Rani Therapeutics

Announcing RaniPill™ HC

February 2022

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Rani Platforms & Payloads

DEVICE	CAPACITY	~ # OF DRUGS ENABLED	SELECT POTENTIAL DRUGS
Current RaniPill™ capsule	Up to 3 mg	>40	• Octreotide • Parathyroid hormone for osteoporosis • Parathyroid hormone for hypo • Human growth hormone • Anti TNF-α antibody
RaniPill™ HC (High-Capacity)	Up to 20 mg	**>50**	• Pembrolizumab / Keytruda® • Etanercept / Enbrel® • Trastuzumab / Herceptin® • Secukinumab / Cosentyx®

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The RaniPill™ HC

The high payload RaniPill™ HC will enable delivery of a wider variety of drugs and **significantly expand our market opportunity**

RaniPill™ HC Study

High Payload System: Study Objectives

- Demonstrate ability to deliver high drug payloads (up to 20 mg) in canines

- Verify that the absorption profile of adalimumab delivered via the RaniPill™ HC device is consistent with previously established historical controls with an adalimumab biosimilar

RaniPill™ HC – Adalimumab: Protocol Summary

- Test Device
  - RaniPill™ HC device without enteric-coated capsule shell or chemical reactants
- Test Article & Dose
  - Adalimumab: 18 mg / 20 mg
- Protocol
  - RaniPill™ HC device inserted directly into the jejunum lumen via a laparotomy
  - The RaniPill balloon was inflated by an external syringe pump (actuation pressure similar to existing RaniPill device)
  - Incisions closed with sutures
- Blood Sample Collection
  - 3 mL blood samples collected at the following time points: 0 (pre-dose), 4-hr, 8-hr, 12-hr, 24-hr, 2-day, 3-day, 4-day, and 5-day

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Study Animal Details

Animal ID	Animal #5074	Animal #5077	Animal #5080	Animal #5042	Animal #5084
Species:	Canine	Canine	Canine	Canine	Canine
Sex:	Male	Male	Female	Male	Female
Weight:	13.1 kg	14.2 kg	11.6 kg	16.7 kg	11.8 kg
Adalimumab Dose:	18 mg	18 mg	18 mg	20 mg	20 mg
Route of Admin:	RaniPill™ HC	RaniPill™ HC	RaniPill™ HC	SC	SC

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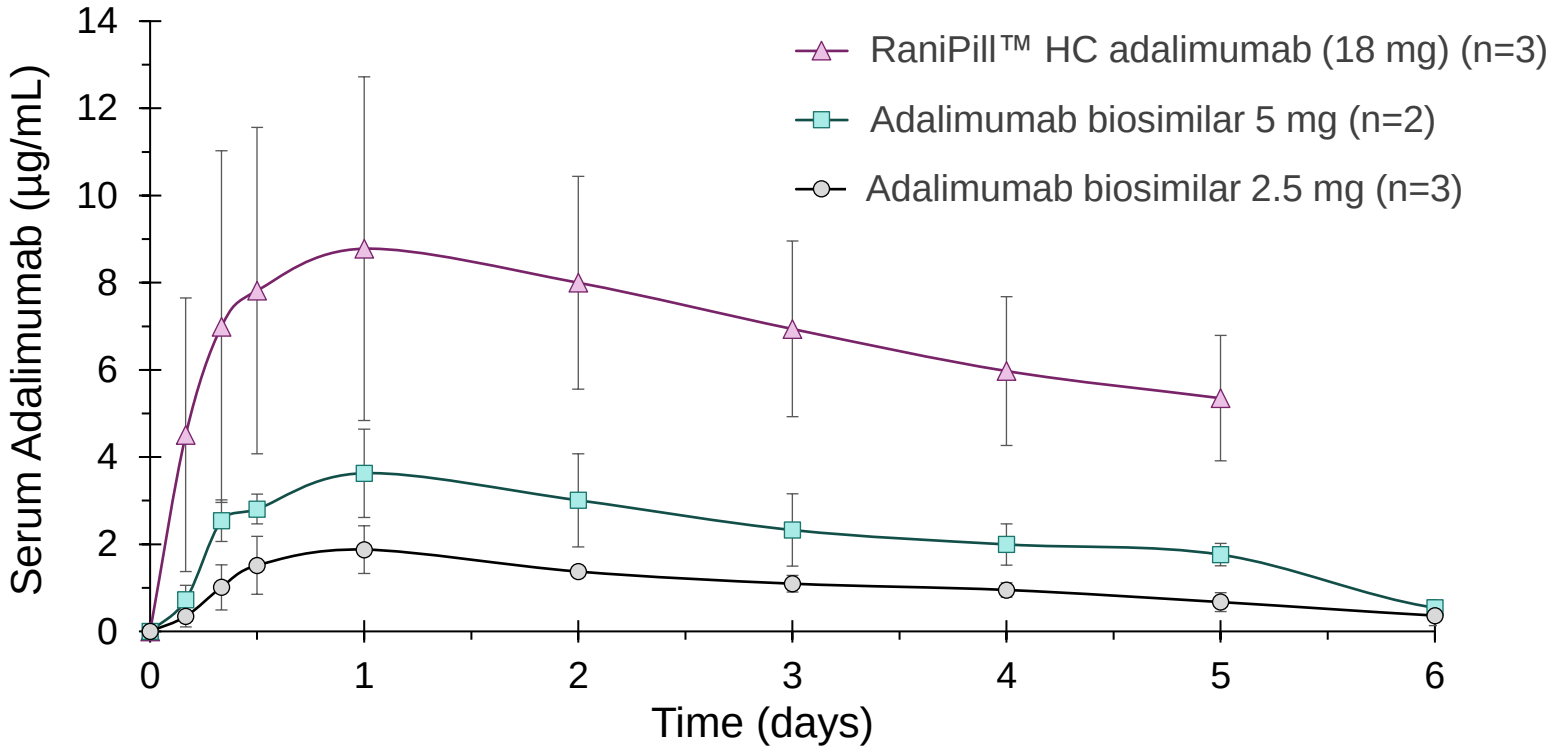
SC = Subcutaneous

