



Rani Therapeutics and ProGen Collaboration

June 24, 2024



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Today's Agenda

- 01** Rani Therapeutics and Progen Introduction & Deal Overview
- 02** Obesity Strategy
- 03** Overview of Rani's Technology Platform
- 04** Overview of PG-102
- 05** RT-114 / RPG-102 (Obesity)
- 06** Q&A

Presenters



Talat Imran

- Chief Executive Officer, Rani Therapeutics
- >15 years experience in Healthcare
- Venture capitalist for several Silicon Valley healthcare funds



Jong Gyun Kim, PhD

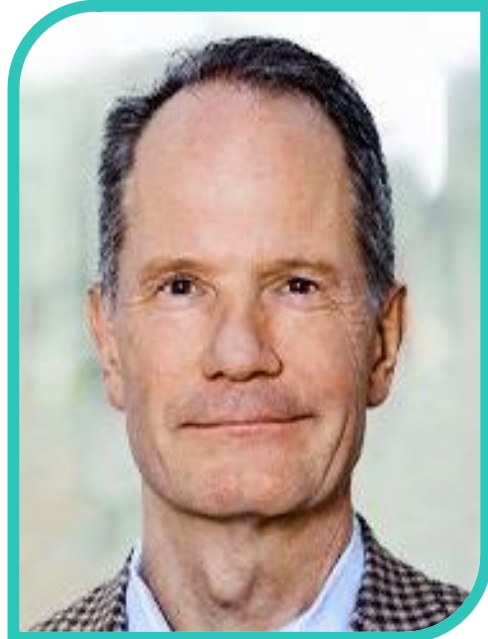
- Chief Executive Officer, ProGen
- >30 years of extensive experience in pharmaceutical industry
- R&D and strategic planning for drug development across multiple therapeutic areas

Leadership Team



Mir Hashim, PhD

- Chief Scientific Officer, Rani Therapeutics



Jesper Høiland,

- Strategic Advisor, Rani Therapeutics



Kyung-Hwa Son, PhD

- Chief Development Officer, Progen



Sae Won Kim, PhD

- Chief Scientific Officer, Progen



Our mission at Rani is to end painful injections for the millions of patients suffering from chronic diseases

Rani Therapeutics
NASDAQ: RANI

Clinical-stage biotech focused on Oral Delivery of Biologic Drugs with Bioavailability Comparable to Parenteral Products

TECHNOLOGY:

RaniPill

- 200 μ L Capacity (20-40mgs*)
- Liquid Drug Formulation

PIPELINE:

Programs across a variety of high value indications, including obesity, psoriasis, and osteoporosis

DISCOVERY:

Broad applicability across Nanobodies, Hemophilia, Bispecific MABs, Fertility, Genetic Medicine

IP:

472 Granted Patents and Pending Applications, 262 Granted Patents**

Rani's Strategic Vision in the 50 / 50 Partnership with ProGen



RaniPill



PG-102
GLP-1/GLP-2

Drug-agnostic oral delivery platform for biologics

Long-acting Fc fusion platform for multivalent agonists

Differentiated oral delivery mechanism, with bioavailability comparable to SubQ injection

Differentiated anti-obesity mechanism, with preclinical data showing improved body composition compared with Tirzepatide

Clinically demonstrated equivalent PD to SubQ delivery of GLP-1 through Rani route of administration – at the same dose

Clinically demonstrated favorable safety and differential PK profiles

Versatile delivery platform with broad applicability to address significant opportunities across large market indications in immunology, endocrinology, and beyond

Versatile metabolic benefits with broad applicability to address significant opportunities across broad market indications including T2D, MAFLD/MASH and CVD

Deal Rationale:

- ✓ Targeting optimized delivery + optimized therapeutic
- ✓ Differentiated oral, low dose, convenient once-weekly GLP-1 / GLP-2 agonist, with potential to preserve lean mass & improve nutrient absorption
- ✓ Validating preclinical and clinical data

Rani / ProGen Deal Structure

Rani and ProGen have entered into a collaboration agreement for the development and commercialization of a RaniPill capsule containing PG-102 (GLP-1 / GLP-2 dual agonist) for weight management (including obesity).



Deal Structure

- No upfront payment
- Co-Development Deal
- 50/50 WW revenue and cost share
- Development initially focused on major markets



Commercial Rights

- Rani holds exclusive rights to commercialize in the US, Europe, UK, Canada and Australia
- ProGen holds exclusive rights to commercialize in rest of world
- Each party has the right to sublicense within its territories



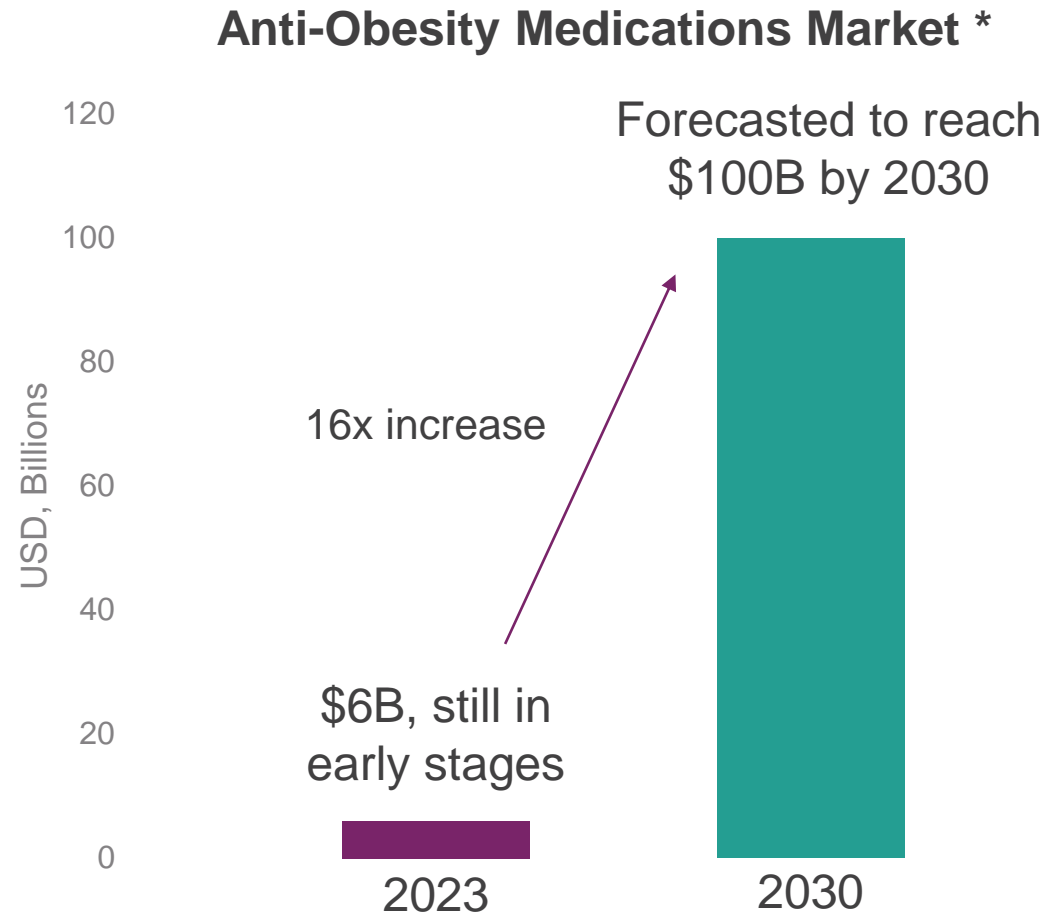
Manufacturing

- ProGen manufactures the drug substance
- Rani manufactures the drug product

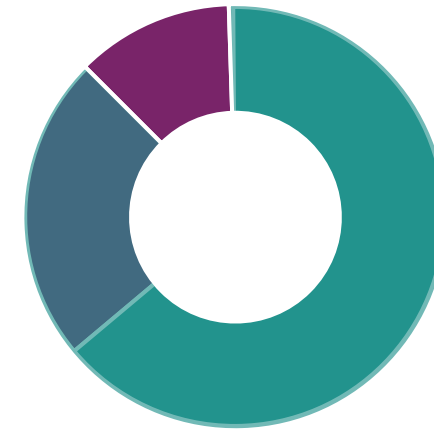


Obesity Strategy

Obesity is a Fast-Growing Market; Potential for Oral Options to Play an Important Role



