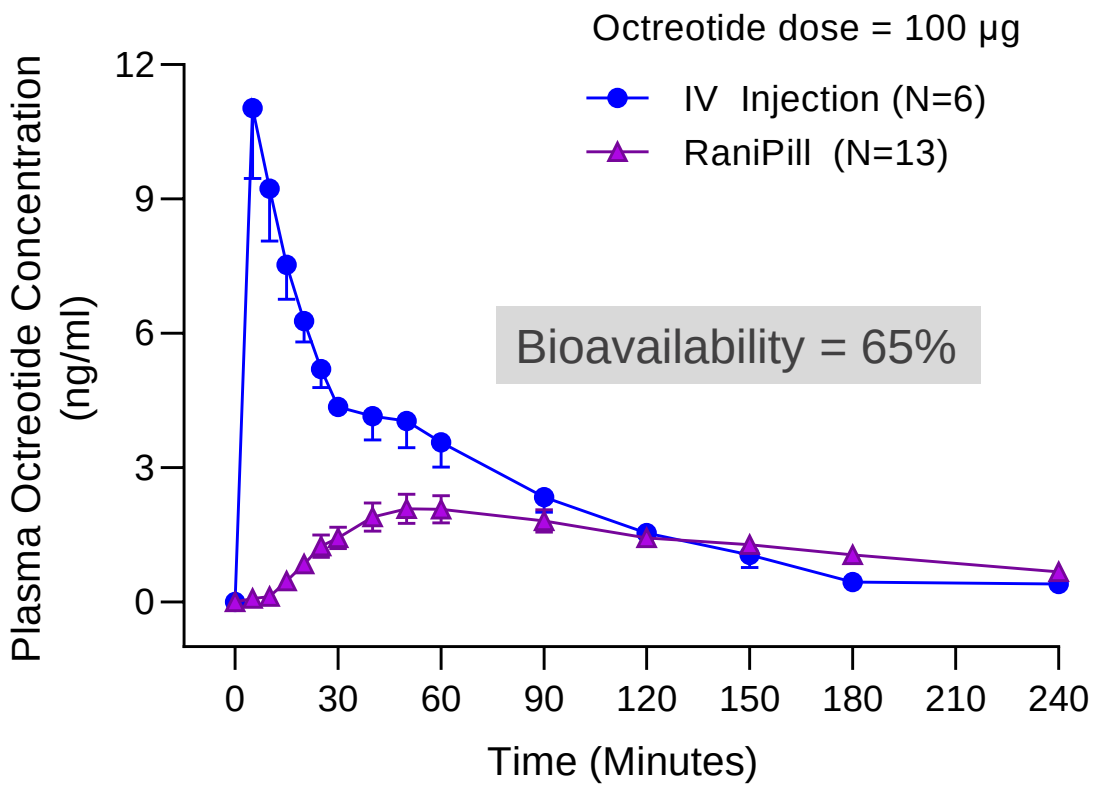
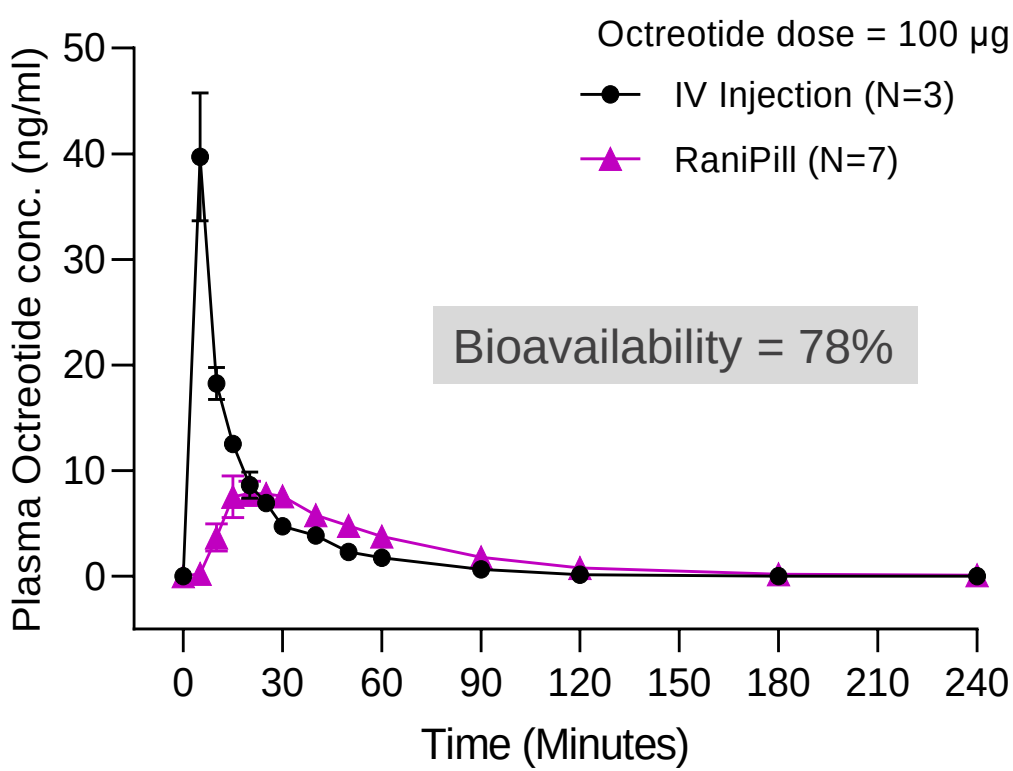
Canine Model Could Be Predictive of Human PK Data

