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

Rani Therapeutics Corporate Presentation

RT-111 Phase 1 Data

NASDAQ: RANI

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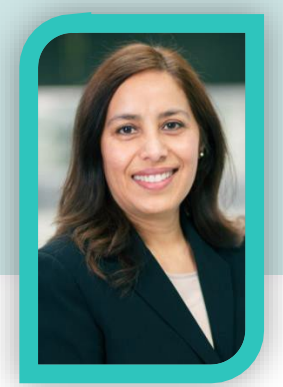

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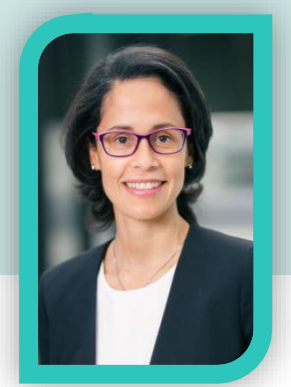

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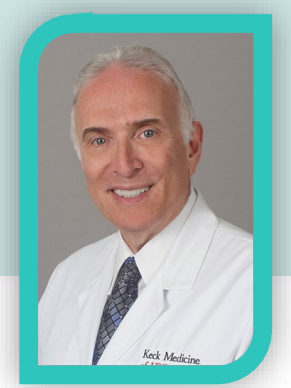

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Rani Therapeutics is a public, clinical-stage biotech company developing a platform technology for the oral delivery of biologic drugs.

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

FOCUS: **Oral Delivery of Biologic Drugs with Bioavailability Comparable to Parenteral Products**

TECHNOLOGY:

- 3mg Capacity
- Solid Drug Formulation

- 200 µL Capacity
- Liquid Drug Formulation

PIPELINE: **Immunology & Endocrinology**

DISCOVERY: **Obesity, Nanobodies, Hemophilia, Bispecific MABs, Fertility**

425+ Patent Applications, 225+ Granted Patents

Development Pipeline

	INDICATION(S)	FORMULATION	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	KEY MILESTONE*
CORE PROGRAMS							
RT-111	Psoriasis	Ustekinumab**					Phase 1 Study Completed
RT-102	Osteoporosis	PTH-OP					Initiate Phase 2 in 2024
RT-105	Psoriatic Arthritis	Adalimumab**					Initiate Phase 1
RT-110	Hypo-parathyroidism	PTH-Hypo					Initiate Phase 1

RT-XXX refers to the RaniPill™ capsule containing a biologic in a proprietary Rani formulation
* Clinical timelines are subject to potential regulatory agency review delays
** Partnered with Celltrion, Inc. Celltrion grants Rani a license and drug supply for the drug and has a right of first negotiation following a Phase 1 study

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Development Pipeline

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RT-111 Phase 1 Study Data

Study Overview

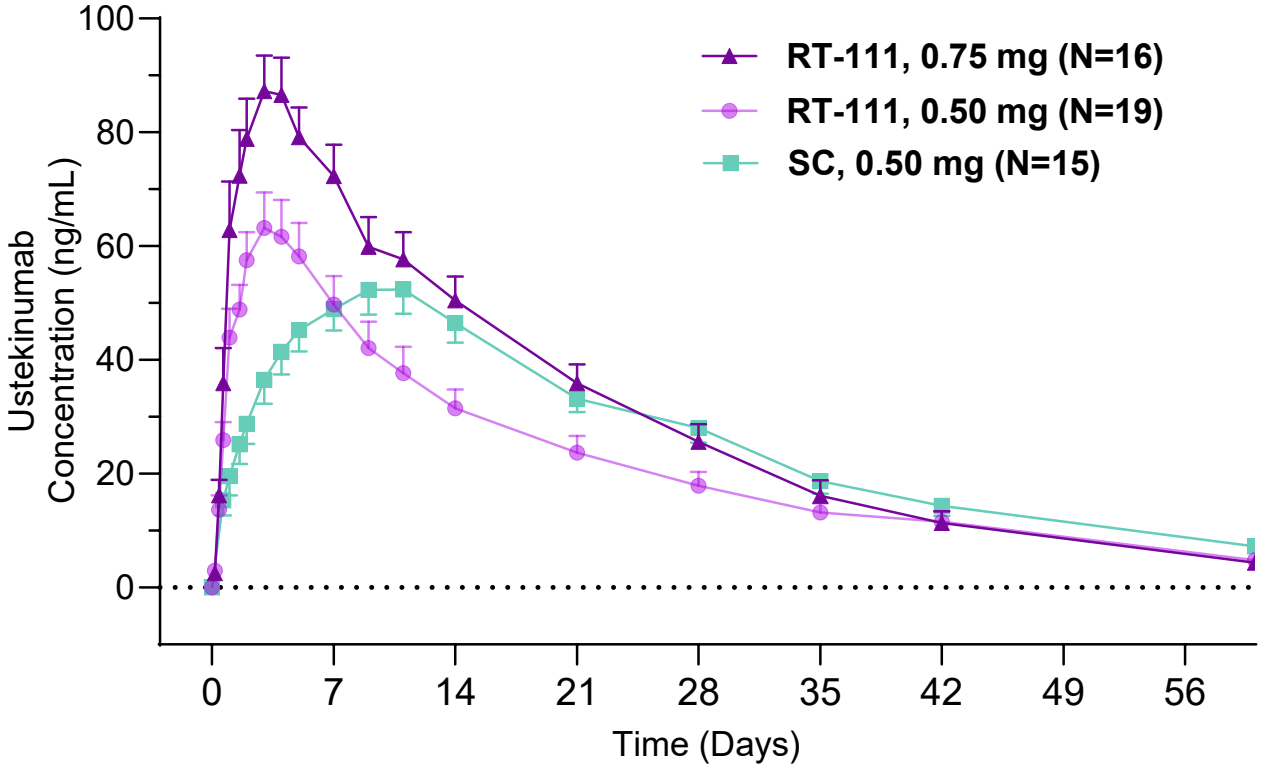
A Phase 1 Study to Evaluate the Safety, Tolerability and Pharmacokinetics (PK) of RT-111 – RaniPill Capsule Containing Ustekinumab (CT-P43) – Administered Orally to Healthy Volunteers	
Objective	To assess safety, tolerability and PK of Ustekinumab delivered via Oral RaniPill
Study Population	Healthy men and women volunteers recruited from the general population
Study Site	Single site in Australia
End Points	PK parameters, safety and tolerability