Across various therapeutic areas, patients prefer daily pill over current injection regimen **



64%-88% of patients with injection regimens of daily to every 6 months

* *Why the anti-obesity drug market could grow to \$100 billion by 2030*, Goldman Sachs published 30 Oct 2023

RaniPill Delivery Technology May Solve for the Shortcomings of Current Orals in Development



Low Bioavailability

Oral chemistry-based formulations demonstrate **bioavailability as low as <1%** ^[1]



High API Cost & Supply Chain Issues

Extremely high doses to reach therapeutic effectiveness

- Novo's Oral semaglutide **350mg** per week vs Wegovy **2.4 mg** injectable dose (145x higher dose) ^[2]
- Novo's Oral amycretin and Viking's oral GLP-1/GIP may require **280-350 mg of API/week** to compete ^[3]



Restrictive Administration Requirements

Restrictive pre-treatment requirements can impact efficacy and patient adherence

- Rybelsus (oral semaglutide) patients instructed to take drug **in fasted state** as it may increase absorption ^[4]
- Rybelsus clinical success rate 67% ^[5]



Inconvenient Dosing Regimen

BID or daily dosing often required to reach therapeutic serum concentrations



Tolerability Risk

Twice-daily Danuglipron (small molecule) **discontinued** due to **tolerability issues and discontinuation rates** ^[6]

RaniPill

Potential Advantages



Significantly better bioavailability than other oral biologic technologies



Significantly less API amount and cost needed than current orals in development



No evidence of food effect so may avoid restrictive administration requirements

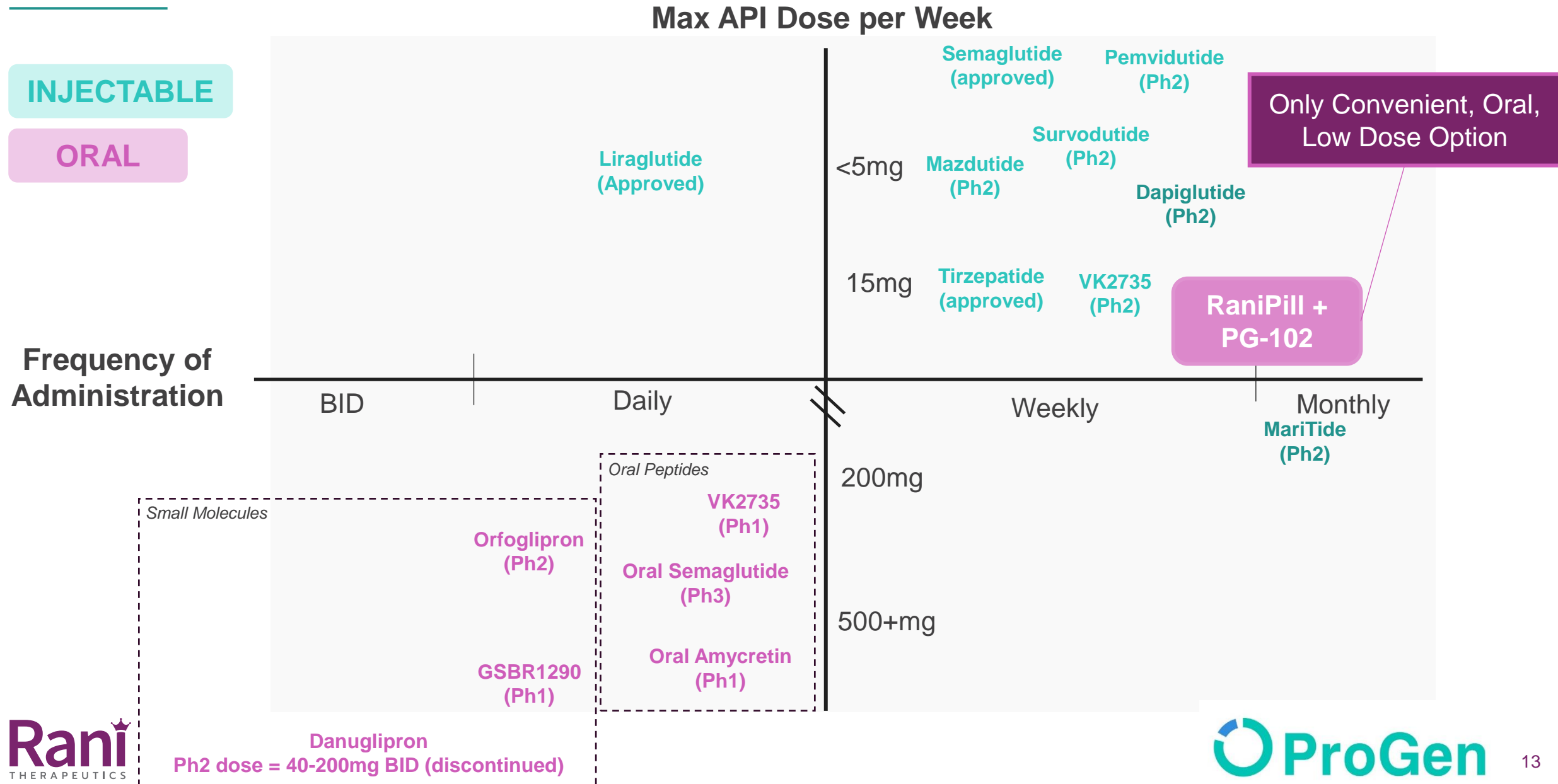


Can dose infrequently compared to other orals (weekly or monthly)



Can dose more frequently than SC to limit tolerability issues

Clear Opportunity in Obesity Landscape for RT-114/RPG-102 [7]





Overview of Rani's Technology Platform

RaniPill Development Progress and Safety

Preclinical

15 Molecules Assessed

antibodies, peptides, and large proteins
delivered with high bioavailability

>7000 Capsules

tested *in vitro* & *in vivo*

60-Day GLP Study

completed with no clinical findings

Clinical

3 Phase 1 Studies*

completed

233 RaniPill Capsules

administered to 146 humans

7-Day Repeat Dose Study

completed



* As of 3/1/24; clinical studies with
solid-dosage form

Well-Tolerated with No Serious Adverse Events Observed in
Clinical Studies Completed to Date

Demonstrated Equivalent PD to SC through Rani Route of Administration

– At Same Dose

Objective

- To evaluate the PK-PD profiles of Triagonist (a unimolecular incretin agonist for GLP-1, GIP and Glucagon receptors) in Beagle dogs delivered SC or via endoscopically guided transenteric injection (to mimic the Rani route of administration)