Pharmacokinetics (PK) of Adalimumab ~18 mg Delivered via the RaniPill™ HC

PK Curves of an Adalimumab Biosimilar (2.5 and 5 mg, Historical Data) delivered via the RaniPill capsule in awake canines vs. Adalimumab ~18 mg delivered via RaniPill™ HC

All data are means ± Standard Deviation (SD)



- Adalimumab data with the RaniPill™ HC are presented alongside historical control PK data with an adalimumab biosimilar delivered orally at lower doses (with 1 or 2 RaniPill capsules of 3 mg capacity)
- The PK curves indicate linear, dose-dependent increases in drug exposures

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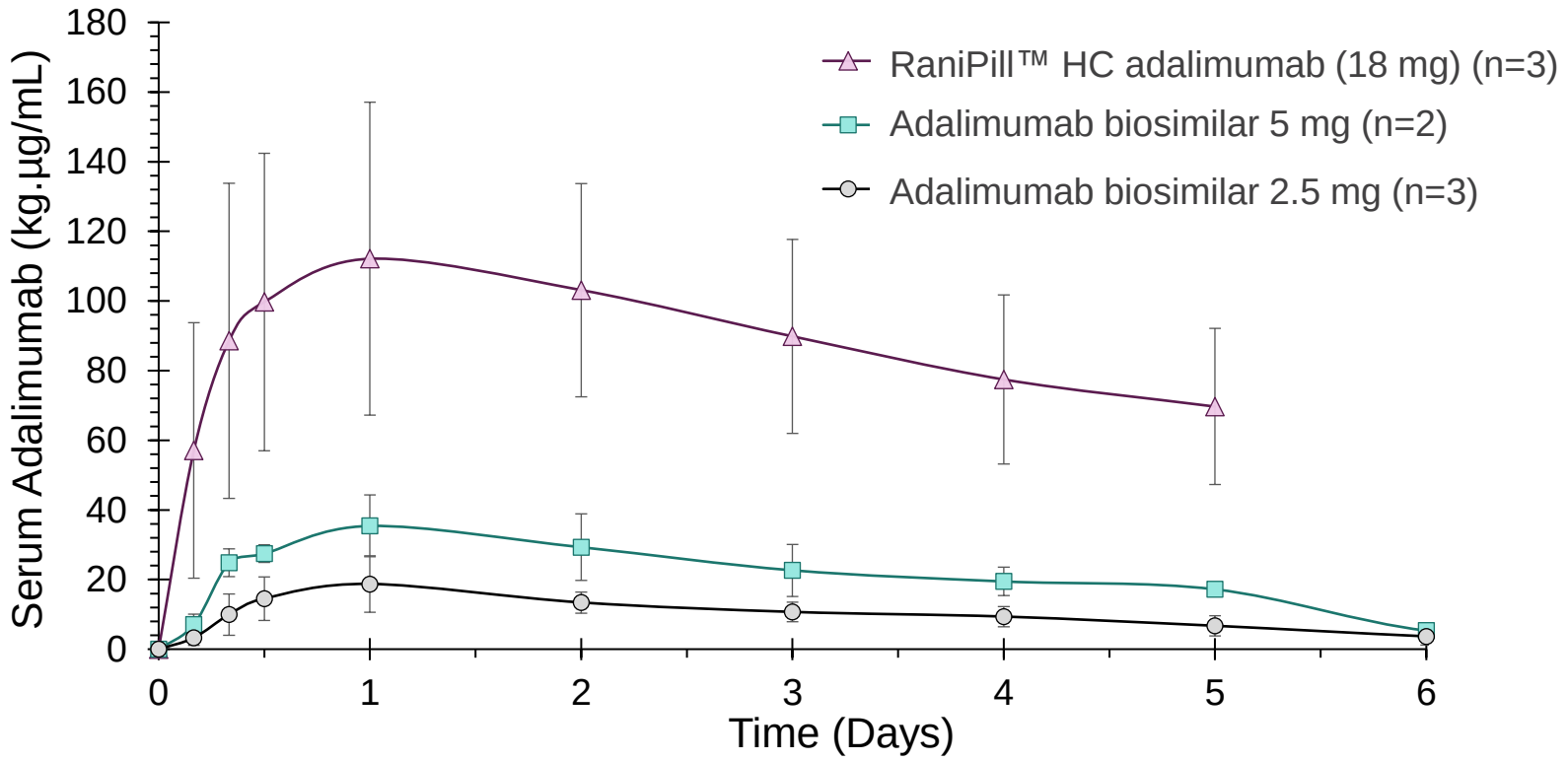
PK of Adalimumab ~18 mg Delivered via the RaniPill™ HC