Study Design: Single Ascending Doses

- **Study Groups**
  - Control Group: 0.50 mg Stelara SC (N=15)
  - RT-111 Group: 0.50 mg CT-P43 in RaniPill (N=20)
  - RT-111 Group: 0.75 mg CT-P43 in RaniPill (N=20)
- **Protocol**
  - Participants were given a single dose of the study drug (SC or Oral) after an overnight fast
  - Blood samples were collected at various time points over 60 days and analyzed for ustekinumab concentrations
  - Blood samples were analyzed for anti-drug antibodies at 3 timepoints
  - Excretion of device remnants confirmed with imaging

Pharmacokinetics

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



Pharmacokinetic Parameters

Group	C_{max} (ng/mL)	T_{max} (days)	AUC_{0-t} (day.ng/mL)
SC 0.5mg (N=15)	56 ± 4	10 ± 0.8	1,566 ± 130
RT-111 0.5mg (N=19)	67 ± 7	3.1 ± 0.2	1,315 ± 150
RT-111 0.75mg (N=16)	92 ± 8	3.3 ± 0.2	1,814 ± 165

84% Estimated Bioavailability Relative to SC

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Data shown are Mean ± SE, Data pending final QA review. Estimated bioavailability based on 0.5mg dose

Safety & Tolerability

Incidence of Adverse Events

	Adverse Events	SC, 0.50 mg (N=15)	RT-111, 0.50 mg (N=20)	RT-111, 0.75 mg (N=20)
	All	1	2	0
Drug-Related	Abdominal Bloating	0	1 (5%)	0
	Injection Site Rash/Reaction	1 (6.7%)	0	0
RaniPill-Related	Burning Sensation in stomach*	N/A	1 (5%)	0

*Burning sensation in stomach perceived 1 hour after capsule administration and lasted for 30 minutes. However, drug levels were not seen for 10 hours after capsule administration indicating that the capsule had not deployed at time of the reported pain which suggests that this AE is not related to the drug or RaniPill deployment. However, presence of the undeployed capsule in the stomach could have causality to the reported pain.

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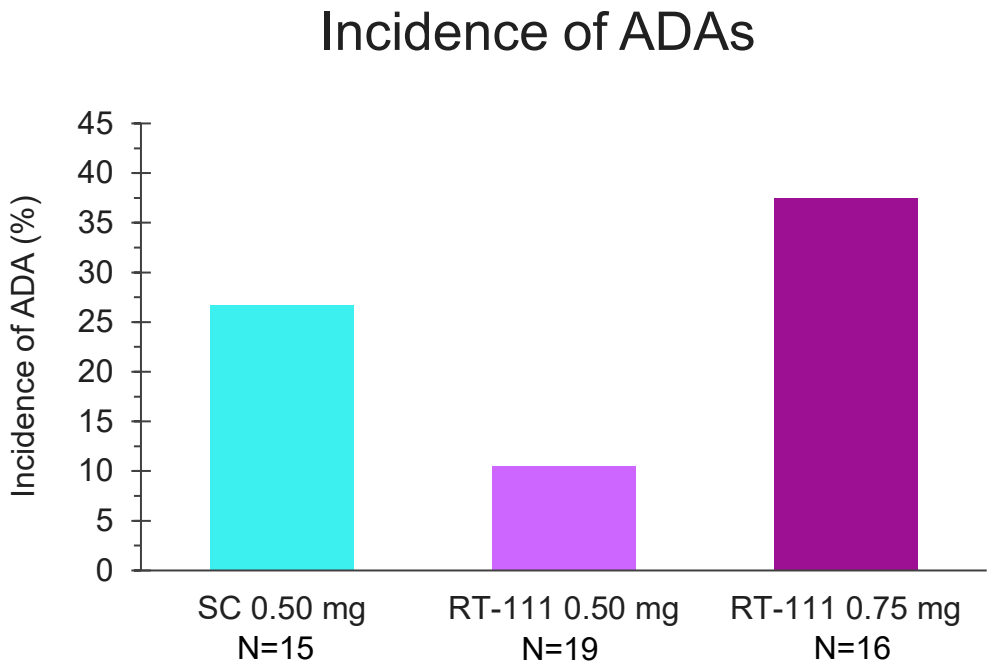
Incidence of Anti-Drug Antibodies (ADAs)

		Stelara SC 0.50 mg N=15	RT-111 0.50 mg N=20	RT-111 0.75 mg N=20
Drug Signal Detected		N=15	N=19	N=16
	Number of ADA Positive Cases			
Total ADA Positive*	N	4	2	6
	%	27%	11%	38%