Subjects

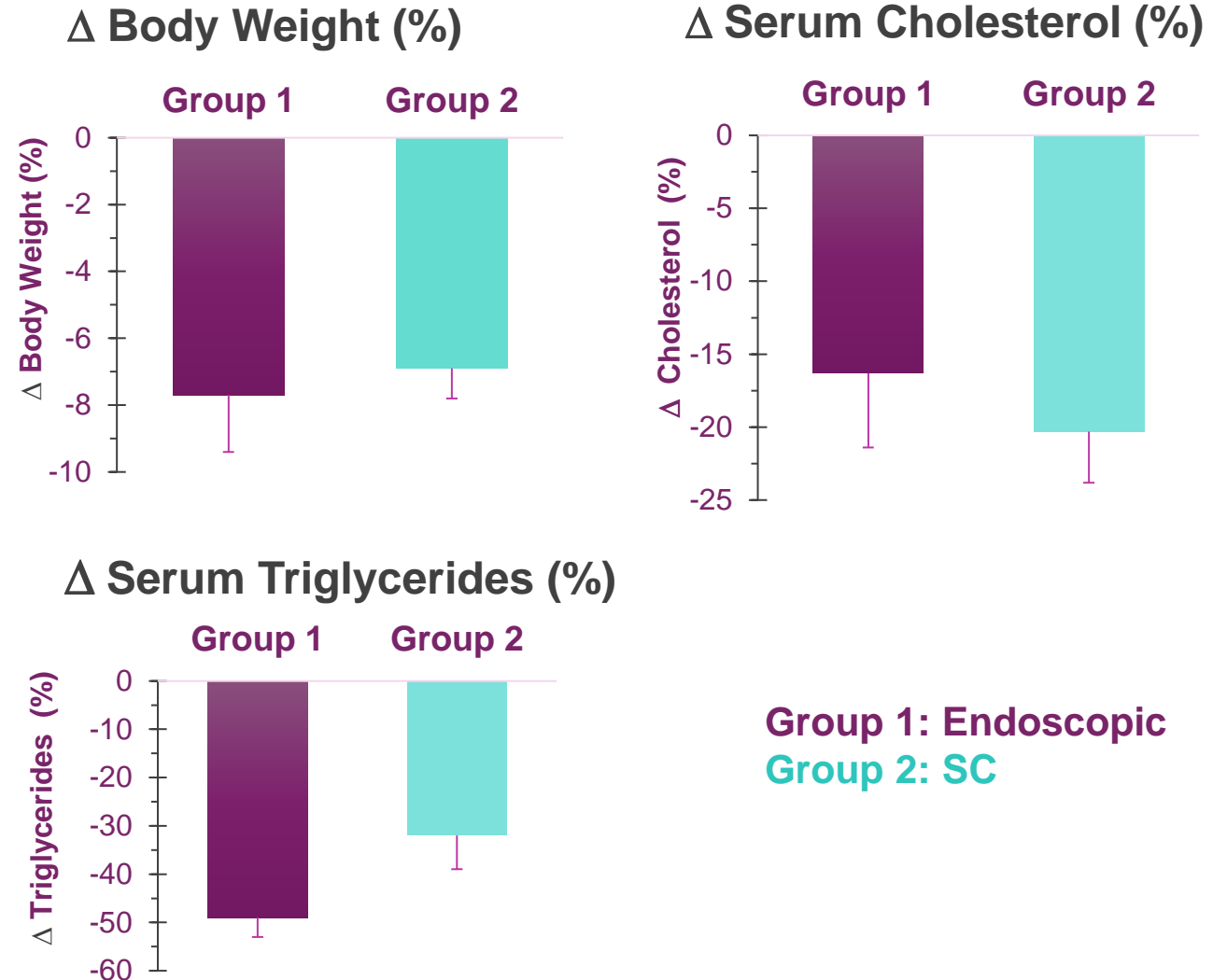
- Beagles, adult male, 11 - 13 kg, Total N=10

Test Groups

- Group 1 Transenteric (N=5): Triagonist, 0.12mg/kg (0.05ml/kg) injected via endoscopic access
- Group 2 SC (N=5): Triagonist, 0.12mg/kg (0.04ml/kg) injected subcutaneously

Protocol

- All animals were dosed after an overnight fast
- Over 2 weeks, fasted body weights were taken, and blood samples were serially collected for tracking serum drug concentrations and various PD & safety biomarkers

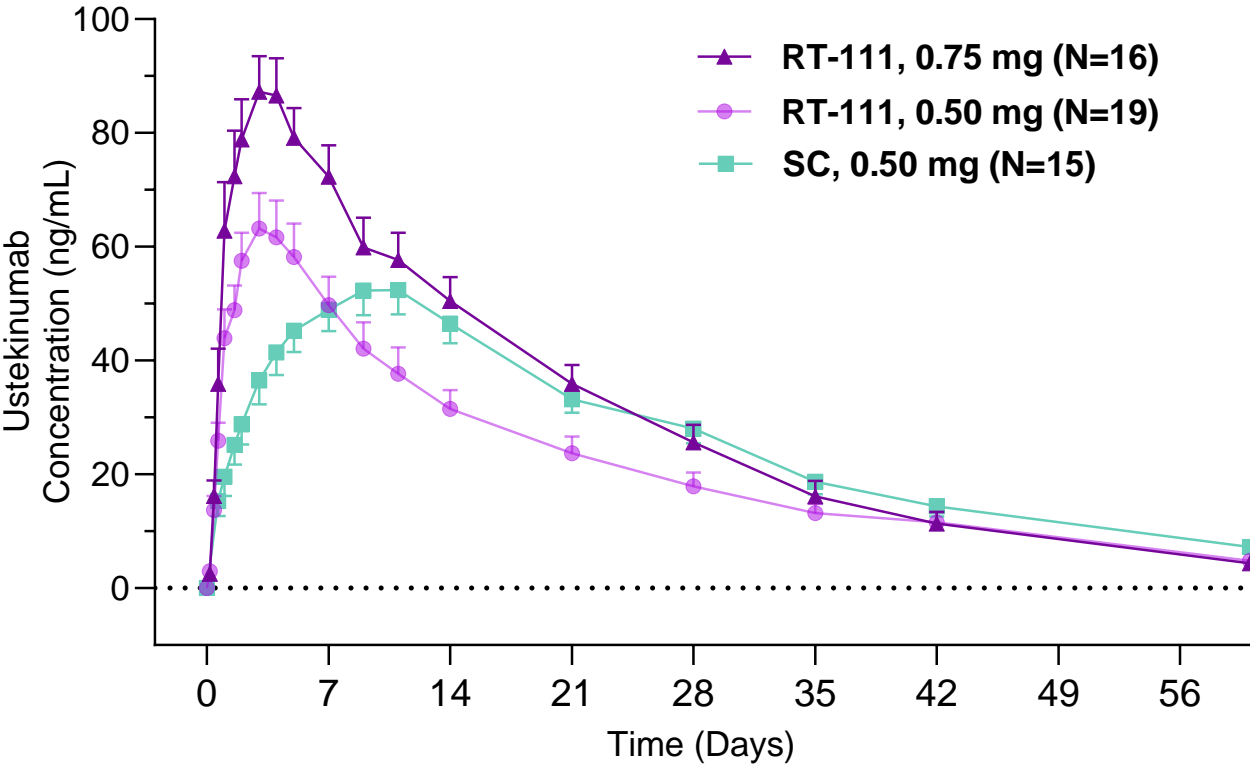


Rani Has Demonstrated Bioavailability Comparable to Subcutaneous Injection in Preclinical and Clinical Studies

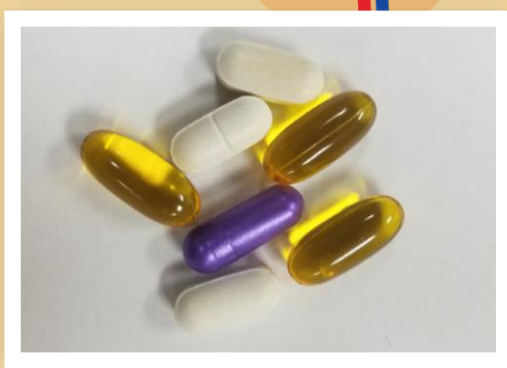
Biotherapeutic	Mean RaniPill Relative Bioavailability Compared to SC*
Ustekinumab Biosimilar	91-159%
Dupilumab	89-102%
Adalimumab Biosimilar	93-103%
FSH alpha/Gonal-F	110-146%
Exenatide	80%

* Data from preclinical head-to-head studies conducted by Rani.