HUMAN



CANINE



Preclinical Data from Canine Model May Translate Well to Human Clinical Development

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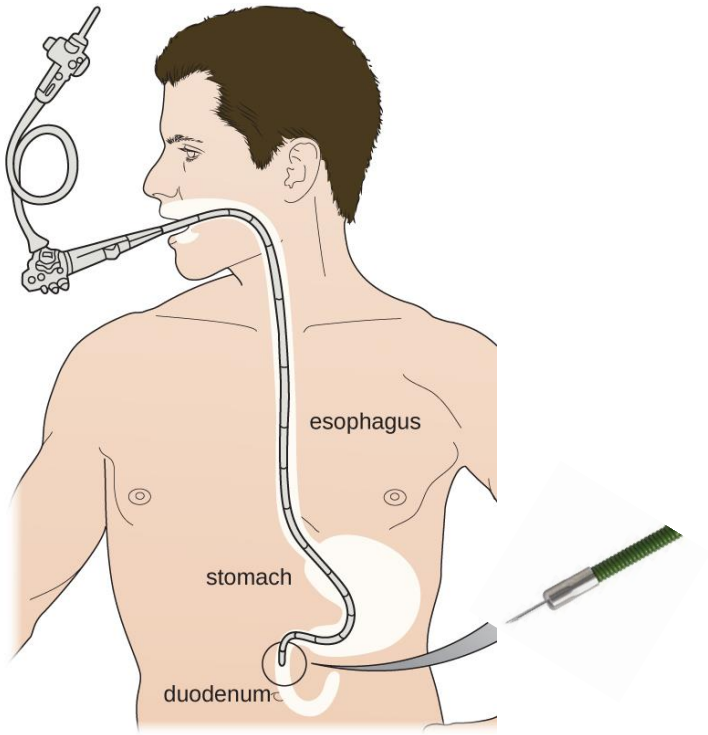
Additional Human Studies

Endoscopic Intrajejunal Administration in Humans

- Objective: to obtain an early read on the PK profile via Rani route in humans
- Methods: Using an endoscopic approach, an approved drug (commercial formulation) is injected into the jejunal wall (IJ route) to mimic the Rani route of administration
- We have determined PK of three drugs in these type of studies
  - Sandostatin (octreotide)
  - Byetta (exenatide)
  - Humira (adalimumab)