*ADA positive post dosing, increase in titer compared to pre-dose level

Summary

RT-111 was well-tolerated No SAEs

Oral delivery of Ustekinumab biosimilar via RaniPill with High Bioavailability

No meaningful difference in ADA development via Rani route of delivery compared to SC injection

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RT-111 Oral Ustekinumab
Target Product Profile

Psoriasis Competitive Landscape – Select Injectables(1)

	Humira	Cosentyx	Taltz	Tremfya	Skyrizi	Stelara	Potential RaniPill Opportunity
Administration	SC	SC	SC	SC	SC	SC	Oral
Maintenance Frequency	Q2W	Q4W	Q4W	Q8W	Quarterly	Quarterly	3-Day Monthly Short Course
Target	TNF-α	IL-17A	IL-17A	IL-23	IL-23	IL-12/IL-23	IL-12/IL-23
Revenue*	$21.2B	$4.8B	$2.5B	$2.7B	$5.2B	$9.7B	--
Total Number Annual SC Injections	26	13-26	13	6-7	4	4	0
48-60 Week % Patients PASI 75**	63%	74%	74-83%	88%	92%	89%	Efficacy Similar to Injectable
12 - 16 Week % Patients PASI 75**	71-78%	75-87%	87-90%	83-91%	87-89%	66-76%	Targeting 81+%

SC = subcutaneous

* Product revenue from all indications in 2022.

** Data do not represent head-to-head studies.

Significant Potential Opportunity to Capture Portion of Psoriasis Market Based on Improvement in Convenience and Potential Improved Efficacy

Psoriasis Competitive Landscape – Select Orals[2]

	Otezla	Sotyktu	JNJ-2113*** (PTG-200)	Potential RaniPill Opportunity
Frequency	BID	Daily	Daily / BID	3-Day Monthly Short Course
Target	PDE4	TYK2	IL-23	IL-12/IL-23
Revenue*	$2.2B	$.1B (Q1-Q3 2023)	NA	--
Total Number of Pills	730	365	365 / 730	36
52 Week % Patients PASI 75**	61%	72.6%	NA	Efficacy Similar to Injectable
12 - 16 Week % Patients PASI 75**	33%	61%	65% / 79%	Targeting 81+%

* Product revenue from all indications in 2022. unless otherwise indicated.
** Data do not represent head-to-head studies.
*** Not yet approved.

Significant Potential Opportunity to Capture Portion of Psoriasis Market Based on Improvement in Convenience and Potential Improved Efficacy

Historical Data Shows Potential Opportunity to Improve Efficacy and Safety with Higher Loading Doses

Ustekinumab Efficacy at 12 Weeks*

Dose Groups	One 45mg dose	One 90mg dose	Four weekly 45mg dose	Four weekly 90mg dose
75 PASI Score	52%	59%	67%	81%
90 PASI Score	23%	30%	44%	52%
Patients with at least 1 AE	90%	81%	78%	68%

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* Data from third party study - N Engl J Med 2007; 356:580-592 DOI: 10.1056/NEJMoa062382, February 8, 2008. Safety data at 20 weeks.

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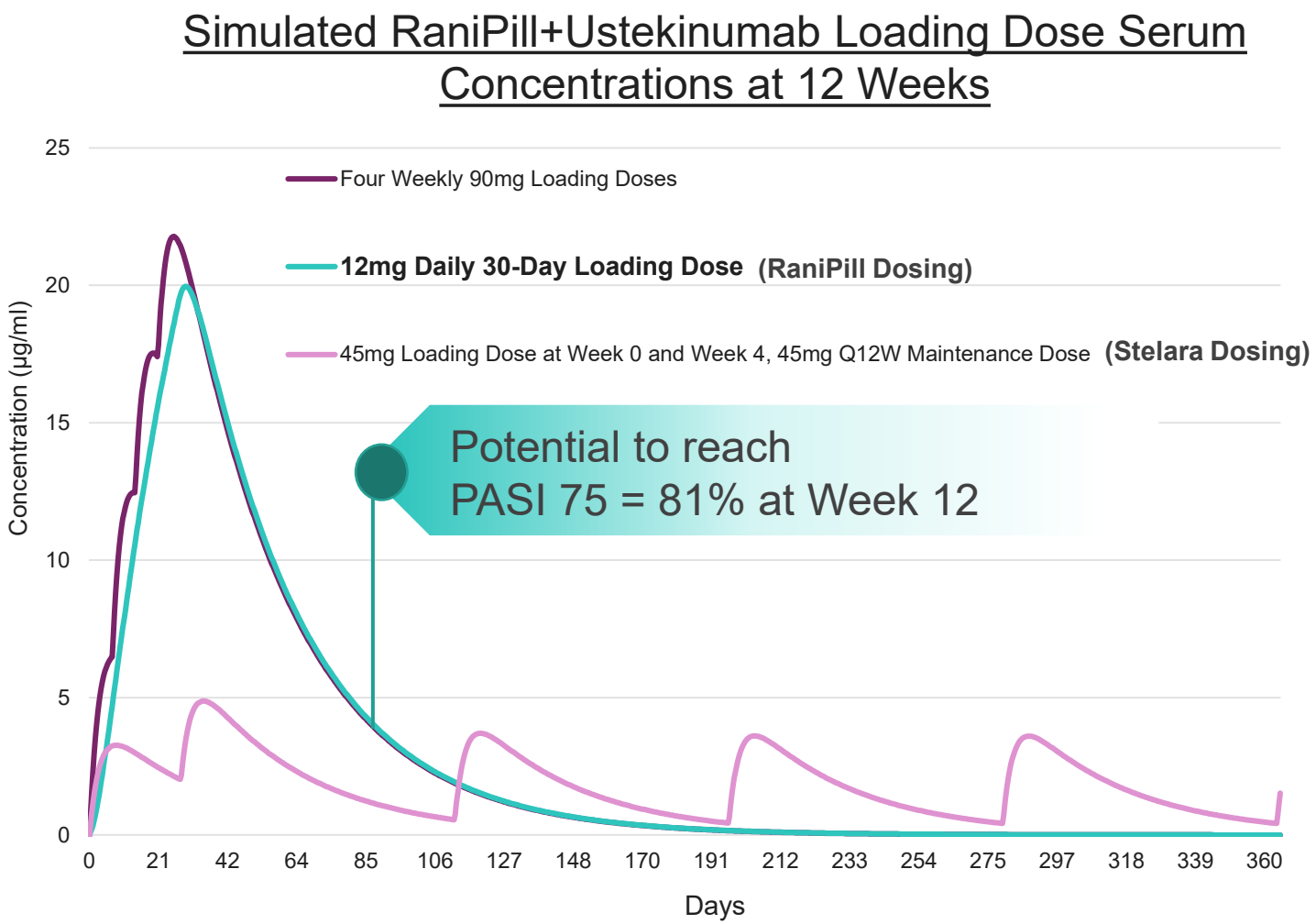
The RaniPill Could Enable Higher Loading Phase Doses with the Convenience of Oral Administration