PK Profiles of Single Doses of RT-111 (Oral Ustekinumab Biosimilar) vs SC Stelara® Injection



Data shown are Mean ± SE,
SC = Subcutaneous injection



Rani's Approach

- Designed to deliver any biologic
- Painless, transenteric injection
- Highly efficient route of delivery
- Bioavailability comparable to a subcutaneous injection

Mucosal cell barrier
prevents drug
absorption

Chemical Approach

- Only applicable to small peptides
- Highly inefficient delivery
- Poor bioavailability, typically $<1\%$
- High variability



Overview of PG-102



*Our Mission at Progen is to Improve Patients' Quality of Life
with Longer-acting Protein Therapeutics*

Progen
KONEX: 296160

**Clinical-stage Biotech Company Developing Next Generation Long-acting,
Multi-specific Fusion Protein Therapeutics**

TECHNOLOGY:

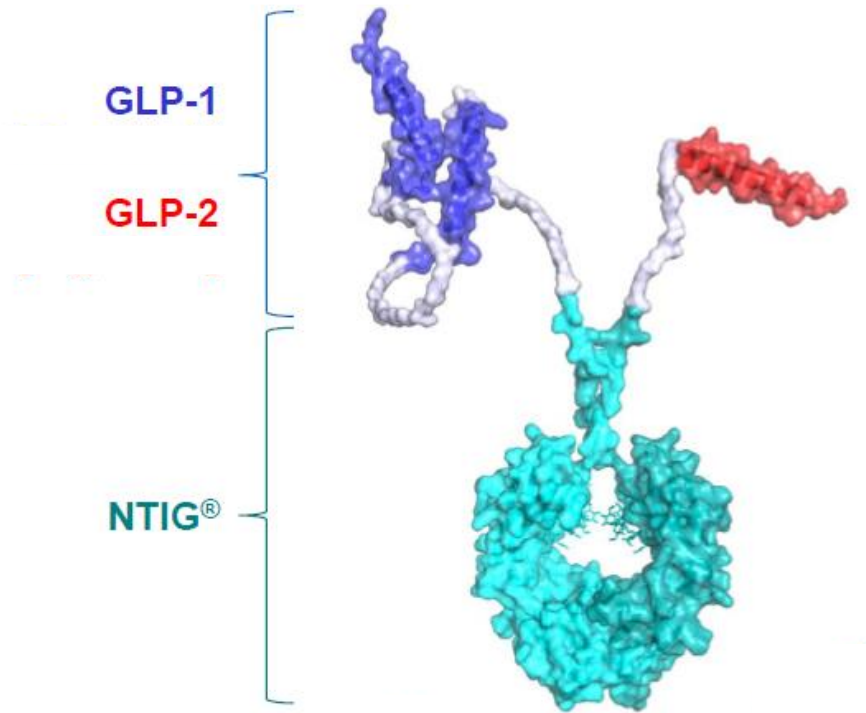


- Multi-specific Fc fusion protein
- Long-acting injectables

PIPELINE:

- PG-102 for Obesity & T2D (Phase 1)
- Bispecific ADCs for Autoimmune diseases & cancer

PG-102: Long Acting, Bispecific GLP-1/GLP-2 Dual Agonist for the Treatment of Obesity



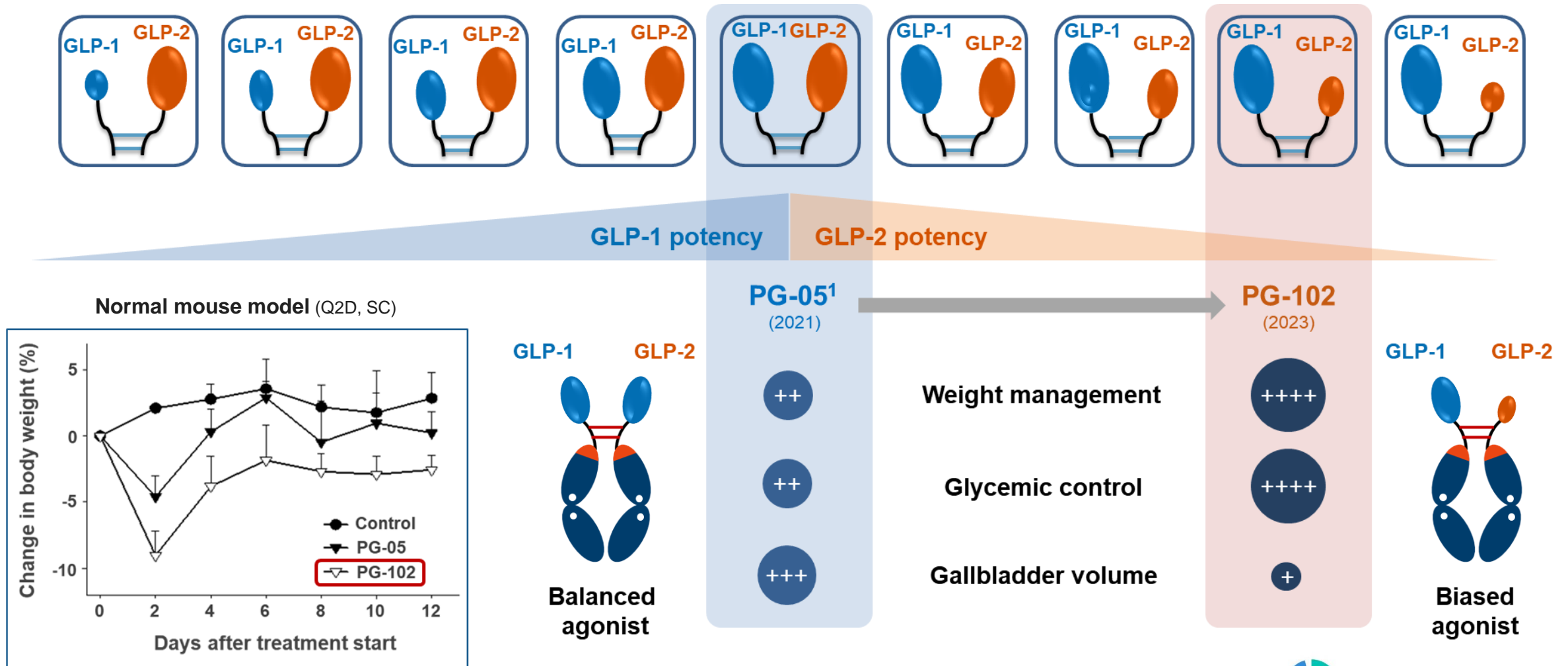
▶ Bispecific GLP-1/GLP-2, with optimized ratio biased toward GLP-1

▶ Heterodimeric Fc Fusion Protein

▶ Prolonged Half-Life

PG-102: An Experimentally-optimized, Biased Agonist

Biased agonism provided better weight management & glycemic control



Source: 1. Kim ER et al., Hepatology. 2022 Jun;75(6):1523-1538 .
Q2D=once every 2 days; SC=subcutaneous