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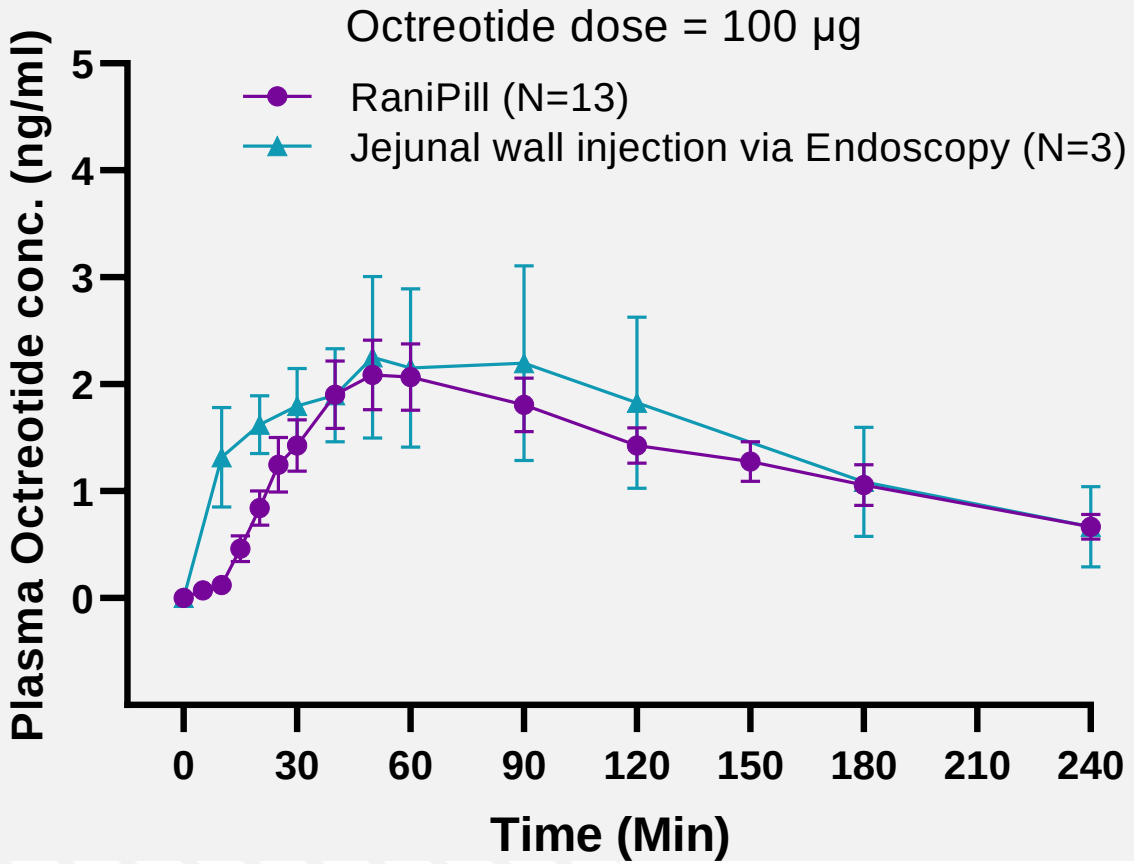
PK Data of Octreotide with Endoscopic Injections vs. Oral RaniPill



