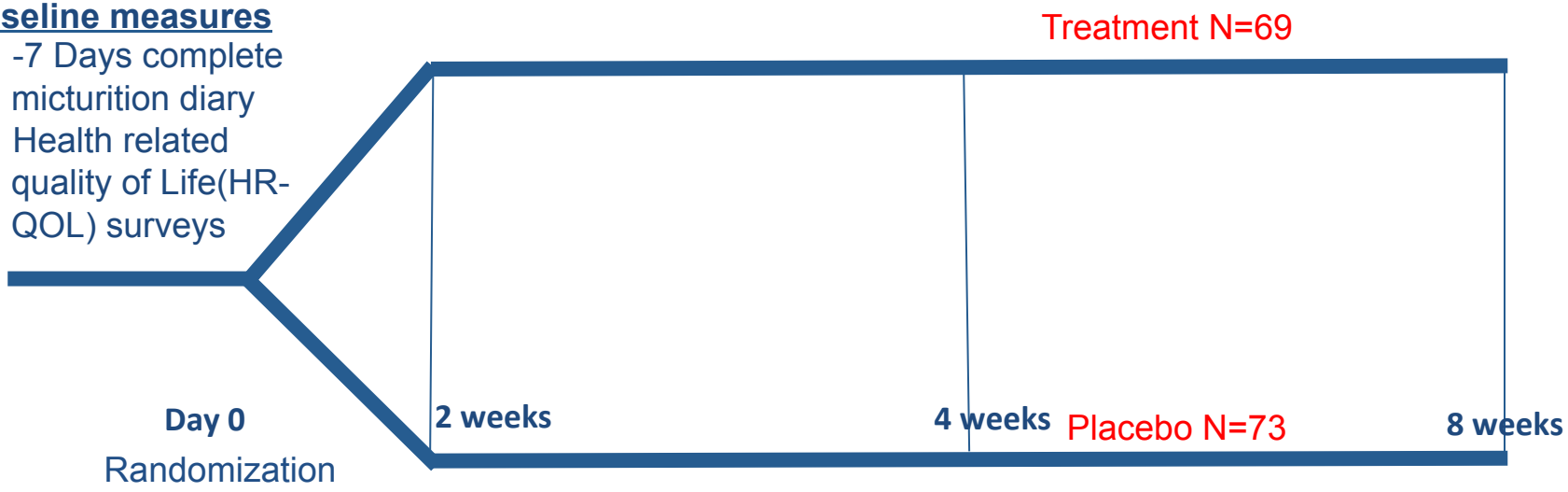
UriVarx® - Ph 2 Clinical Study Design

Treatment Period : 8 weeks 150 randomized

2 capsules – per day (840mg)

Baseline measures

- -7 Days complete micturition diary
- Health related quality of Life(HR-QOL) surveys



Data collection 2, 4, and 8 weeks

- 3 day self reported symptom diary
- Quality of Life surveys

Clinical Study Evaluation Methods

Data collection 2, 4, and 8 weeks

- 3 day self reported symptom diary (frequency, nocturia, urgency and incontinence episodes)
- Health-related quality of life (HR-QOL) questionnaire (short versions)
  - Overactive Bladder Questionnaire (OAB-SF) – used if urgency at baseline
  - Urinary Distress Inventory (UDI) – used in incontenance cases
  - Incontinence Impact Questionnaire (IIQ) – incontinence cases

Primary efficacy endpoints:

- Day urinary frequency - number of voluntary diurnal micturitions per day
- Nocturia frequency - number of voluntary nocturnal micturition's per day

Secondary endpoints:

- Urinary urgency – number of urgency episodes per day
- Urge incontinence frequency - number of incontinence episodes per day
- Stress incontinence frequency – number of episodes of incontinence per day

Safety: Monitoring adverse events (AEs)