Weight-Normalized PK Curves of an Adalimumab Biosimilar (2.5 and 5 mg, Historical Data) delivered via the RaniPill capsule vs. Adalimumab ~18 mg delivered via RaniPill™ HC

All data are weight-normalized means ± Standard Deviation (SD)



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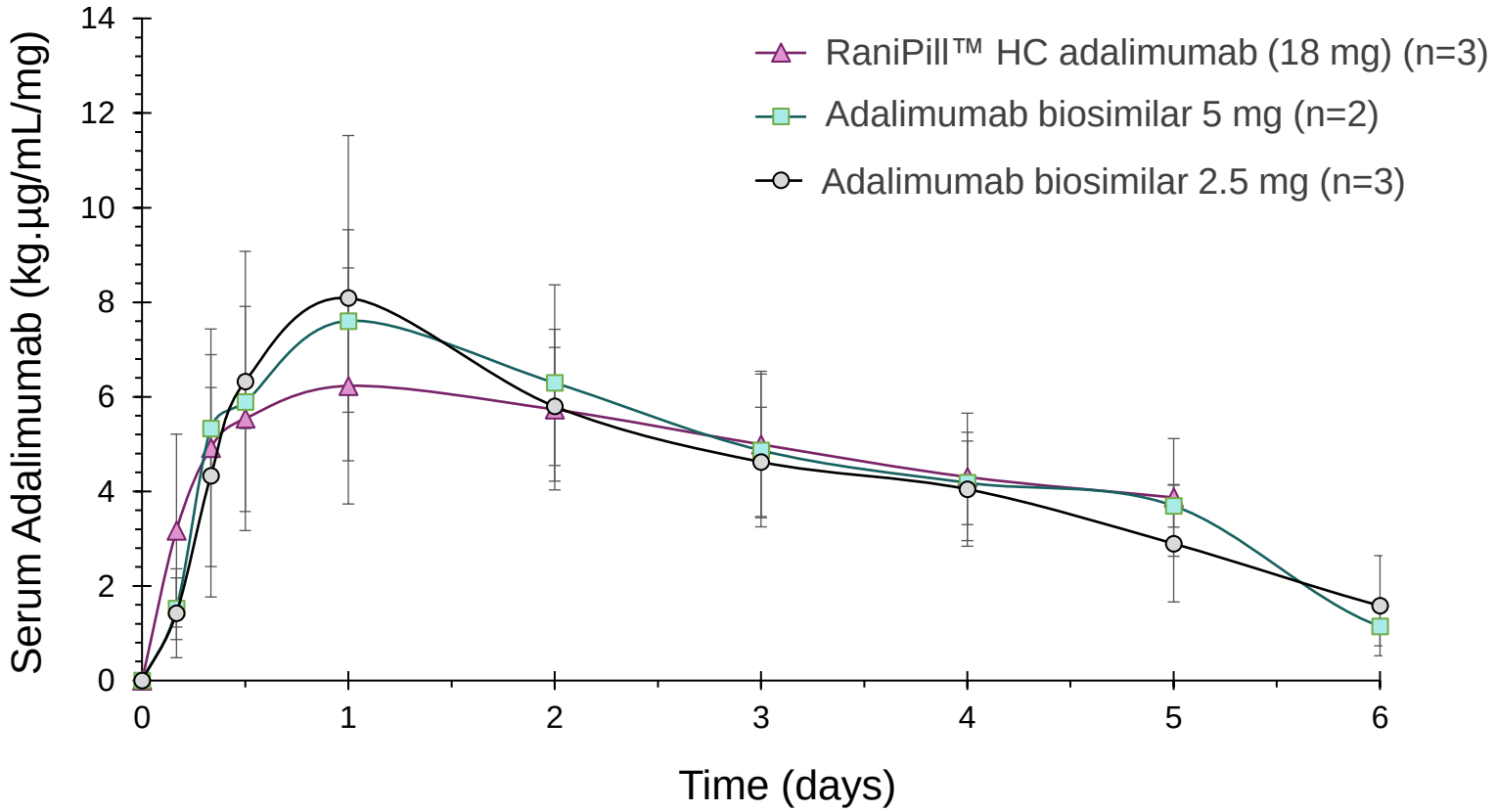
Adalimumab PK Profiles Delivered via the RaniPill Route