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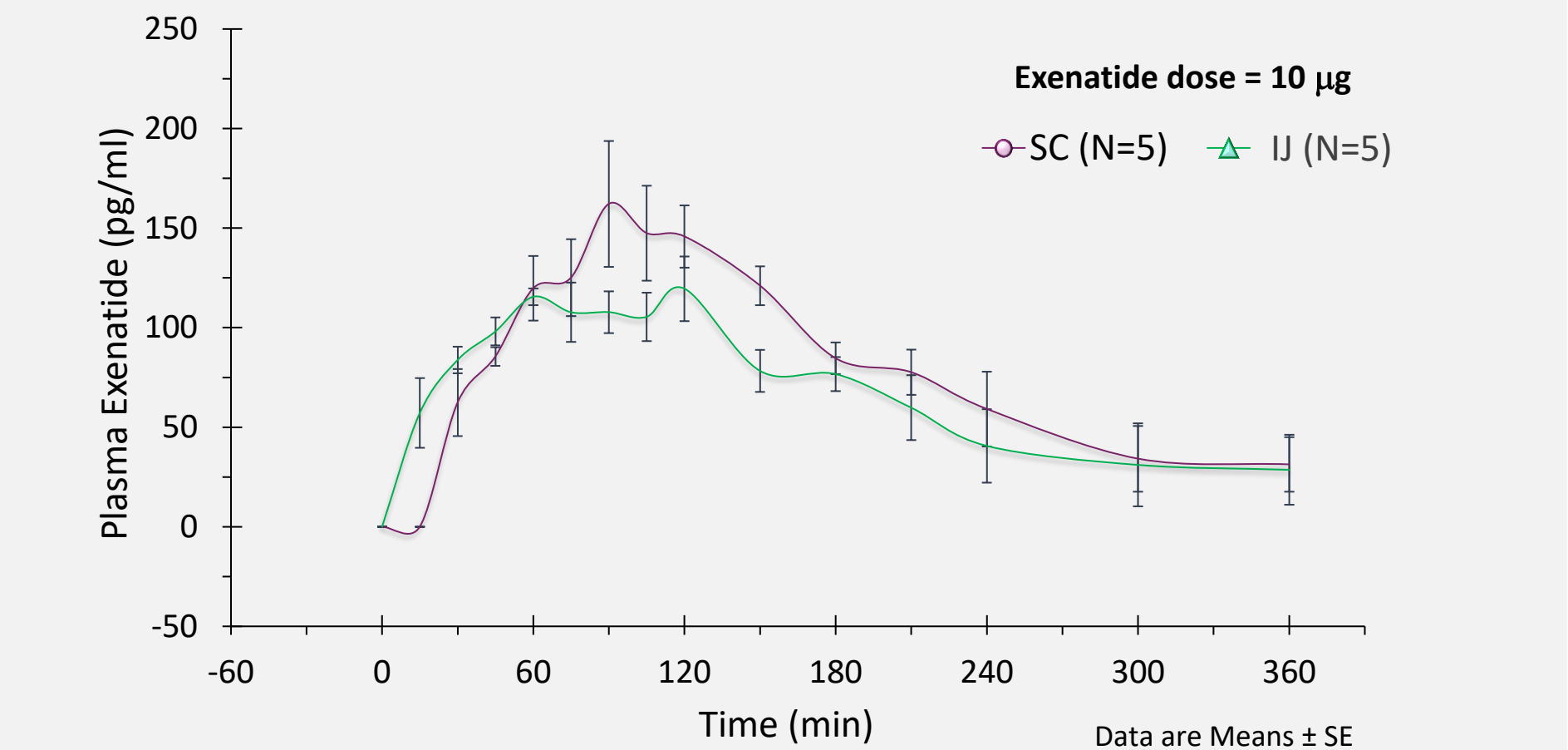
Endoscopic Intrajejunal Administration of Exenatide (GLP-1 Analog) in Humans