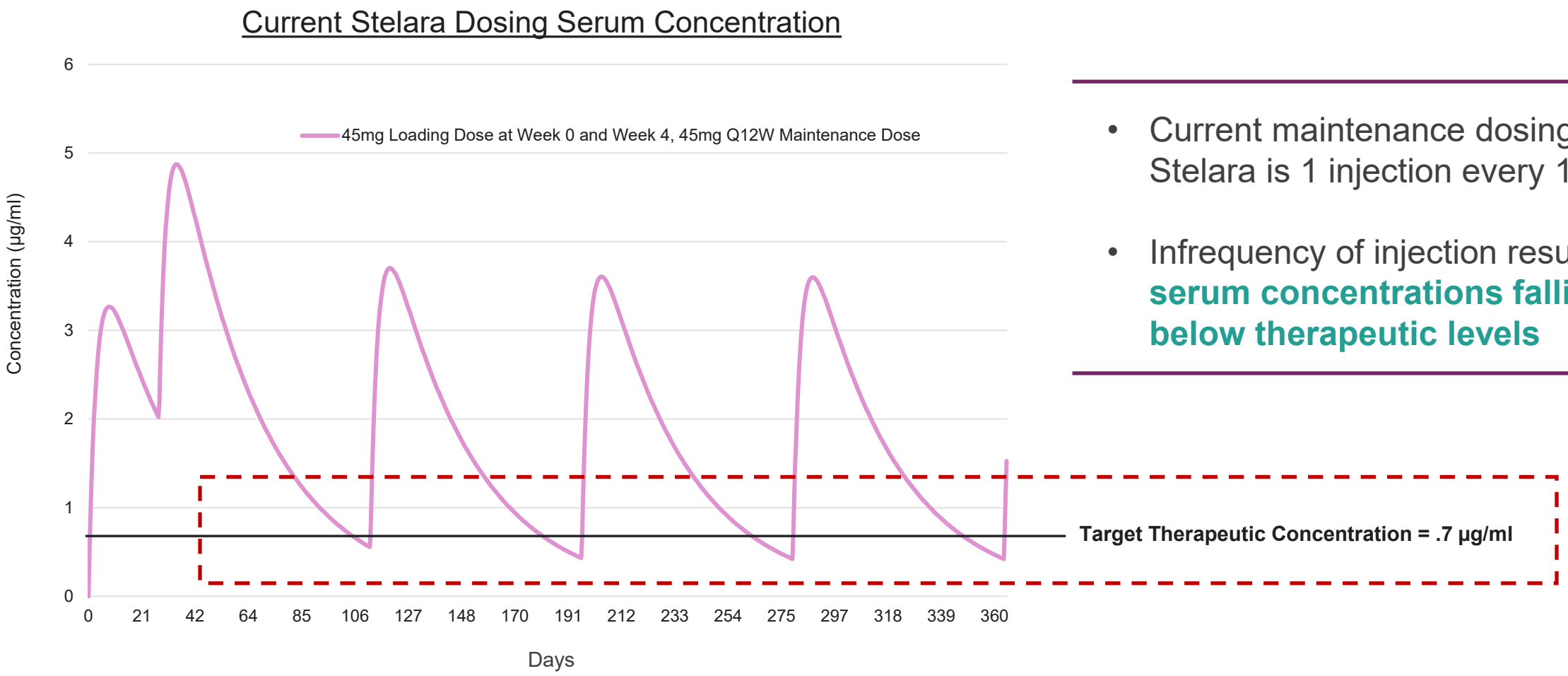


Daily Oral Administration with RaniPill Could Deliver Higher Loading Dose Regimen

Potential for Better Treatment of Acute Flare Ups at the Start of Therapy

Simulation based on ustekinumab published data (see Table 10 of BLA Number 125,261/ Supplement 150 of Janssen Biotech, Inc. submitted to FDA on September 30, 2019).