Dose- and Weight-Normalized PK Curves of an Adalimumab Biosimilar (2.5 and 5 mg, Historical Data) delivered via the RaniPill capsule vs. Adalimumab ~18 mg delivered via RaniPill™ HC



- The PK curve of adalimumab generated with the RaniPill™ HC device is similar to historical PK curves generated with an adalimumab biosimilar delivered via 3 mg RaniPill capsules
- Note that elimination phase of RaniPill™ HC was not fully captured as data were collected for only up to 5 days in this initial study

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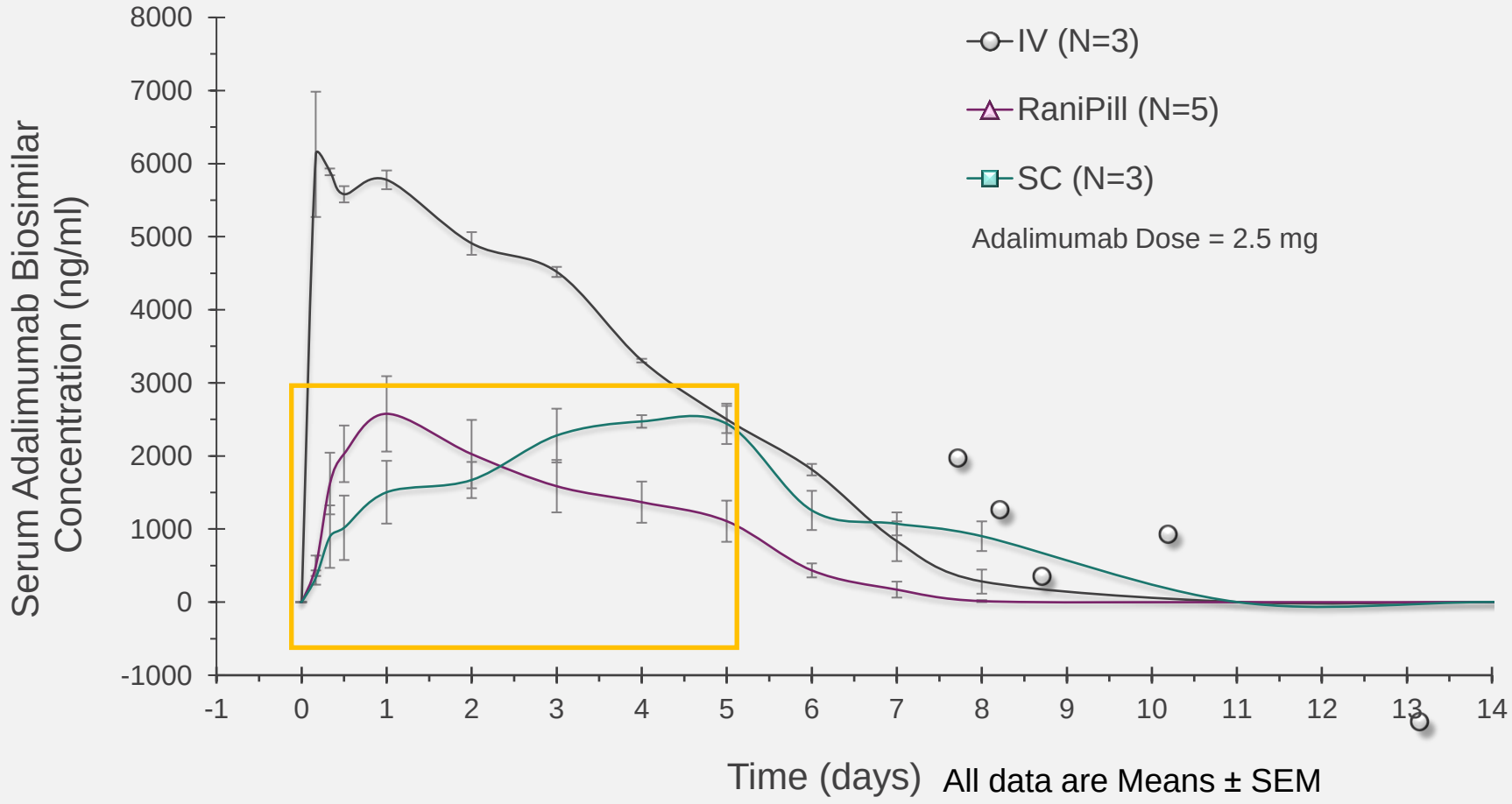
Historical PK of Oral Adalimumab Biosimilar in Awake Canines



