Poster
SAT-435

Daily Administration of An Oral Robotic Pill (RT-102) Safely and Reliably Delivers Teriparatide with High Bioavailability in Women Volunteers: A Phase 1 Study

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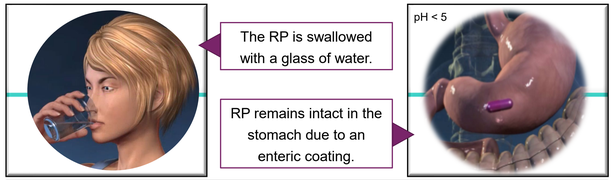
Rani Therapeutics LLC, San Jose, CA & San Antonio, TX

INTRODUCTION & STUDY OBJECTIVE

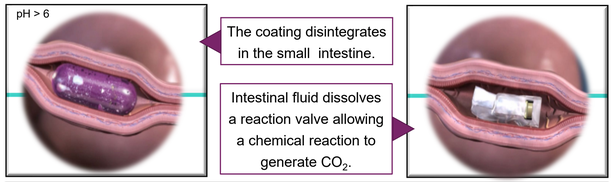
Rani Therapeutics is developing RT-102, a novel, orally ingestible robotic pill (RP) containing teriparatide, as an oral anabolic therapy for osteoporosis. RP represents a novel, transenteric route of drug delivery for which bioavailability has been shown to be similar to SC injections. This Phase 1 study evaluated the safety, tolerability and pharmacokinetic (PK) profiles following daily administration of teriparatide via the RP for seven consecutive days to healthy female volunteers.

HOW THE RP WORKS

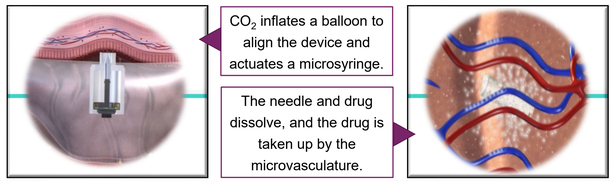
1. Enteric-Coated Robotic Pill is Ingested



2. Enteric Coating Disintegrates in Small Intestine



3. Drug is Delivered



STUDY DESIGN

- Study was conducted at a single site in Australia
- End Points: Safety and Tolerability of repeat doses of RT-102
- Seventeen healthy & post-menopausal female volunteers were enrolled in the study and 10 completed daily dosing with RT-102 for 7 days
- Seven participants were excluded due to: menstruation (N=2), capsule remnant criteria* (N=2), gastric emptying time ≥7 hrs (N=1), unrelated adverse event (N=1), cannulation issue (N=1)
- On Days 1-6, participants were allowed to eat at 3 hrs post-dose and only three blood samples were taken to measure the presence of drug
- PK profiles of RT-102 were obtained on Day 7 after determining T=0 for PK sampling

*Protocol defined total # of remnants allowed per GI location. Participants were asymptomatic.

STUDY DEMOGRAPHICS

	Healthy Volunteers	Post-menopausal
	N=5	N=5
Mean Age (Range)	25.6 years (22-35)	60 years (54-65)
	Mean ± SD (Min - Max)	**Mean ± SD (Min - Max)**
Height (cm)	158.8 ± 5.6 (154 - 168)	159.8 ± 4.7 (154 - 165)
Weight (kg)	60.6 ± 9.8 (50.2 - 76)	64.3 ± 10.1 (55.6 - 75.4)
Body Mass Index (kg/m^2)	23.7 ± 2.5 (20.4 - 26.9)	25.3 ± 5 (20.9 - 31.7)

INCIDENCE OF ADVERSE EVENTS

	Adverse Event	All Enrolled Participants (N=17)	Participants Completed (N=10)
PTH-related	Constipation*	1 (5.9%)	1 (10%)
	Diarrhea*	1 (5.9%)	1 (10%)
	Headache	1 (5.9%)	0 (0%)
RaniPill-related	Abdominal Pain	2 (12%)	1 (10%)
	Burping	1 (5.9%)	1 (10%)

* Same subject reported both AEs on different days

DEVICE PERFORMANCE

#	Subject Type	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	HV	Y	Y	Y	Y	Y	Y	Y
2	HV	Y	Y	Y	Y	Y	Y	Y
3	HV	Y	N	Y	Y	Y	Y	Y
4	HV	N	Y	Y	Y	Y	Y	Y
5	HV	Y	N	Y	Y	Y	Y	Y
6	PM	Y	Y	Y	Y	Y	Y	Y
7	PM	N	Y	Y	Y	Y	Y	Y
8	PM	*	Y	Y	N	Y	N	Y
9	PM	Y	Y	Y	Y	Y	Y	Y
10	PM	Y	Y	Y	Y	Y	Y	Y

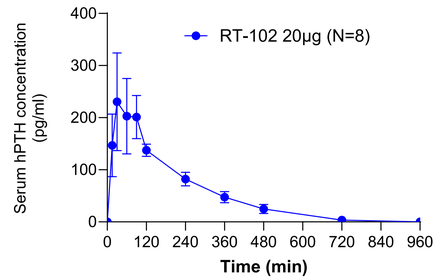
HV: healthy volunteer, PM: post-menopausal, 'Y' indicates drug signal detected, 'N' indicates drug signal not detected, * Pill not deployed at the time samples were taken

- Overall rate of successful drug delivery with RT-102 was 91% (63/69)

Food Effect:

- Days 1-6, number of successful drug deliveries observed before (35) and after (37) food was consumed were not different, suggesting that presence of food does not affect device performance

PHARMACOKINETICS



Complete PK curves were obtained from 8 out of 10 subjects

SUMMARY & CONCLUSIONS

Safety:

- **RT-102 was well-tolerated by all participants**
- **No SAEs were observed in the study**
- **Device remnants passed out in all subjects without sequalae**

Reliability:

- **Drug delivery success was 91%**

Pharmacokinetics:

- **RT-102 displayed robust and reproducible PK curves resulting in higher bioavailability compared to historical data for Forteo® SC**

These data provide the basis for further clinical development of RT-102 as a potential oral osteoanabolic alternative to the current chronic injection regimen of teriparatide.

Visit www.ranitherapeutics.com to learn more or scan the QR code to see a video of the Robotic Pill in action.