Phase 1a SAD Results Show Good Tolerability

Target Population	Healthy Subject
Administration	Single
Dosing Regimen	PG-102 vs Placebo
Primary Endpoint	Safety / Tolerability / PK
N=	8 Subjects per Group

Safety and Tolerability are a main concern with metabolic therapies due to high discontinuation rates

Summary of treatment-emergent adverse events (during 28-day period, Phase 1 SAD)

TEAEs	PG-102				
	Placebo	5 mg	15 mg	30 mg	60mg
Decreased appetite	0	0	1 (12.5%)	2 (25%)	2 (25%)
Nausea	0	0	0	0	3 (37.5%)
Diarrhea	1 (12.5%)	0	0	0	0
Vomiting	0	0	0	0	1 (12.5%)
Dyspepsia	0	1 (12.5%)	0	2 (25%)	2 (25%)
Constipation	1 (12.5%)	0	0	1 (12.5%)	0

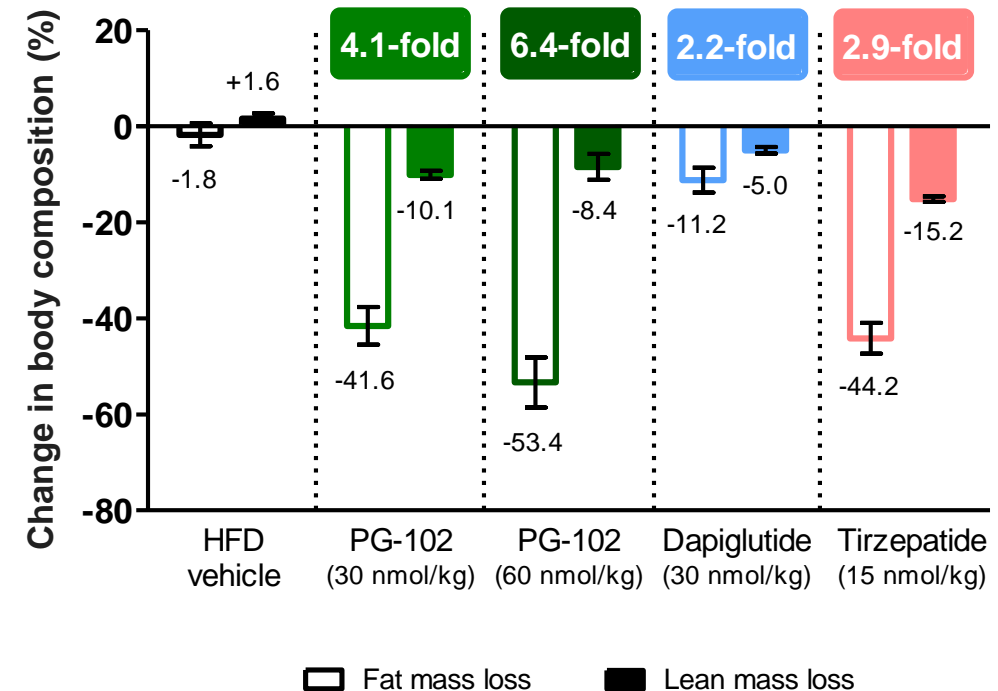
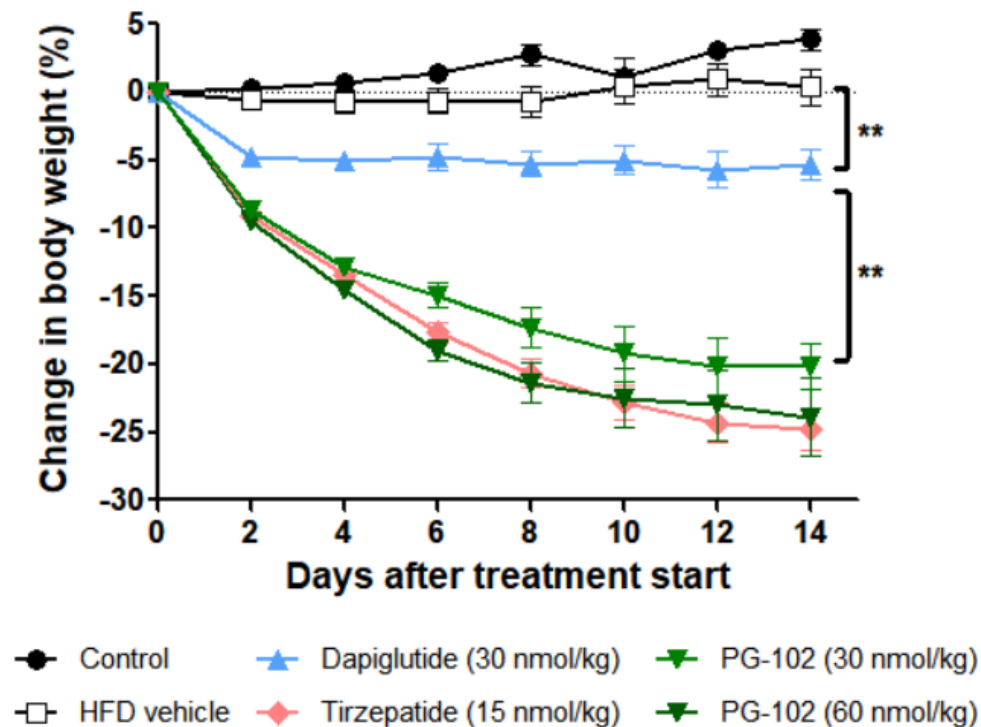


RT-114 / RPG-102 (Obesity)

Differentiation, Dosing and Development

PG-102 Reduces Body Weight & Improves Body Composition (DIO mice)

Improvement of body composition (fat vs. lean mass loss),
under similar weight loss condition (vs. Tirzepatide)