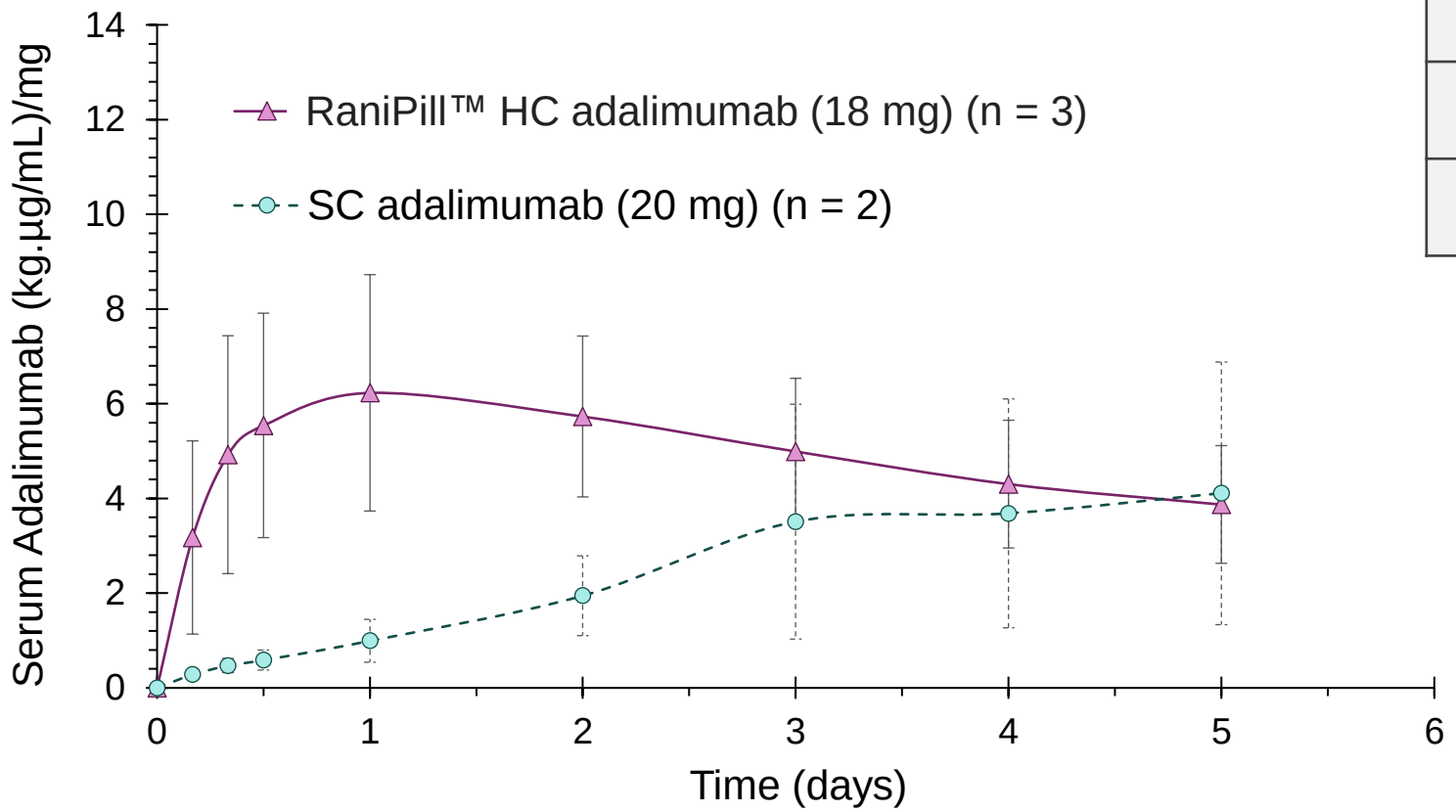
BIOAVAILABILITY* (%)	
SC	46 ± 3
Rani	49 ± 6

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

IV = Intravenous
Rani or RaniPill = RaniPill capsule
SC = Subcutaneous

PK Comparison: RaniPill™ HC vs Subcutaneous (SC) Controls

All data are weight- & dose-normalized means ± SD



	RaniPill™ HC (n = 3)	SC (n = 2)
C_{max} (kg.µg/mL)/mg	6.4 (3.81, 7.24, 8.06)	4.1 (2.15, 6.07)
T_{max} (hours)	32 (48, 24, 24)	120 (120, 120)

- The shorter Tmax and higher Cmax seen with the RaniPill™ HC-adalimumab are consistent with historical data with an adalimumab biosimilar delivered via 3 mg RaniPill capsules
  - Recall that in our studies the absolute bioavailability (%F) of adalimumab delivered via the RaniPill route is on par with SC injections
- Note that elimination phase was not fully captured as data were collected for only up to 5 days in this initial study

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Summary

- Using the RaniPill™ HC device, we have demonstrated successful delivery of a high dose (18 mg) of adalimumab in canines
- Adalimumab 18 mg administered by the RaniPill™ HC device showed a dose-proportional increase in serum concentrations in comparison to historical controls with an adalimumab biosimilar (delivered via current RaniPill capsule) at lower doses (2.5 mg and 5 mg)
  - Tmax of adalimumab was shorter with the RaniPill™ HC device compared to SC controls
  - Data are consistent with Rani historical controls with an adalimumab biosimilar

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Market Research

Patient Preference Surveys*

	LANTUS insulin glargine injection 100 Units/mL	HUMIRA adalimumab	Simponi golimumab	EVENITY	Cosentyx (secukinumab)	Entyvio vedolizumab	Stelara (ustekinumab)	prolia
Frequency	Daily	Every 2 weeks	Every month	Every month	Every month	Every 2 months	Every 3 months	Every 6 months
% Likely to Switch to Daily Pill Over Current Injectable	**87%**	**88%**	**74%**	**73%**	**75%**	**77%**	**64%**	**76%**