PK in Healthy Subjects - SC vs. Intrajejunal (IJ)



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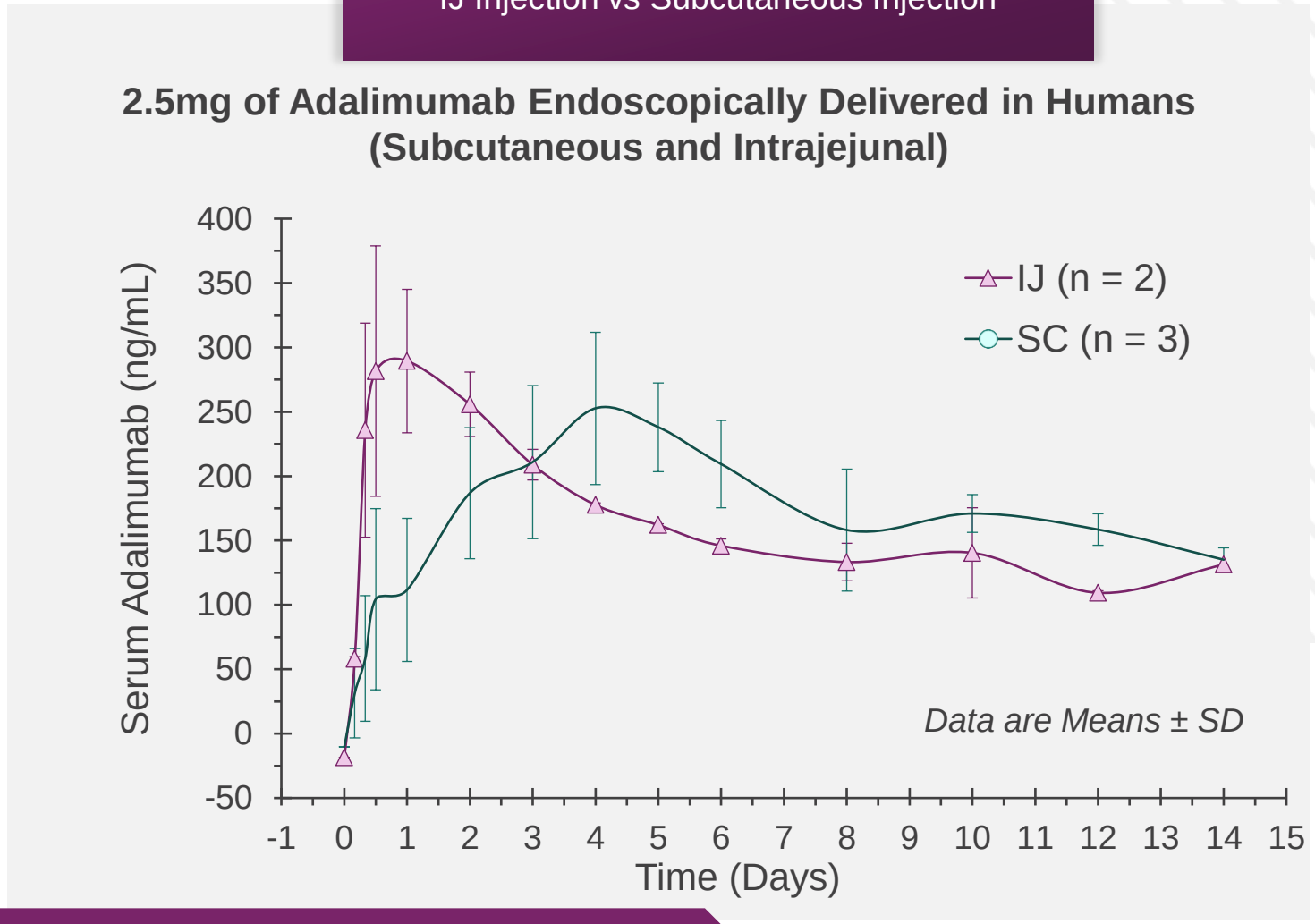
Endoscopic Intrajejunal Administration of Anti TNF-α Antibody in Humans