Inclusion Criteria

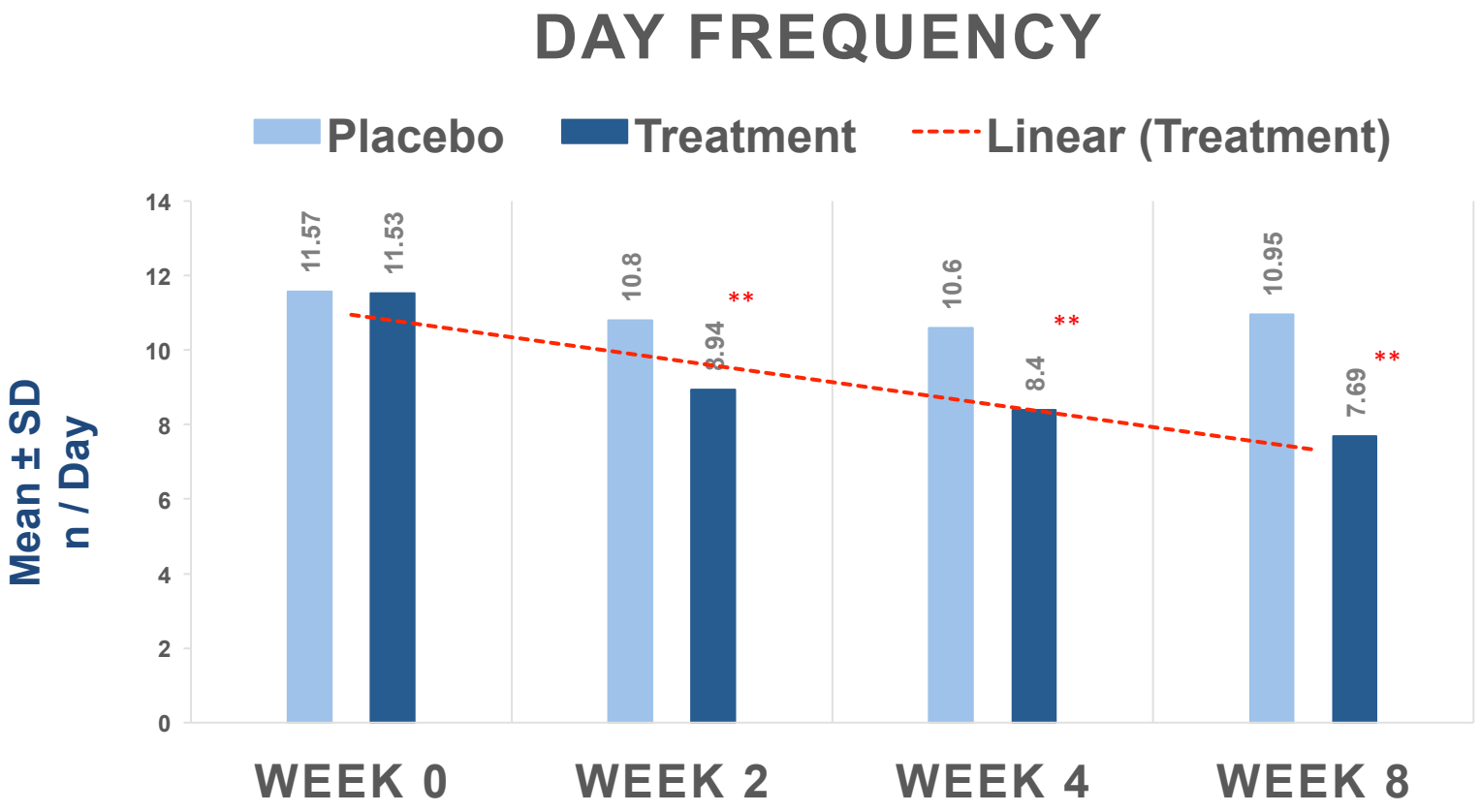
- Male and female
- Age 18 ≤ years (Adult, senior)
- Minimum of 2 symptoms of overactive bladder (OAB) for at least 6 months

Micturition	≥ 10 per day
Nocturia	≥ 2 per night
Incontinence	≥ 1 per day
Urgency	≥ 2 per day

UriVarx™ - Baseline Demographics

Descriptor	Treatment	Placebo
N, Qualified/completed (PP)	75/69	75/73
Age (years;mean ± SD)	64.21 ± 12.11	62.26 ± 13.87
Sex (F/M)	40/35	48/27
Weight (kg; mean ± SD)	79.90 ± 18.78	79.74± 22.74
Day Frequency ≥ 10 (n)	50	57
Nocturnia≥ 2 (n)	70	61
Urgency ≥ 2 (n)	63	62
Urgency Incontinence ≥ 1 (n)	34	35
Stress Incontinence ≥ 1 (n)	11	11
Any Incontinence ≥ 1 (n)	35	43
Two symptoms	24	23
Three symptoms	33	29
Four symptoms	18	23