*Data for Entyvio, Simponi, Evenity, Cosentyx, Stelara, and Prolia obtained from an independent third-party survey commissioned by Rani in the second quarter of 2021 to investigate U.S. patient preference for a daily oral drug alternative versus injections. Patients surveyed (n=611) were aged 18 years or older and presently used an injectable biologic to treat a condition. Six patient groups each included 100-103 patients with current primary treatment being injections of Simponi, Entyvio, Stelara, Prolio, Evenity, or Cosentyx.

*Data for Lantus and Humira obtained from an independent third-party survey commissioned by Rani in 2017 to investigate U.S. patient preference for a daily oral alternative. Patients surveyed were aged 18 years or older. Two patient groups included 501 patients taking Humira for the treatment of an inflammatory condition and 577 patients taking basal insulin for the treatment of diabetes.

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Mock-RaniPill Swallow Study Overview

- **Objective**: To evaluate the ease of swallowability of a mock RaniPill capsule by patients of different ages
- **Patient Population**: Patients currently taking injections of various drugs
- **Study Design**
  - Three cohorts of patient age groups: 21-50, 51-65, 66-75 years
  - N = 50 in each group
- **Test Article**: An enteric coated mock RaniPill capsule (of same weight and size as RaniPill) filled with potato starch
- **Endpoints**
  - Swallowability and palatability of the mock RaniPill capsule
  - Participants' preference to choose a pill instead of their current injection therapy
- Study initiated in June 2021 and completed in September 2021

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Swallow Study Results

Study Groups (years)	# Total Enrolled	# successfully swallowed Mock-RP	# Prefer Pill over Injection	% Prefer Pill over Injection	# Prefer Injection over Pill
21-50	50	50	44	88%	6
51-65	50	50	48	96%	2
66-75	50	50	44	88%	6
Total	**150**	**150**	**136**	**91%**	**14**

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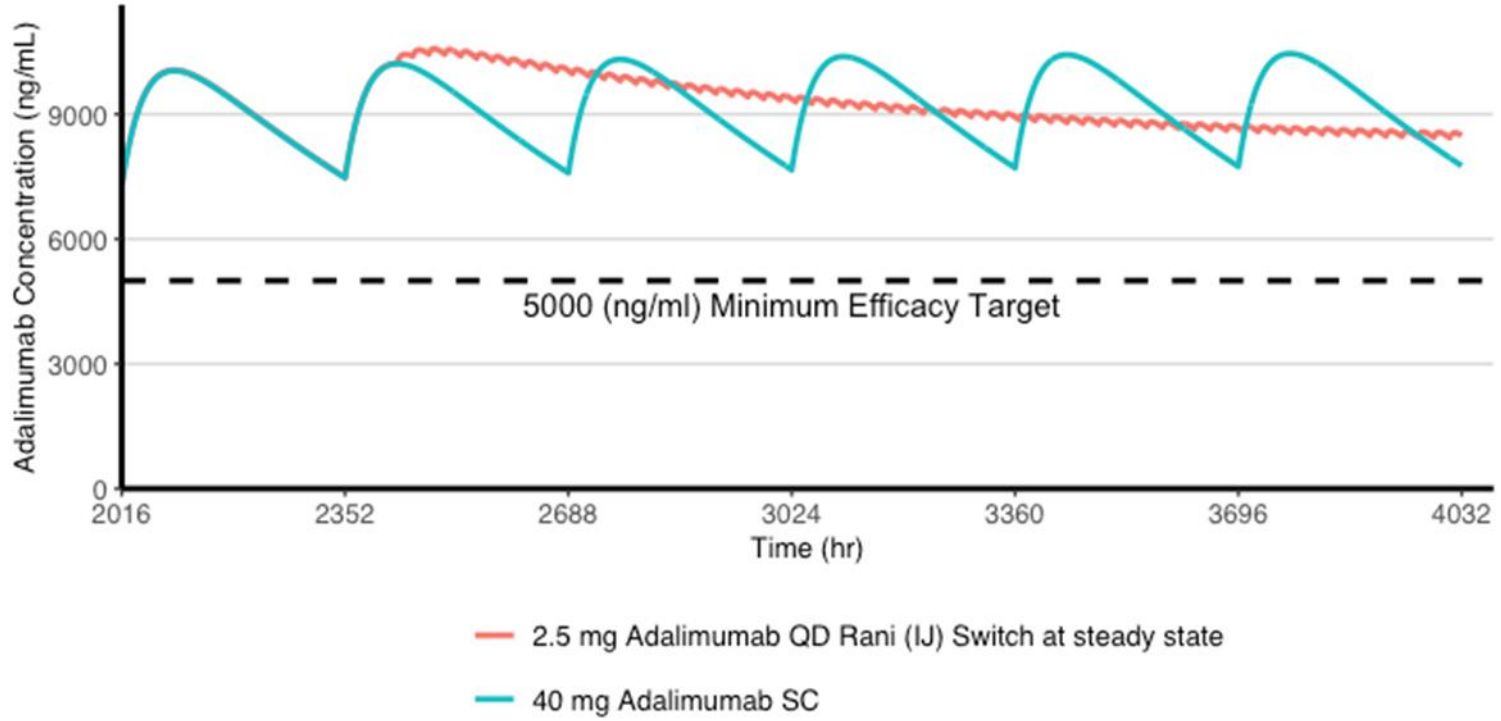
Adalimumab: Simulations of Daily Oral RaniPill Dosing