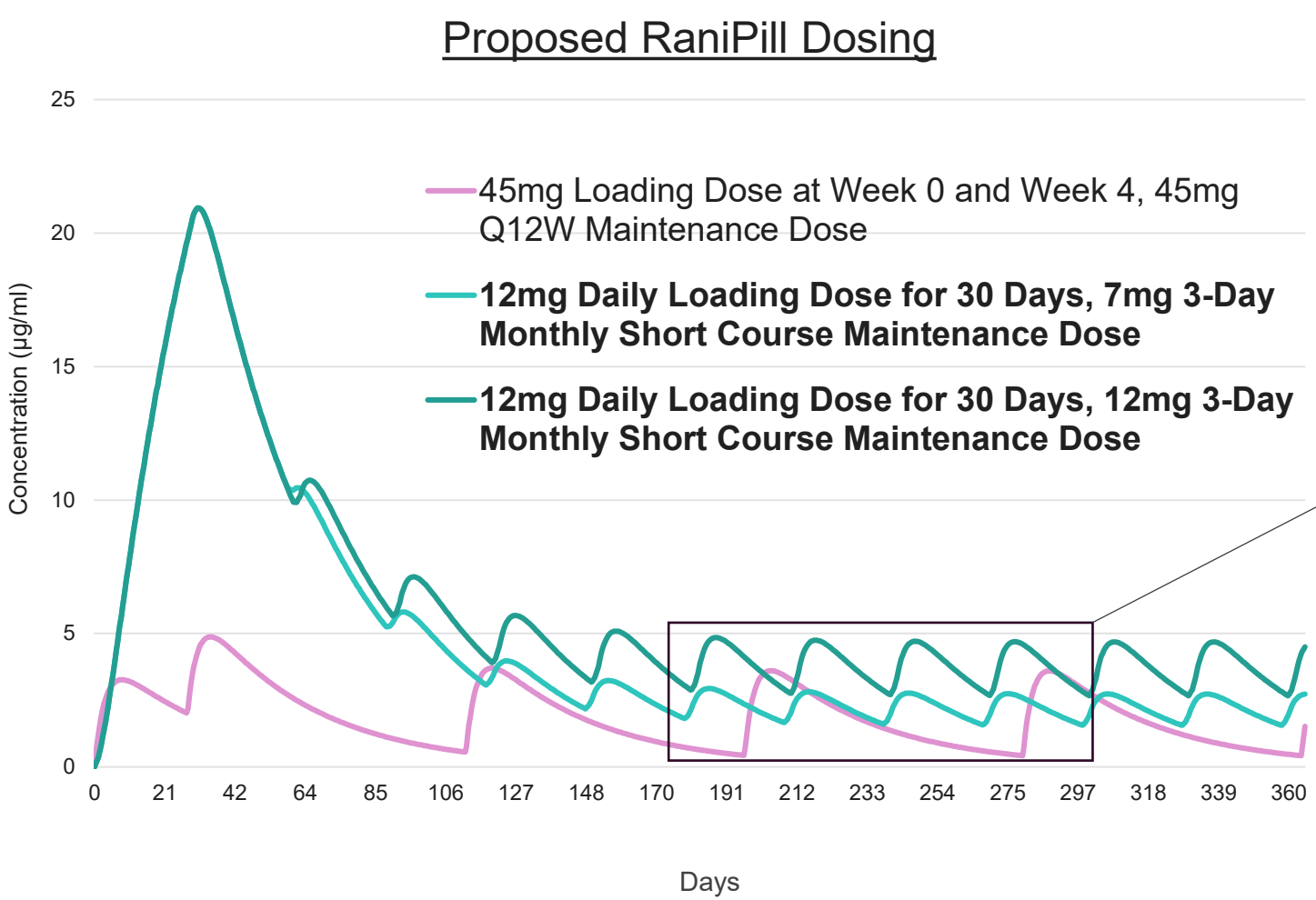
Current Stelara Maintenance Phase

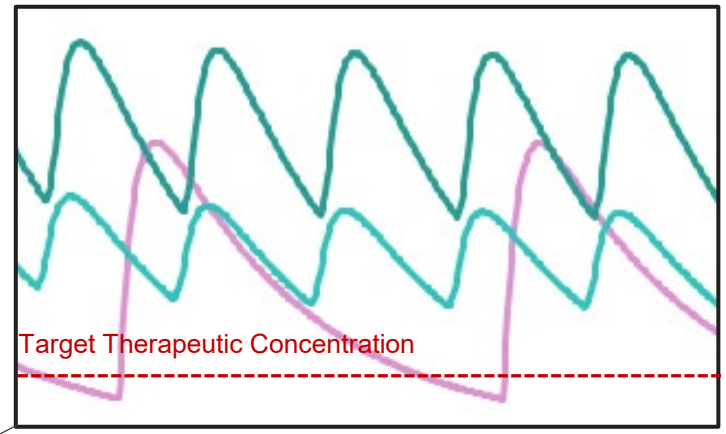


- Current maintenance dosing for Stelara is 1 injection every 12 weeks
- Infrequency of injection results in **serum concentrations falling below therapeutic levels**

Simulation based on ustekinumab published data (see Table 10 of BLA Number 125,261/ Supplement 150 of Janssen Biotech, Inc. submitted to FDA on September 30, 2019).