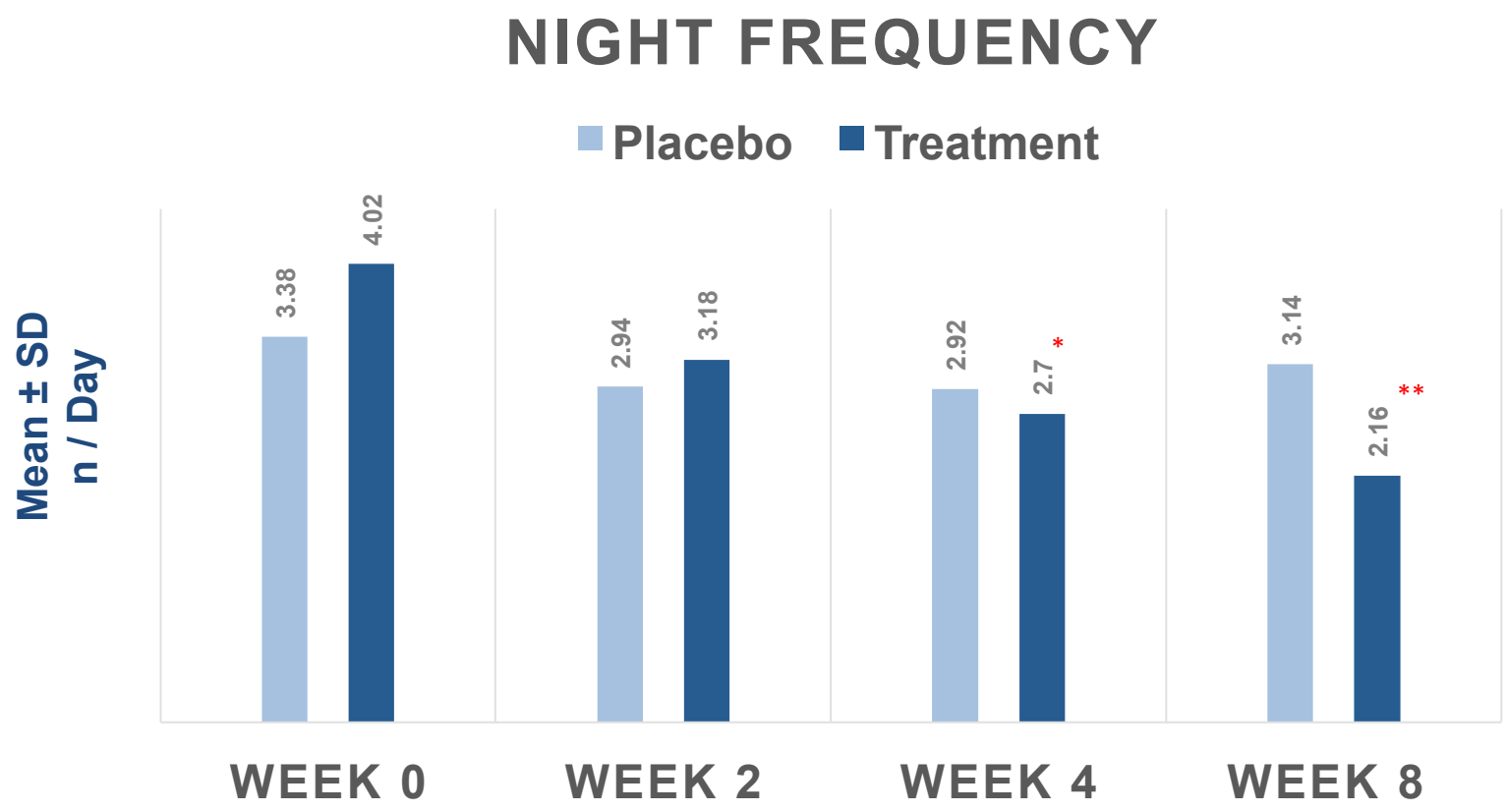
UriVarx™ Clinical Efficacy- Primary Endpoint
Diurnal Micturitions