The Power of Daily Dosing

- Adalimumab is dosed at 40 mg every 2 weeks, which we hypothesized would be approximately equivalent to a ~2.5 mg daily dose
- Using the data from our human endoscopic study (2.5 mg of adalimumab injected intra-jejunally), we commissioned steady-state simulations to model the pharmacokinetics of a once daily oral RaniPill dose of 2.5 mg adalimumab
- Based on the simulations, it is projected that:
  - Therapeutic levels of serum adalimumab can be achieved with a once daily oral RaniPill dose of 2.5 mg
  - Loading doses (i.e., 40 mg subcutaneous dose or 2 weeks of twice daily oral dosing) reduce the amount of time to reach therapeutic levels
  - Patients currently on adalimumab 40 mg biweekly dosing regimen can switch to the daily RaniPill regimen at any point following the last SC dose of adalimumab

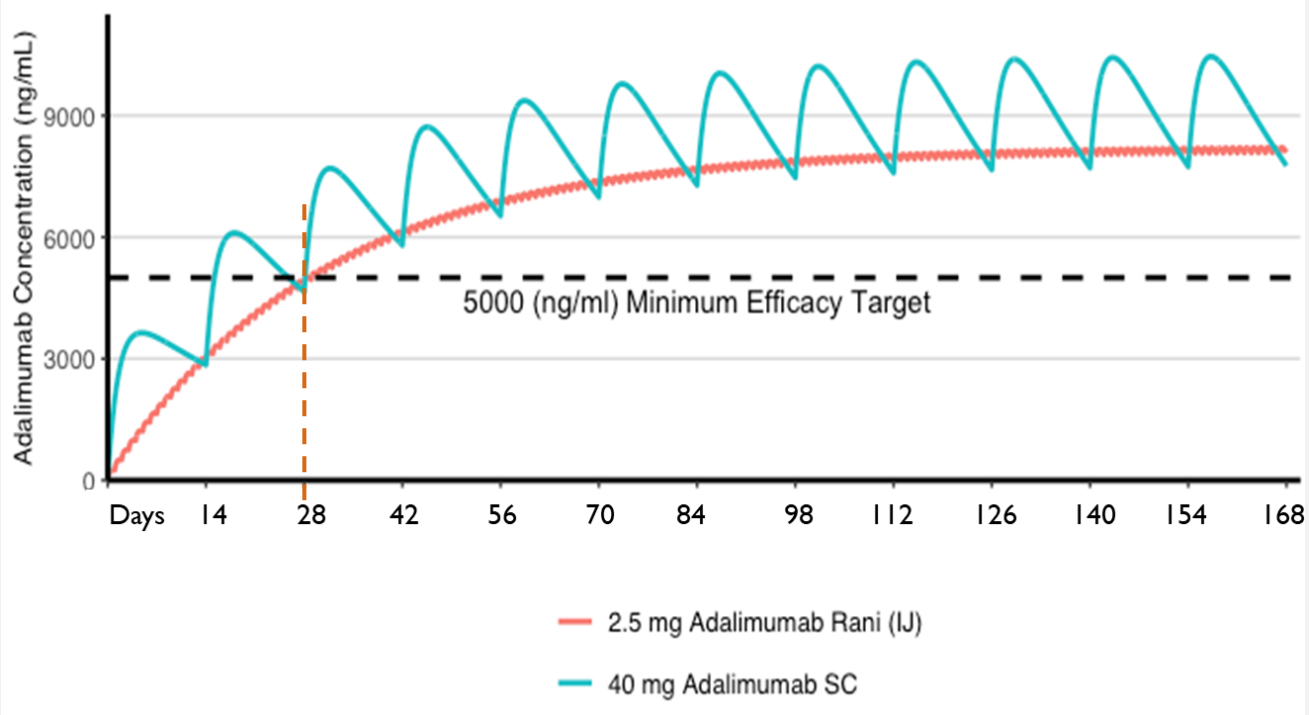
Steady State PK Simulations of Adalimumab Intrajejunal (IJ) Data: Switching from Subcutaneous

It is projected that patients currently on adalimumab 40 mg biweekly dosing regimen could switch to the daily RaniPill regimen at any point following the last subcutaneous dose of adalimumab