RaniPill + Ustekinumab Proposed Maintenance Dosing





RaniPill may enable increased frequency of dosing which translates to:

- Lower peak-to-trough variability
- Tighter banding of therapeutic concentrations

Simulation based on ustekinumab published data (see Table 10 of BLA Number 125,261/ Supplement 150 of Janssen Biotech, Inc. submitted to FDA on September 30, 2019).

Target Dosing: RaniPill + Ustekinumab

Loading Phase

DAILY

30-days of 7-12mg Daily Dosing

- Potential for better early-onset clinical efficacy

Maintenance Phase

MONTHLY

7-12mg 3-day Monthly Short Course

– *Total of 36 pills per year per patient*

- Potential for tighter banding of therapeutic concentration levels

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Advantages of RaniPill Technology in Psoriasis

Other Oral Options

- Less Efficacious than Biologics
  - Otezla, JAK Inhibitors
- Additional Safety Concerns
  - JAK Inhibitors
- Inconvenient Dosing
  - BID Dosing
    - Otezla, JNJ-2113 (testing daily and BID)

Injectables

- Inconvenient & Painful to Administer
- Dosing Regimen not Maximizing Clinical Efficacy
- Higher AE Profile
- Significant Penalty for Lapses in Patient Adherence

RaniPill Targets

- Efficacy Comparable to Injectable Biologics
- More Convenient than Other Oral Options
- Potentially Safer Product
- More Forgiving of Lapses in Patient Adherence

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Celltrion Supply Agreement Includes ROFN

Ustekinumab Biosimilar (RT-111)

- **Lead Indication:** Psoriasis
- **Market Size:** $9.7B in Stelara (ustekinumab) sales worldwide in 2022 (3)

Adalimumab Biosimilar (RT-105)

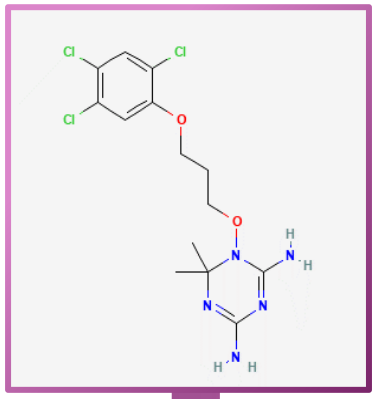
- **Lead Indication:** Psoriatic Arthritis
- **Market Size:** $21.2B in Humira (adalimumab) sales worldwide in 2022 (4)

CELLTRION

- Combining proven, high value drugs with competitive and disruptive technology
- Two partnerships that validate the RaniPill platform

Potential to Disrupt Billion-Dollar Markets with First Oral Option for Biologic Therapies in Psoriasis and Psoriatic Arthritis

Target Product Profile of RaniPill Products



- Efficacy
- Long Half-Life
- Safety

Of a Monoclonal Antibody

- Convenience
- Dosing Flexibility
- Patient Preference

Of a Pill

Goals

More convenient than small molecule

Equal or **better efficacy** compared to injectables

Potentially **lower AEs** than injectable biologics & small molecule

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Anticipated Upcoming Milestones & Progress

- Initiate Phase 2 clinical trial with RT-102 in 2024
- Advance clinical development of RT-111 at higher doses
- Progress development of RaniPill HC towards clinic
- Evaluate platform further in strategic areas of focus


Thank You
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Additional Updates

Transenteric Delivery of GLP-1/GIP/Glucagon Molecule Elicits Rapid Weight Loss in Beagle Dogs

Objective

- To evaluate the PK-PD profiles of Blinded 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

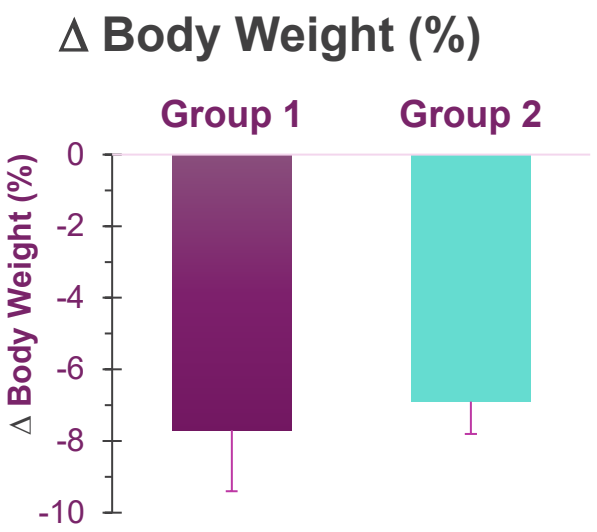
- Beagles, adult male, 11 - 13 kg, Total N=10

