

Self-administration of burosumab in children and adults with X-linked hypophosphataemia in two open-label, single-arm clinical studies

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SUPPLEMENTARY DATA

Self-administration of burosumab in children and adults with X-linked hypophosphataemia in two open-label, single-arm clinical studies

PAEDIATRIC DATA

KRN23-003 and KRN23-004 (paediatrics): Baseline characteristics of patients with self-administration

Characteristic	KRN23-003 (n=15)	KRN23-004 (n=5)	Total (n=20)
Age, years, mean \pm SD	6.7 \pm 3.2	9.2 \pm 3.9	7.4 \pm 3.4
Female, n (%)	13 (86.7)	1 (20.0)	14 (70.0)
Weight, kg, mean \pm SD	20.9 \pm 7	28.9 \pm 14.1	22.9 \pm 9.5
Height, cm, mean \pm SD	113.8 \pm 20.2	122.2 \pm 22.6	115.9 \pm 20.5
Serum phosphate, mg/dL, mean \pm SD	2.6 \pm 0.3	2.2 \pm 0.4	2.5 \pm 0.4
TmP/GFR, mg/dL, mean \pm SD	2.4 \pm 0.5	2.0 \pm 0.6	2.3 \pm 0.5
Serum 1,25(OH) ₂ D, pg/mL, mean \pm SD	24.7 \pm 12.7	43.2 \pm 23.3	29.3 \pm 17.3
Serum iFGF23, pg/mL, mean \pm SD	182.6 \pm 67.3	N/A	182.6 \pm 67.3

KRN23-003 (Paediatrics): Baseline characteristics of patients with self-administration – genetic analysis

Parameter (unit)		KRN23-003 (n=15)
PHEX mutation, n (%)	Positive	13 (86.7)
	Undone	2 (13.3)
	Other	0

KRN23-003 and KRN23-004 (paediatrics): Summary of drug exposure of patients with self-administration

Parameter (unit)		KRN23 (N=20)
Duration of prescribed treatment (week)	n	20
	Mean	105.860
	SD	16.678
	Min	73.90
	Median	114.800
	Max	119.90
Prescribed dose (mg)	n	1076
	Mean	20.263
	SD	7.990
	Min	7.52
	Median	17.360
	Max	51.00

KRN23-003 and KRN23-004 (paediatrics): Serum phosphate over time of patients with self-administration

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
Phosphate (mg/dL)	Baseline	n	20
		Mean	2.51
		SD	0.38
		Min	1.7
		Median	2.60
		Max	3.0
	Week 1	n	15
		Mean	3.67
		SD	0.48
		Min	2.9
		Median	3.70
		Max	4.5
	Week 2	n	18
		Mean	3.53
		SD	0.59
		Min	2.5
		Median	3.50
		Max	4.7
	Week 4	n	18
		Mean	3.66
SD		0.60	
Min		2.7	
Median		3.60	
Max		4.8	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
Phosphate (mg/dL)	Week 8	n	20
		Mean	3.48
		SD	0.47
		Min	2.8
		Median	3.40
		Max	4.6
	Week 12	n	20
		Mean	3.40
		SD	0.54
		Min	2.7
		Median	3.20
		Max	4.6
	Week 16	n	20
		Mean	3.38
		SD	0.51
		Min	2.5
		Median	3.30
		Max	4.4
	Week 20	n	15
		Mean	3.28
SD		0.62	
Min		2.4	
Median		3.20	
Max		4.3	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
Phosphate (mg/dL)	Week 24	n	20
		Mean	3.29
		SD	0.49
		Min	2.5
		Median	3.20
		Max	4.2
	Week 28	n	15
		Mean	3.50
		SD	0.46
		Min	2.7
		Median	3.40
		Max	4.3
	Week 32	n	15
		Mean	3.53
		SD	0.43
		Min	3.0
		Median	3.30
		Max	4.2
	Week 36	n	20
		Mean	3.40
SD		0.34	
Min		2.8	
Median		3.35	
Max		3.9	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
Phosphate (mg/dL)	Week 40	n	15
		Mean	3.51
		SD	0.45
		Min	2.8
		Median	3.40
		Max	4.3
	Week 48	n	4
		Mean	2.90
		SD	0.29
		Min	2.6
		Median	2.85
		Max	3.3
	Week 52	n	15
		Mean	3.53
		SD	0.52
		Min	2.8
		Median	3.30
		Max	4.7
	Week 60	n	5
		Mean	2.86
SD		0.30	
Min		2.5	
Median		2.90	
Max		3.3	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
Phosphate (mg/dL)	Week 64	n	15
		Mean	3.49
		SD	0.46
		Min	2.7
		Median	3.30
		Max	4.1
	Week 72	n	5
		Mean	3.10
		SD	0.34
		Min	2.7
		Median	3.00
		Max	3.5
	Week 76	n	15
		Mean	3.44
		SD	0.46
		Min	2.5
		Median	3.40
		Max	4.1
	Week 84	n	1
		Mean	3.30
		SD	-
Min		3.3	
Median		3.30	
Max		3.3	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
Phosphate (mg/dL)	Week 88	n	13
		Mean	3.55
		SD	0.51
		Min	2.6
		Median	3.40
		Max	4.3
	Week 100	n	15
		Mean	3.47
		SD	0.41
		Min	2.7
		Median	3.50
		Max	4.2
	Week 112	n	14
		Mean	3.62
		SD	0.47
		Min	2.6
		Median	3.70
		Max	4.3
	Week 124	n	3
		Mean	3.83
		SD	0.25
Min		3.6	
Median		3.80	
Max		4.1	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
Phosphate (mg/dL)	End of study	n	5
		Mean	2.94
		SD	0.29
		Min	2.5
		Median	3.10
		Max	3.2
	End of treatment	n	14
		Mean	3.58
		SD	0.36
		Min	3.0
		Median	3.60
		Max	4.2
	Withdrawal	n	1
		Mean	3.40
		SD	-
		Min	3.4
		Median	3.40
		Max	3.4