Steady State PK Simulations of Adalimumab IJ Data: Daily Dosing

RT-105
Regimen: daily dosing of 2.5 mg RaniPill, no loading dose



- With **biweekly adalimumab SC injections at a dose of 40 mg, it takes 28 days** to reach target efficacy steady states
- With **once daily oral RaniPill dose of 2.5 mg, it is projected to take ~28 days** to reach target efficacy steady state

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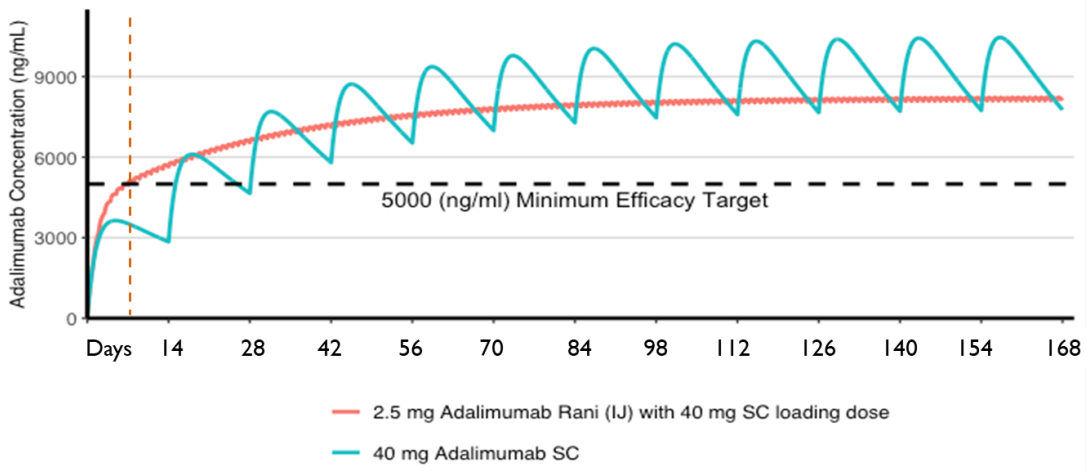
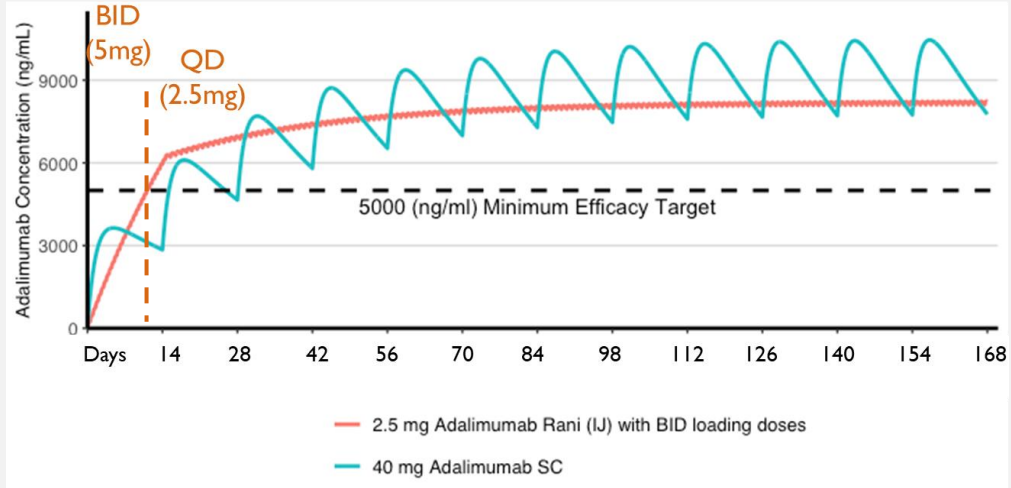
Steady State PK Simulations of Adalimumab IJ Data: Loading Doses



- Starting with an initial 40 mg SC loading dose, it is projected to take 7 days to reach target efficacy steady state with the 2.5 mg RaniPill capsule



- With initial 2 week BID (twice daily) RaniPill capsule loading doses, it is projected to take ~10 days to reach target efficacy steady state
  - After 2 weeks of BID dosing, the patient would switch to QD (daily) maintenance dose with a single RaniPill capsule

Our Goal is to Become *The* First-Line Biologics Company

INDICATION	STARTING THERAPIES		STANDARD INJECTABLES	
Type 2 Diabetes	Metformin (oral)	DPP-4 (oral)	Basal Insulin & GLP-1 (injections)	
Osteoporosis	Bisphosphonates (oral)		Teriparatide (injection)	Denosumab (injection)
Hypoparathyroidism	Calcitrol (oral)		PTH(1-84) (injection)	
Rheumatoid Arthritis	Methotrexate (oral)	JAK inhibitors (oral)	TNF-α (injection)	
High Cholesterol	Statins (oral)		PCSK-9 Inhibitors (injection)	
Crohn's Disease	Steroids & 5-aminosalicylates (oral)		TNF-α, α4-Integrin (injection)	IL-12/23 (injection)

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Oral RaniPill® Biologics

Nearly all previous attempts to convert biologic drugs into pills have failed to deliver sufficient drug levels into the blood stream

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Thank you!