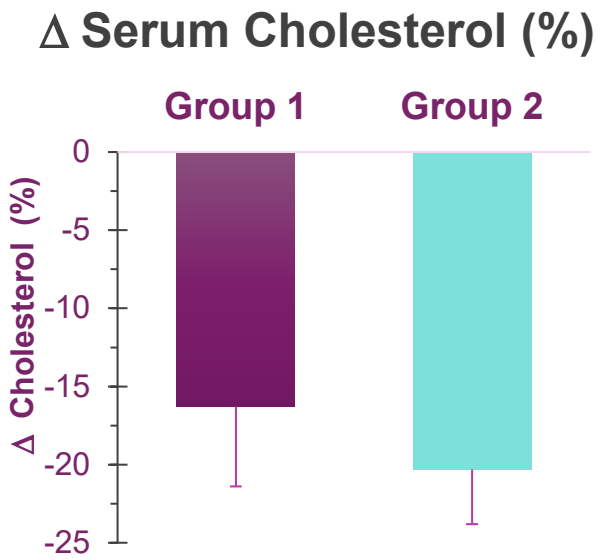
Test Groups

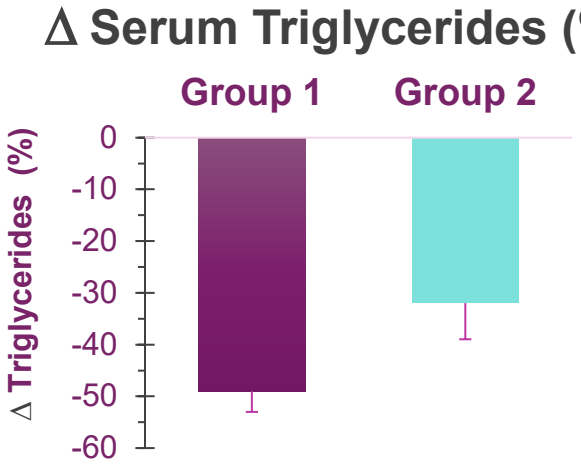
- Group 1 Transenteric (N=5): Triagonist, 0.12mg/kg (0.05ml/kg) injected via endoscopic access
- Group 2 SC (N=5): Triagonist, 0.12mg/kg (0.04ml/kg) injected subcutaneously

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







Group 1: Endoscopic
Group 2: SC

All data are Means ± SE

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Obesity Market Potential Opportunity

	Wegovy	Mounjaro	Retatrutide	Oral Semaglutide	Orfoglipron	Danuglipron	Potential RaniPill Opportunity
Administration	SC	SC	SC	Oral	Oral	Oral	Oral
Frequency	Weekly	Weekly	Weekly	Daily	Daily	Twice Daily	Daily or Weekly
Target	GLP-1	Dual Agonist	Triagonist	GLP-1	GLP-1, small molecule	GLP-1, small molecule	Single, Dual and Triagonist
Dosing	2.4mg weekly	15mg weekly	12mg weekly	50mg daily	45mg daily	120mg twice daily	Comparable to SC
Mean Body Weight Loss	15%	21%	24%	15%	15%	NA	Targeting Comparability to SC
Discontinuation	7%	7%	6-16%	6%	10-17%	34%	Targeting Similar to SC

SC = subcutaneous

Significant Potential Opportunity to Capture Portion of Obesity Market Based on Competitive Landscape [5]

Appendix

RT-111 Phase 1 Additional Data

Study Demographics – RT-111 Phase 1 Study

	SC 0.50 mg	**RT-111 0.50 mg**	**RT-111 0.75 mg**
N	15	20	20
Mean Age, years	**29.3 (19 - 49)**	**28.3 (20 - 39)**	**30 (20 - 58)**
Race			
Hispanic	0% (0/15)	25% (5/20)	5% (1/20)
White-non-Hispanic	60% (9/15)	35% (7/20)	75% (15/20)
Asian	40% (6/15)	35% (7/20)	20% (4/20)
Body Mass Index (kg/m^2)	23.8 ± 3.4	25.5 ± 3.7	22.9 ± 2.2
Height (cm)	172.7 ± 9.8	172 ± 9.7	170.2 ± 8.7
Weight (kg)	71.1 ± 12.7	76 ± 16.5	66.5 ± 9.5