Humira
IJ Injection vs Subcutaneous Injection

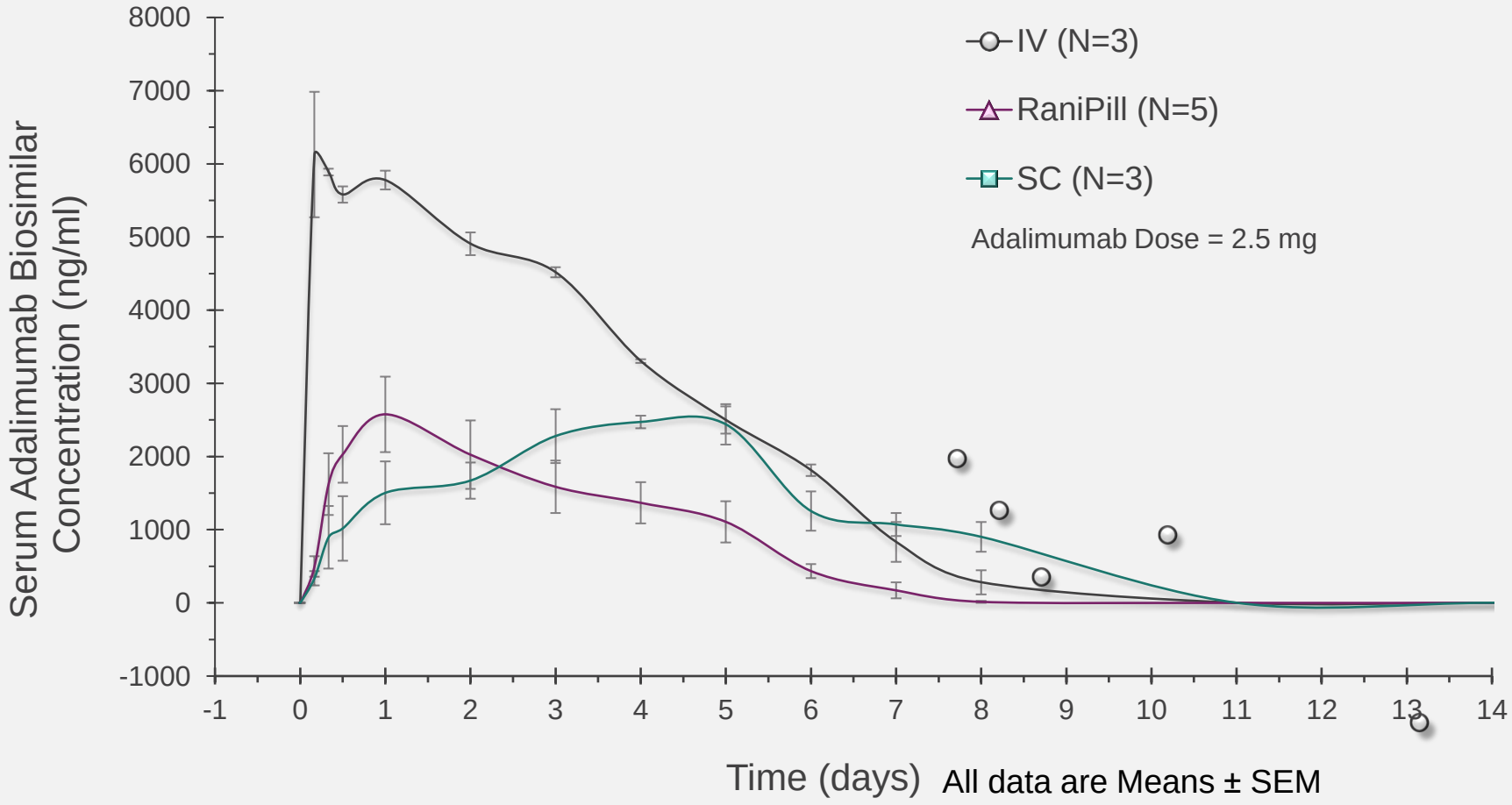


Adalimumab: Phase 1 Initiation – 2023

*Back Bay Report 2018, projected peak revenue

Additional Preclinical Studies

PK of Oral Adalimumab Biosimilar in Awake Dogs



BIOAVAILABILITY* (%)	