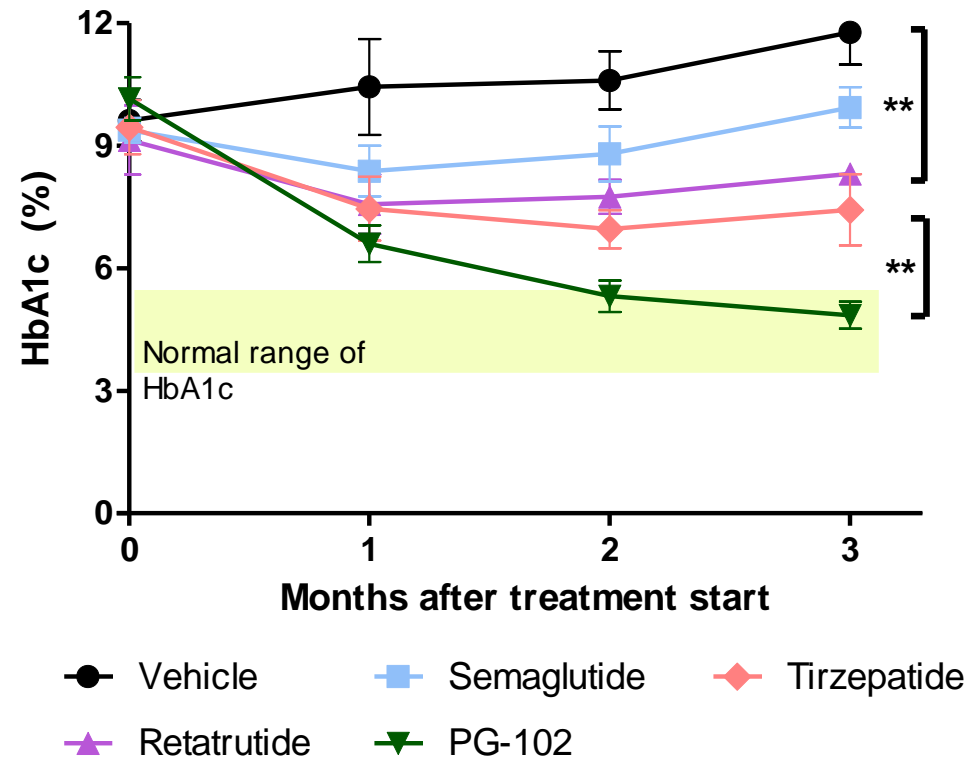


**p<0.01. Data are shown in \pm SEM.

DIO=diet-induced obesity; HFD=high fat diet; SEM=standard error of the mean; VAT=visceral adipose tissue; SAT=subcutaneous adipose tissue
Source: Timothy Oh et al., The Effect of Bispecific GLP-1R/GLP-2R Agonist Compared with Dual GLP-1R/GLP-2R Agonist and Dual GLP-1R/GIPR Diet-Induced Obesity Mouse Model. Presentation at the 83rd ADA Annual Meeting.; †Jastreboff AM et al., N Engl J Med. 2022 Jul 21;387(3):205-216

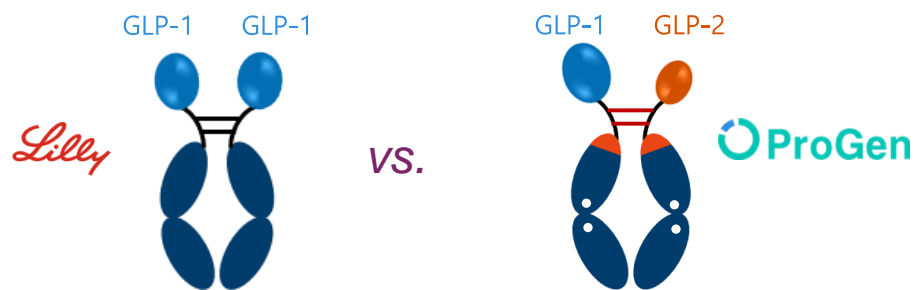
PG-102 Demonstrated Greater Glycemic Control vs Semaglutide, Tirzepatide and Retatrutide (*db/db* mice)

At the same dosage level (30 nmol/kg), PG-102 exerts greater glycemic control than semaglutide, tirzepatide and retatrutide

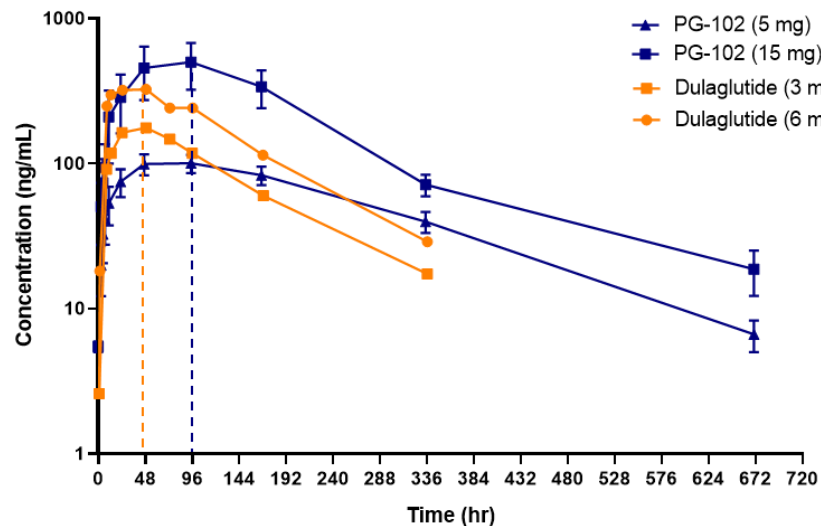


PG-102: Pharmacokinetic Profile

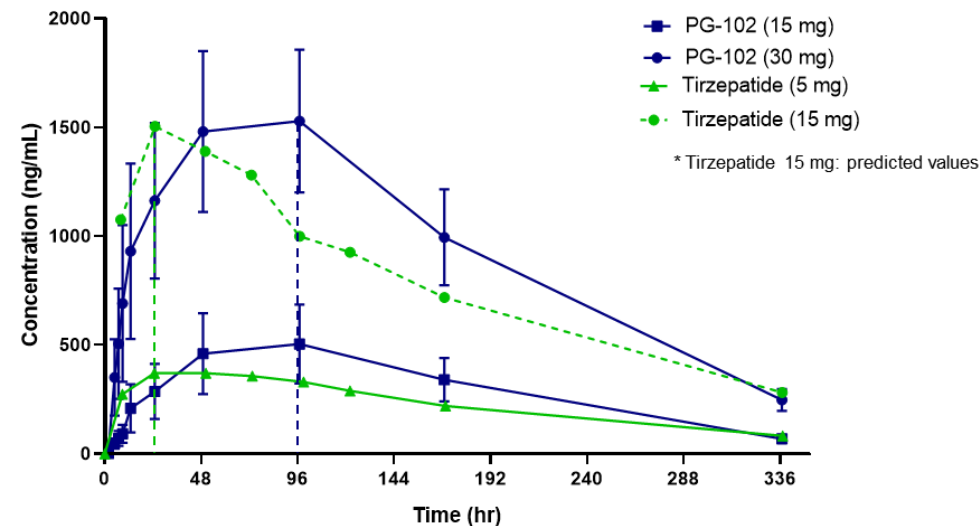
PG-102 shows longer T_{max} & higher AUC_{last} → Tolerability & persistence ↑



PK profile (PG-102 vs Dulaglutide¹)