BMI, Height and Weight data are Mean ± SD

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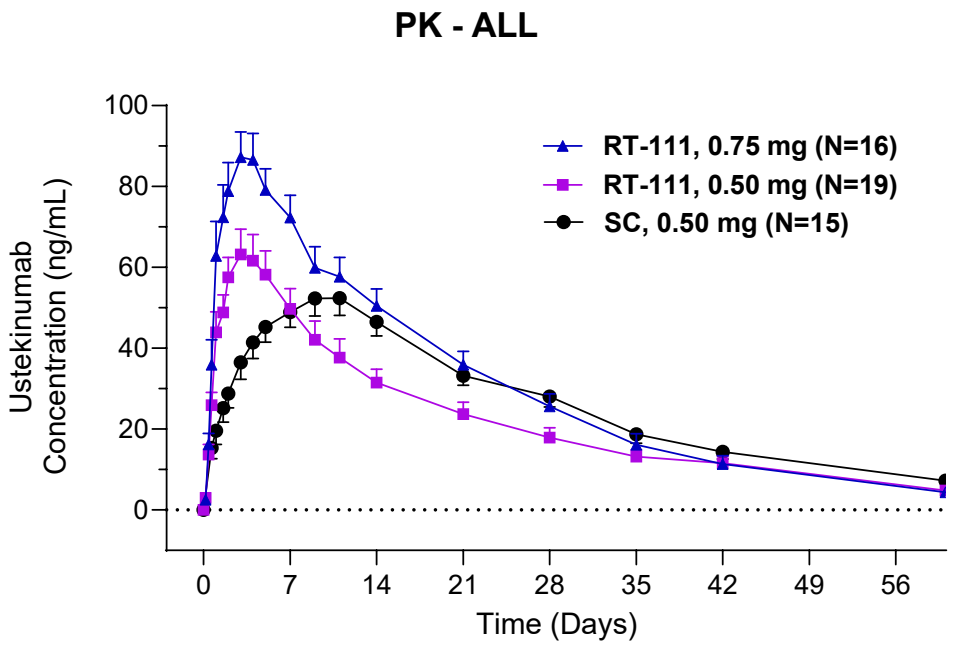
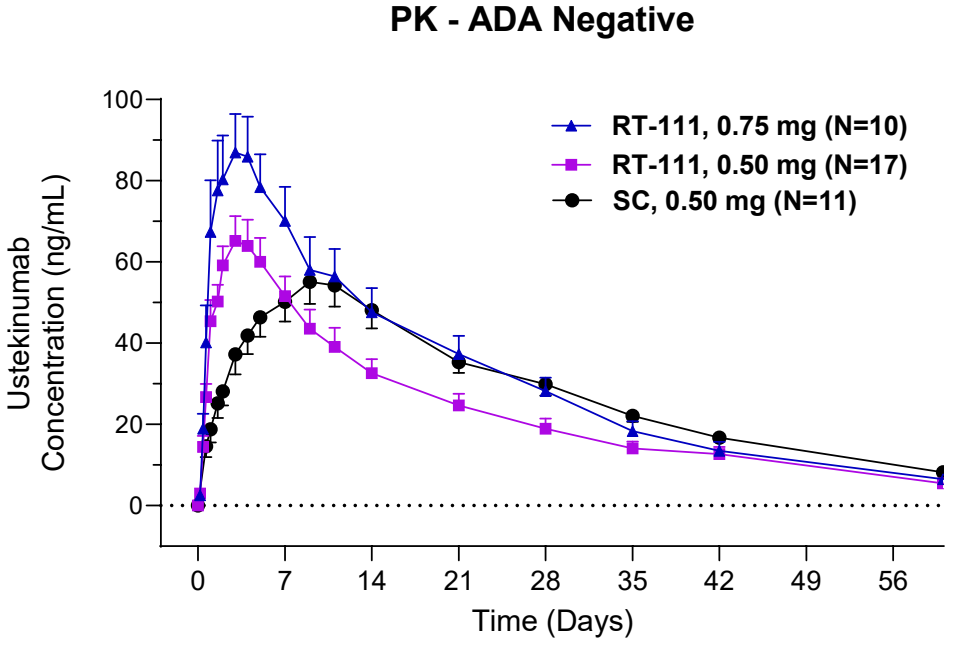
PK Profiles of Oral Ustekinumab Biosimilar (RT-111) vs SC Stelara Injection



	SC 0.50 mg	RT-111 0.50 mg	RT-111 0.75 mg
C_{max} (ng/ml)	56 ± 4	67 ± 7	92 ± 8
T_{max} (days)	10 ± 0.8	3.1 ± 0.2	3.3 ± 0.2
AUC (day*ng/mL)	1,566 ± 130	1,315 ± 150	1,814 ± 165



	SC 0.50 mg	RT-111 0.50 mg	RT-111 0.75 mg
C_{max} (ng/ml)	58 ± 6	67 ± 7	93 ± 12
T_{max} (days)	10.2 ± 0.9	3.2 ± 0.2	3.1 ± 0.4
AUC (day*ng/mL)	1,678 ± 112	1,365 ± 142	1,883 ± 162

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Data are Means ± SEM. Data are pending final QA review.

References

(1) Data of third party molecules are from separate studies published or disclosed by such third parties. Data are not from head-to-head studies. For Humira data and PASI 75 at 16 weeks, see tables 17-18 in U.S. prescribing information. For Humira PASI 75 at 48 weeks, see Table 3 of EMA Summary of Product Characteristics for Tremfya 100mg pre-filled pen and 100mg pre-filled syringe .For Humira revenues and Skyrizi revenues, see AbbVie press release dated February 9, 2023 (AbbVie Reports Full-Year and Fourth-Quarter 2022 Financial Results). For Cosentyx data and PASI 75 at 12 weeks, see U.S. prescribing information and for PASI 75 at 52 weeks for 300mg dose, see Table 4 in EMA Summary of Product Characteristics for Cosentyx 75mg. For Cosentyx revenues, see Novartis In Society Integrated Report 2022, Financial Performance..For Taltz data and PASI 75 data at 12 weeks, see U.S. prescribing information. For Taltz PASI 75 at 60 weeks, see Table 5 of EMA Summary of Product Characteristics for Taltz 80mg pre-filled syringe. For Taltz revenues, see Lilly press release dated February 2, 2023 (Lilly Reports Fourth-Quarter 2022 Financial Results, Core Business Growth and Pipeline Advancements Support Strong Long-Term Outlook). For Skyrizi data , see U.S. prescribing information. For Skyrizi PASI 75 at 12 weeks and 52 weeks, see Table 2 of EMA Summary of Product Characteristics for Skyrizi 150 mg pre-filled pen, and 75mg and 150mg pre-filled syringes. For Tremfya data and PASI 75 data at 16 weeks, see U.S. prescribing information. For Tremfya PASI 75 at 48 weeks, see Table 3 of EMA Summary of Product Characteristics for Tremfya 100mg pre-filled pen and 100mg pre-filled syringe. For Tremfya revenues, see DrugAnalyst market research database. For Stelara data and PASI 75 at 12 weeks, see U.S. prescribing information. For Stelara PASI 75 at 52 weeks, see EMA Summary Product Characteristics for Stelara 45mg and 90mg pre-filled pens. For Stelara revenues, see J&J annual earnings report for 2022.

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(3) Johnson & Johnson 2022 Annual Report.

(4) Abbvie 2022 Annual Report.

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