SC	46 ± 3
Rani	49 ± 6

**Formation of anti-adalimumab antibodies in the canine impacted the accurate determination of bioavailability*

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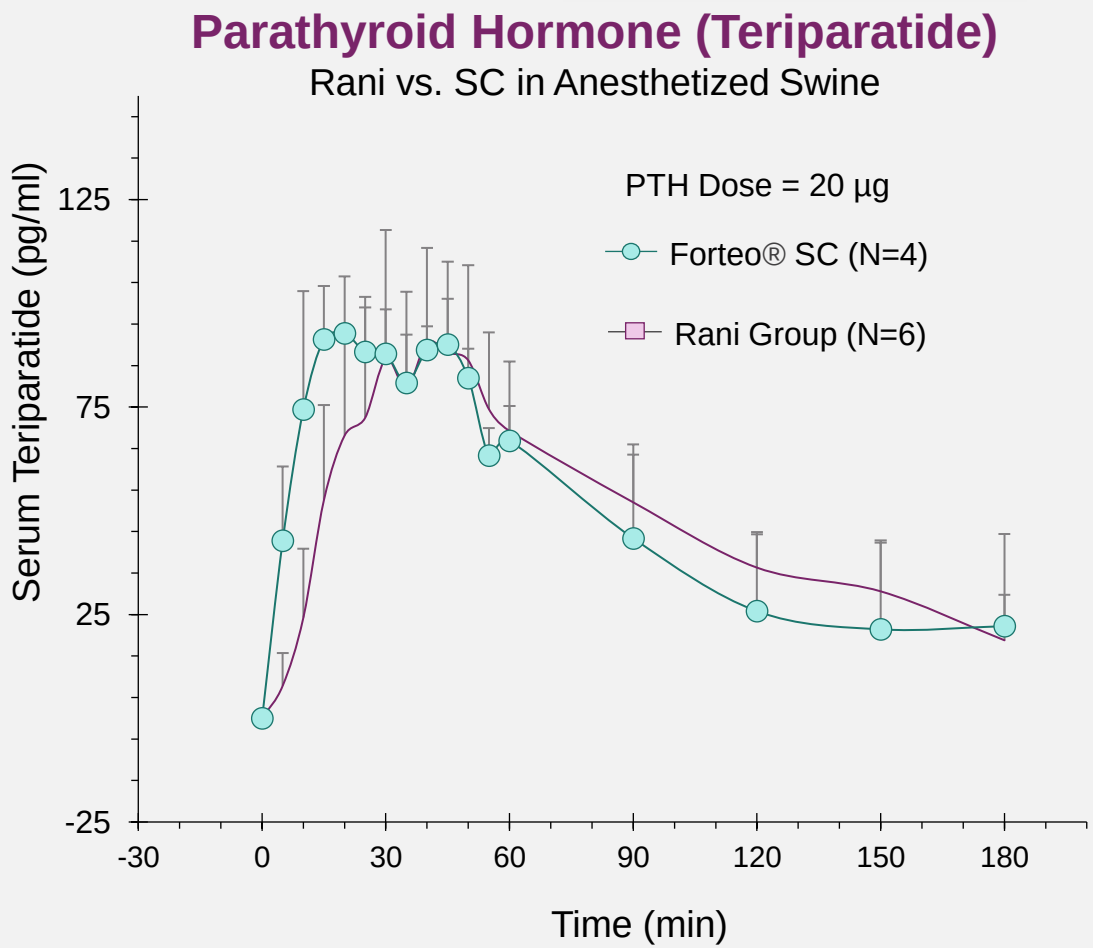
RT-110/102 - PTH (Teriparatide)