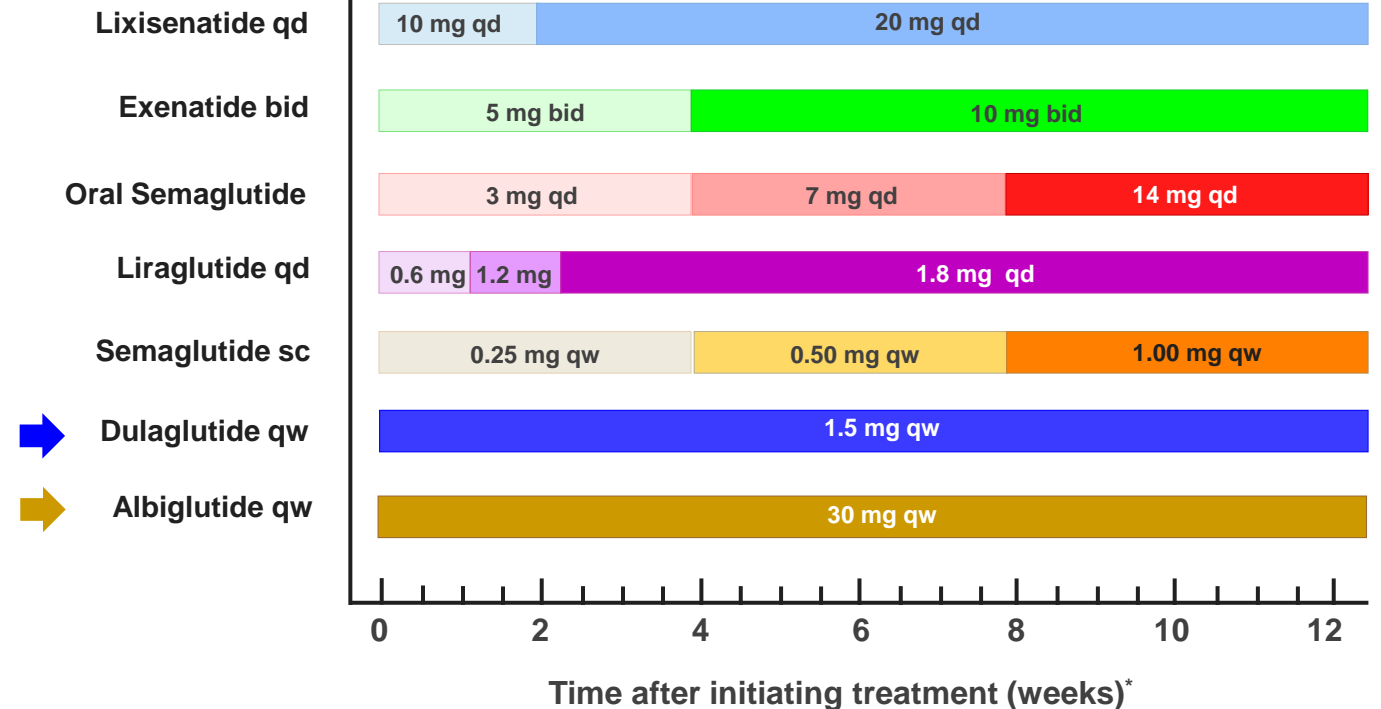
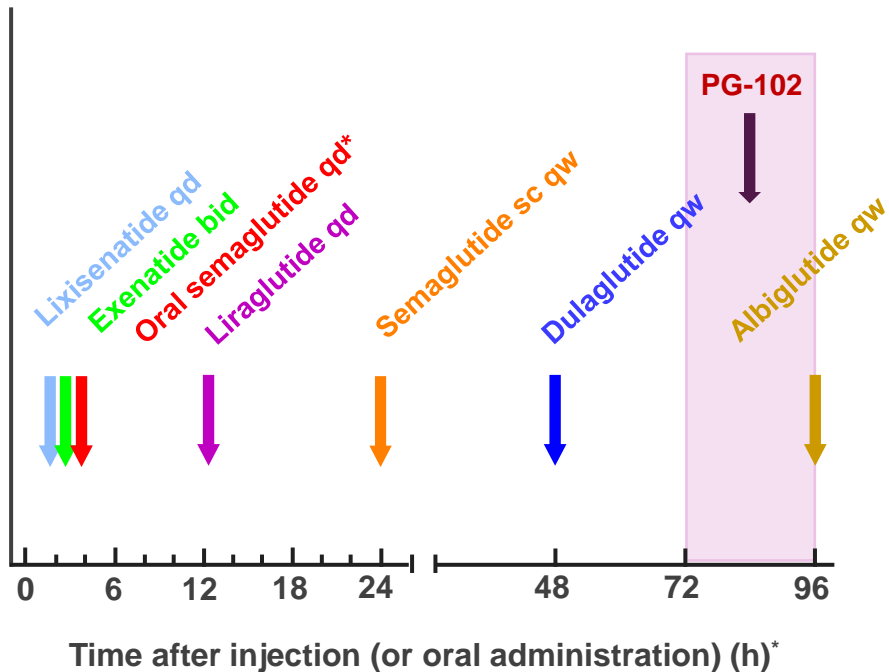
PK profile (PG-102 vs Tirzepatide²)



Association between T_{max} & Up-titration

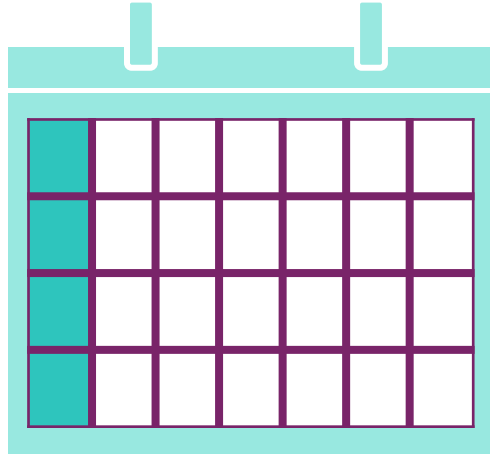
Long T_{max} may obviate need of up-titration

Time to reaching maximum plasma concentrations after injection or oral administration²



* Nauck MA et al. Mol Metab. 2021 Apr;46:101102.
BID=twice a day; qd=once daily; qw=once weekly

RT-114/RPG-102 Target Dosing



Once a Week Oral Dosing

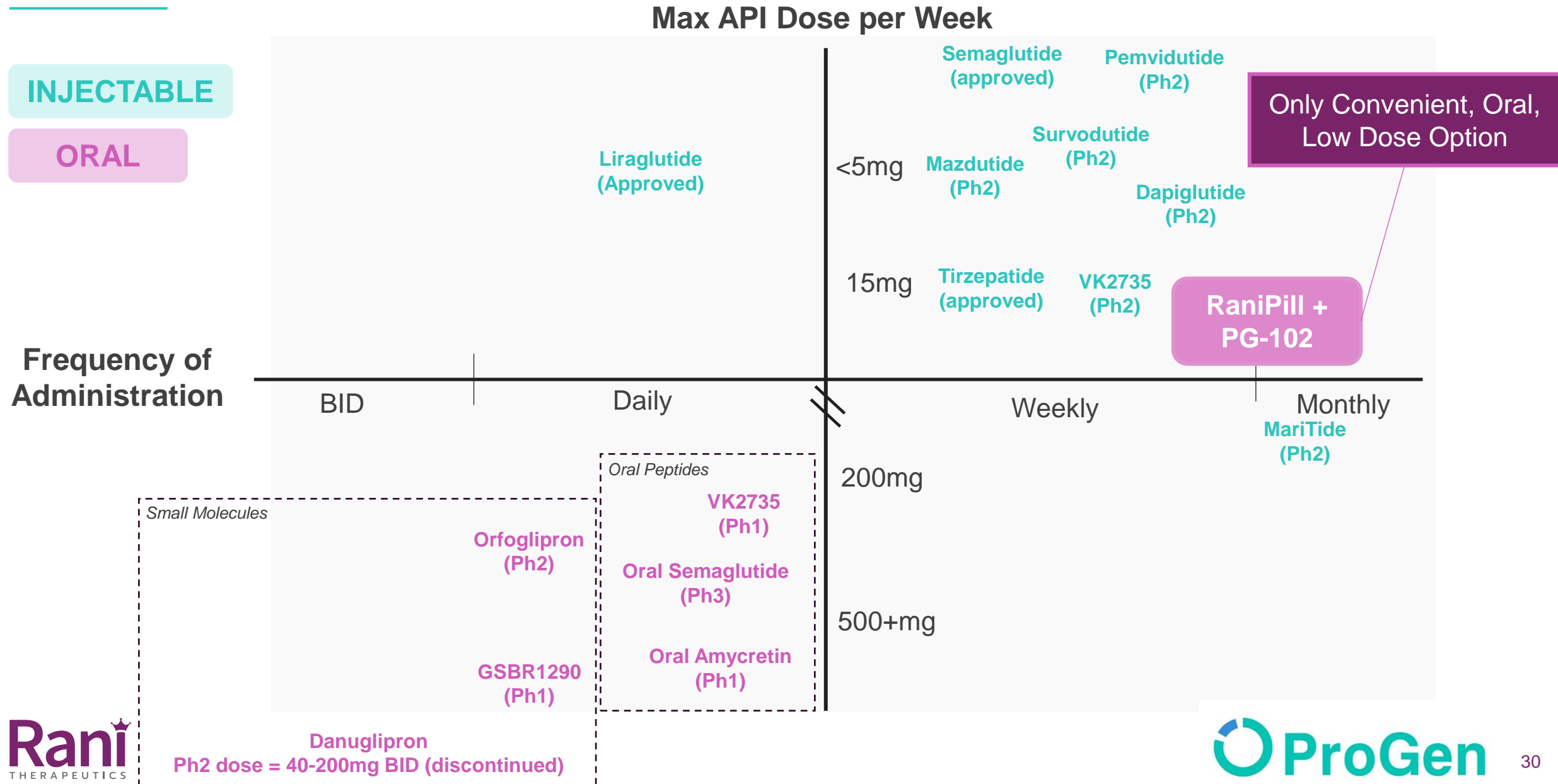
Potential for Monthly Dosing

Total of 52
pills per year
per patient

Key Benefits Targeted:

- No painful injections
- Potential for better tolerability with more frequent, smaller doses than injectable
 - Tighter banding of serum concentrations
- Potential for less frequent administration than oral competitors
 - Other orals expected to require daily or BID dosing
- Potentially no dose titration required
- Less API required compared to chemistry based oral approach

Clear Opportunity in Obesity Landscape for RT-114/RPG-102 [7]



Expected Clinical Development Timeline for RT-114/RPG-102



Phase 1A and 1C

Study Phase	1A	1C
Study Population	HV (BMI 18-30 kg/m ²)	Obese (non-diabetic) (BMI 30-39.9 kg/m ²)
Sample Size	30	40
Design	Open-label	Open-label
Objective(s)	<ul style="list-style-type: none"> ▪ Safety (TEAEs & SAEs) ▪ PK ▪ BA ▪ PD marker 	<ul style="list-style-type: none"> ▪ Safety (TEAEs & SAEs) ▪ PK ▪ PD (% change in BW, lipids, glucose, insulin, C-peptide, glucagon)
Dose group(s)	<ul style="list-style-type: none"> ▪ RaniPill 15 mg (N=10) ▪ RaniPill 30 mg (N=10) ▪ SC Injection 15 mg (N=10) 	<ul style="list-style-type: none"> ▪ Placebo (N=15) QW ▪ RaniPill XX mg (N=15) QW ▪ RaniPill XX mg (N=15) QM/Q2W
Treatment period (F/U)	Single ascending dose - 4 weeks F/U	Repeat Doses 4-7 weeks - 4 weeks F/U
Study duration	4-5 months	6-9 months

Phase 2a Obesity
(12 weeks treatment)

Potential Differentiation of RT-114/RPG-102



Efficacy

- Potential greater fat mass loss & less lean mass loss than competitors
- Potential for improved nutrient absorption and nutritional status



Safety

- Potential less GI side effects (nausea, vomiting, diarrhea)
- Eliminate injection site reactions
- Reduce risk of off-target effects compared to oral small molecules
- Potential to improve tolerability without needing to titrate dosing



Convenience

- Long-acting and oral dosing
- Potential for weekly or monthly dosing
- Do not anticipate food impact or mealtime restrictions



COGS

- Less API required than chemistry-based oral options due to similar bioavailability to SC injections
- Expect competitive commercial COGS



Q&A

References

- [1] Rybelsus U.S. prescribing information, *Pharmacokinetics*.
- [2] For Wegovy, see U.S. prescribing information, *Dosage and Administration*. For oral semaglutide, *Oral semaglutide 50 mg taken once per day in adults with overweight or obesity (OASIS 1): a randomised, double-blind, placebo-controlled, phase trial*, Prof Filip K Knop, MD, The Lancet, 25 Jun 2023.
- [3] For oral amycretin, *Novo Nordisk's oral amycretin outshines Wegovy in early obesity study*, Anna Bratulic, FirstWord PHARMA, 07 Mar 2024. For VK2735 oral, *Viking Therapeutics Announces Results from Phase 1 Clinical Trial of Oral Tablet Formulation of Dual GLP-1/GIP Receptor Agonist VK2735*, Viking Therapeutics press release, 26 Mar 2024.
- [4] Rybelsus U.S. prescribing information, *Indications and Usage*.
- [5] Granhall et al, *Clinical Pharmacokinetics* (2019) 58:781–791 2019. In single dose study of oral semaglutide, highest percentage of subjects with measurable semaglutide plasma concentrations among dose groups was 66.7% (16/24).
- [6] *Pfizer to discontinue twice-daily weight loss pill due to high rates of adverse side effects*, Annika Kim Constantino, CNBC, Health and Science, 01 Dec 2023 6:45am EST, updated 01 Dec 2023 4:22pm EST.
- [7] For Danuglipuron, *Pfizer Announces Topline Phase 2b Results of Oral GLP-1R Agonist, Danuglipron, in Adults with Obesity*, Pfizer press release, 01 Dec 2023. For VK2735 subcutaneous, *Viking Therapeutics Announces Positive Top-Line Results from Phase 2 VENTURE Trial of Dual GLP-1/GIP Receptor Agonist VK2735 in Patients with Obesity*, Viking Therapeutics press release, 27 Feb 2024. For VK2735 oral, *Viking Therapeutics Announces Results from Phase 1 Clinical Trial of Oral Tablet Formulation of Dual GLP-1/GIP Receptor Agonist VK2735*, Viking Therapeutics press release, 26 Mar 2024. For oral amycretin, *Novo Nordisk's oral amycretin outshines Wegovy in early obesity study*, Anna Bratulic, FirstWord PHARMA, 07 Mar 2024. For Orfoglipron, *Daily Oral GLP-1 Receptor Agonist Orfoglipron for Adults with Obesity*, N Engl J Med 2023; 389:877-888, 23 Jun 2023. For Mazdutide, *A phase 2 randomised controlled trial of mazdutide in Chinese overweight adults or adults with obesity*, Linong Ji, Nature Communications, 14 Dec 2023. For Survodutide, *Glucagon and GLP-1 receptor dual agonist survodutide for obesity: a randomised, double-blind, placebo-controlled, dose-finding phase 2 trial*, Prof Carel W. le Roux, The Lancet, 05 Feb 2024. For liraglutide, see Victoza U.S. prescribing information, *Dosage and Administration*. For oral semaglutide, *Oral semaglutide 50 mg taken once per day in adults with overweight or obesity (OASIS 1): a randomised, double-blind, placebo-controlled, phase 3 trial*, Prof Filip K Knop, MD, The Lancet, 25 Jun 2023. For Dapiglutide, *Dapiglutide, a Once-Weekly GLP-1R/GLP-2R Dual Agonist, Was Safe and Well Tolerated and Showed Dose-Dependent Body Weight Loss over Four Weeks in Healthy Subjects*, Minna B. Olsen, Diabetes, 01 Jun 2022. For MariTide, *Amgen's obesity drug takes the weight off and may keep it off, too, early data suggest*, Helen Floersh, FierceBiotech, 7 Feb 2024. For semaglutide (approved), see Wegovy U.S. prescribing information, *Dosage and Administration*. For pemvidutide, *Altimmune Announces Positive Topline Results From MOMENTUM 48-Week Phase 2 Obesity Trial Of Pemvidutide*, Altimmune press release, 30 Nov 2023. For Tirzepatide, see Zepbound U.S. prescribing information, *Dosage and Administration*. For GSBR1290, *Structure Therapeutics Announces Positive Results from Phase 1b Clinical Study of Oral GLP-1 Receptor Agonist GSBR-1290 and Provides Program Update*, Structure Therapeutics press release 29 Sep 2023.