UriVarx™ statistically and significantly superior to placebo

P-values are based on logistic regression analyses
** Statistically highly significant (p <0.01)

UriVarx™ Clinical Efficacy- Primary Endpoint
Nocturia

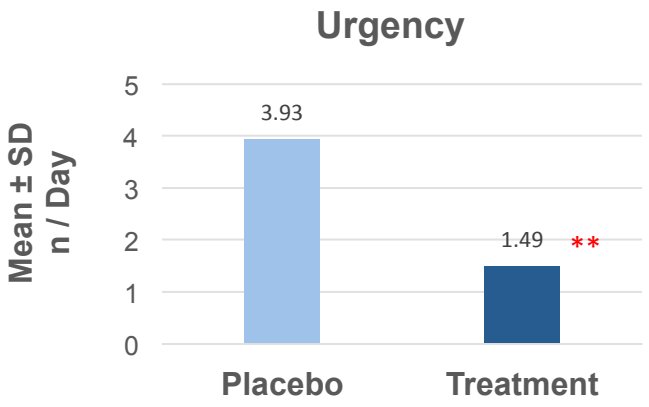


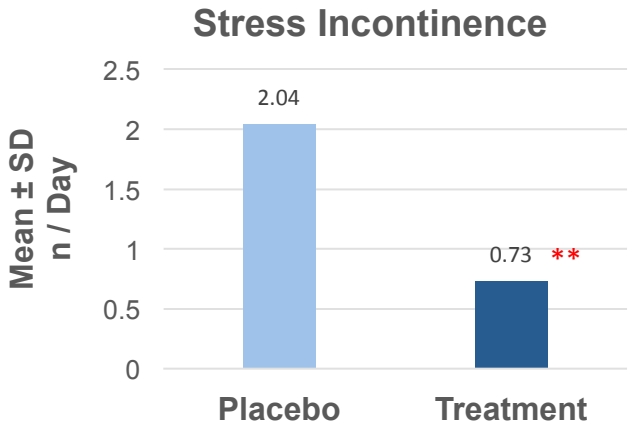
UriVarx™ statistically and significantly superior to placebo

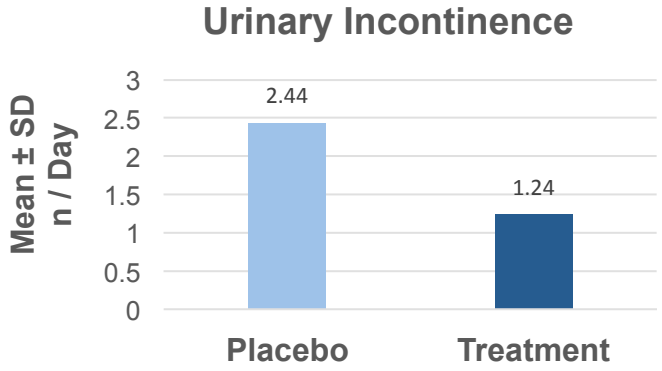
P-values are based on logistic regression analyses
* Statistically significant (p< 0.01) ** Statistically highly significant (p <0.01)

UriVarx™ Clinical Efficacy - Secondary Endpoint Frequency of Urgency , SI and UI

Week 8







P-values are based on logistic regression analyses
* * Statistically highly significant (p< 0.001)

UriVarx™ significantly superior to Placebo

UriVarx™ Clinical Efficacy
OAB-SF Summary Table

Mean difference Placebo vs Treatment following 8 weeks

OAB-SF (N=60 placebo, N=58 treatment)	Mean	95% CI	P value
Total OAB-SF	**-30.83**	-34.75 to -26.93	p<0.001 **
Bothersome	**-11.53**	-13.15 to -9.90	p<0.01 *
Difficulty in coping	**-7.57**	-8.71 to -6.43)	p<0.01 *
Concern/worry	**-4.41**	-5.30 to -3.52	p<0.01 *
Difficulty in sleeping	**-6.51**	-7.58 to -5.44	p<0.01 *
Social interaction	**-1.14**	-1.59 to -0.68	p<0.01 *

P-values are based on logistic regression analyses
* Statistically significant (p< 0.01)
** Statistically highly significant (p <0.01)