- Used in two indications:
  - Osteoporosis (OP) and
  - Hypoparathyroidism (Hypo) (rare disease)
- Must be injected daily
- PTH Market has been stable at ~$2.0B
  - Affects ~10M adult patients in the United States
  - Prevalence increasing due to aging population
  - An oral Teriparatide could dramatically increase the market
  - Teriparatide-based long-acting product demonstrated to be superior (Ascendis). Rani is working to create an oral form
  - Potential multi-billion global market

Estimated Combined Peak Sales: ~$1.4B*

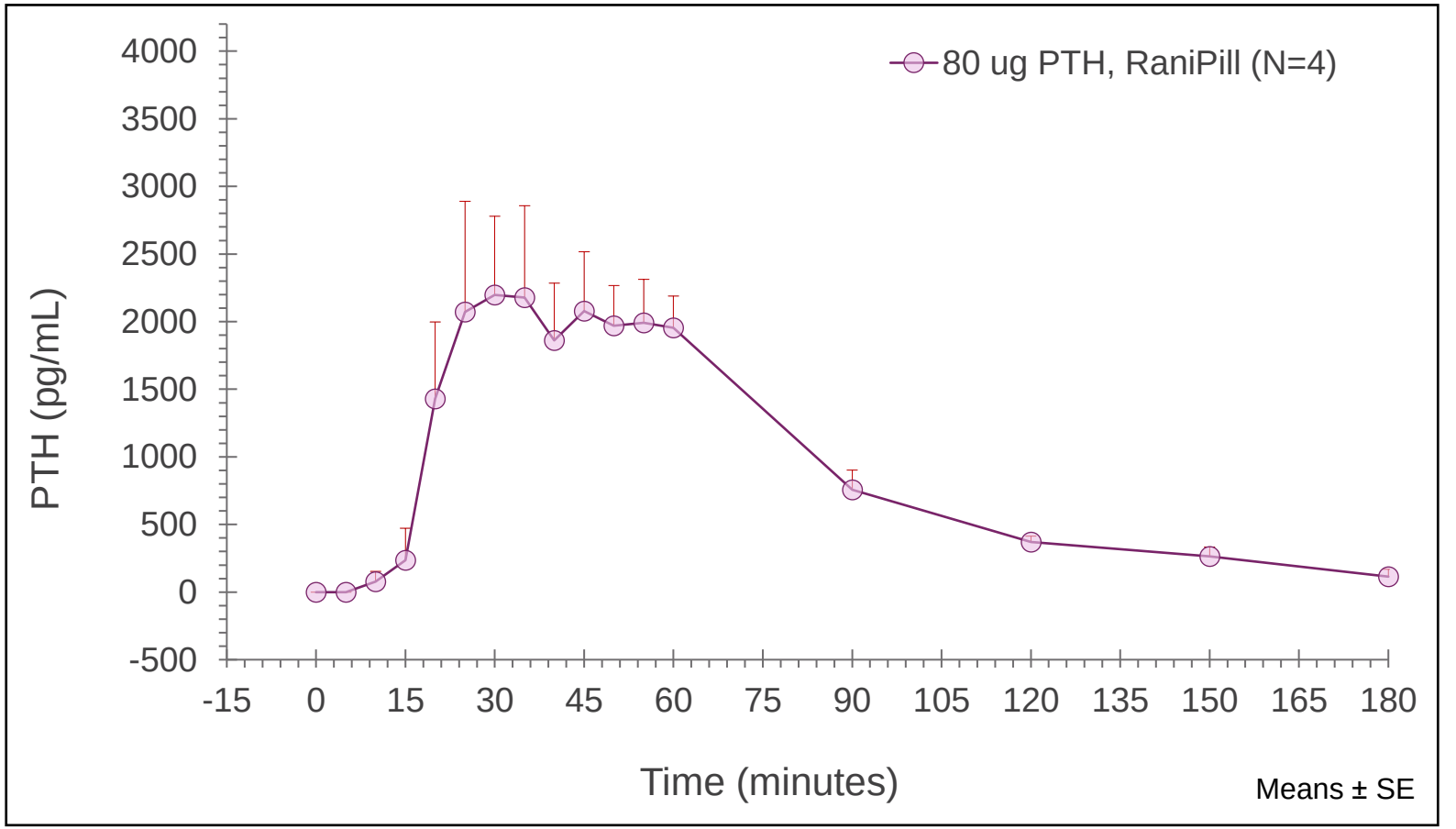


PTH-OP: Phase 1 Initiation – 2022 | PTH-Hypo: 2023

*Back Bay Report 2019, combined OP and Hypo

PK of Oral Teriparatide at 80 µg in Awake dogs

Early Preclinical Data



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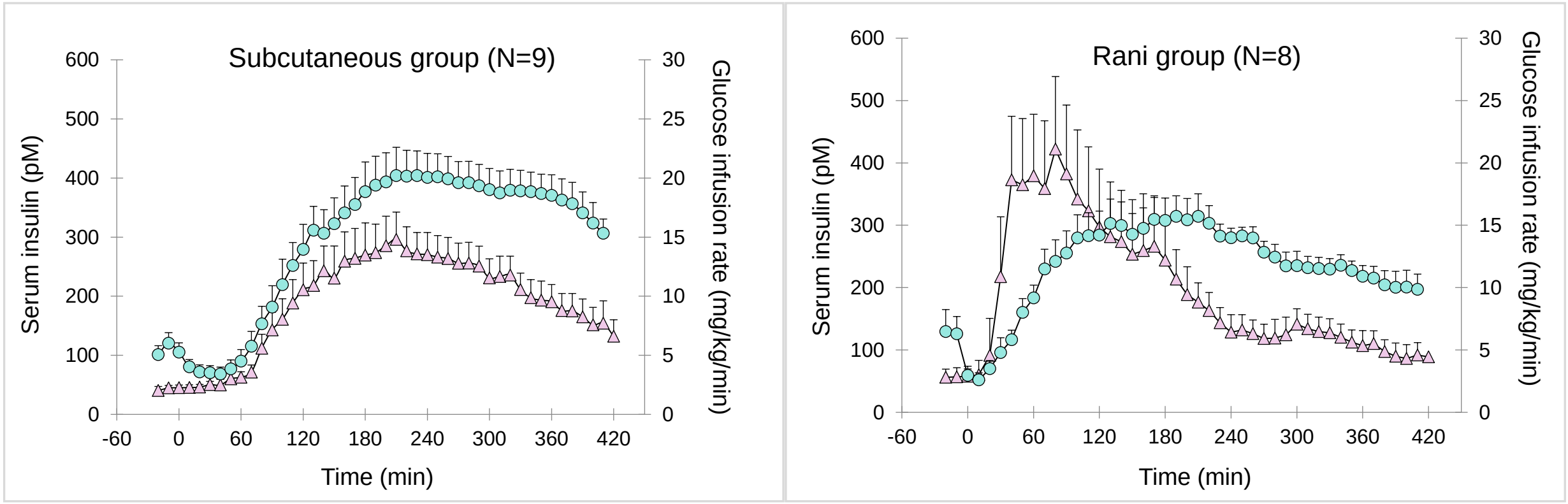
Insulin PK/PD in Juvenile Swine

Insulin dose = 20 IU



Regulatory Strategy

Regulatory Strategy

Based on Pre-submission Meeting with FDA's CDRH

IDE study to evaluate safety & reliability of the RaniPill

- 40 healthy adults, 18-50 years old
- Dosing for 8 weeks
- Using non-drug tracer

RaniPill Master File

CDRH
Center for Devices and Radiological Health

FDA

CBER/ CDER

Clinical Studies for Each Drug

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Thank You

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