KRN23-003 and KRN23-004 (paediatrics): TmP/GFR (2-hour urine) over time of patients with self-administration

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
TmP/GFR (2-hour urine) (mg/dL)	Baseline	n	20
		Mean	2.3304
		SD	0.5389
		Min	1.445
		Median	2.2910
		Max	3.341
	Week 4	n	18
		Mean	3.8372
		SD	0.8688
		Min	2.543
		Median	3.4730
		Max	5.596
	Week 8	n	18
		Mean	3.8752
		SD	0.8233
		Min	2.663
		Median	3.7500
		Max	5.320
	Week 16	n	18
		Mean	3.5732
SD		0.8118	
Min		2.355	
Median		3.3270	
Max		5.046	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
TmP/GFR (2-hour urine) (mg/dL)	Week 24	n	15
		Mean	3.6682
		SD	0.6753
		Min	2.759
		Median	3.3420
		Max	4.693
	Week 32	n	14
		Mean	3.6571
		SD	0.7173
		Min	2.865
		Median	3.3930
		Max	5.066
	Week 40	n	15
		Mean	3.6124
		SD	0.6072
		Min	2.346
		Median	3.5040
		Max	4.571
	Week 48	n	4
		Mean	2.9600
SD		0.4425	
Min		2.613	
Median		2.8100	
Max		3.607	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
TmP/GFR (2-hour urine) (mg/dL)	Week 52	n	15
		Mean	3.7705
		SD	0.7674
		Min	2.868
		Median	3.6030
		Max	5.304
	Week 64	n	15
		Mean	3.7381
		SD	0.5467
		Min	2.528
		Median	3.6330
		Max	4.468
	Week 76	n	15
		Mean	3.6089
		SD	0.5015
		Min	2.820
		Median	3.5680
		Max	4.366
	Week 88	n	13
		Mean	3.7035
SD		0.7378	
Min		2.577	
Median		3.7460	
Max		5.304	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
TmP/GFR (2-hour urine) (mg/dL)	Week 100	n	15
		Mean	3.7209
		SD	0.5028
		Min	2.630
		Median	3.8740
		Max	4.682
	Week 112	n	13
		Mean	3.8863
		SD	0.6296
		Min	2.835
		Median	4.0550
		Max	4.861
	Week 124	n	3
		Mean	4.0430
		SD	0.5818
		Min	3.373
		Median	4.3360
		Max	4.420
	End of study	n	5
		Mean	2.9488
		SD	0.5689
Min		2.345	
Median		3.0930	
Max		3.570	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
TmP/GFR (2-hour urine) (mg/dL)	End of treatment	n	14
		Mean	3.8280
		SD	0.5801
		Min	2.807
		Median	3.9400
		Max	4.958
		Max	4.958
	Withdrawal	n	1
		Mean	3.6740
		SD	-
		Min	3.674
		Median	3.6740
		Max	3.674
		Max	3.674

KRN23-003 and KRN23-004 (paediatrics): 1,25(OH)₂D over time of patients with self-administration

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
1,25(OH) ₂ D (pg/mL)	Baseline	n	20
		Mean	29.30
		SD	17.35
		Min	5.1
		Median	26.35
		Max	66.4
	Week 1	n	15
		Mean	70.81
		SD	21.49
		Min	36.8
		Median	65.40
		Max	125.0
	Week 2	n	18
		Mean	64.87
		SD	23.48
		Min	41.6
		Median	60.90
		Max	130.0
	Week 4	n	18
		Mean	64.48
SD		23.76	
Min		38.5	
Median		59.65	
Max		127.0	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
1,25(OH) ₂ D (pg/mL)	Week 8	n	20
		Mean	60.87
		SD	18.01
		Min	40.8
		Median	54.80
		Max	114.0
	Week 12	n	15
		Mean	55.43
		SD	15.34
		Min	38.7
		Median	55.60
		Max	93.8
	Week 16	n	20
		Mean	62.94
		SD	18.85
		Min	42.6
		Median	58.95
		Max	105.0
	Week 24	n	20
		Mean	60.36
SD		23.14	
Min		37.0	
Median		53.70	
Max		130.0	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
1,25(OH) ₂ D (pg/mL)	Week 32	n	15
		Mean	53.11
		SD	13.15
		Min	35.4
		Median	55.80
		Max	78.3
	Week 40	n	15
		Mean	62.19
		SD	12.50
		Min	43.1
		Median	64.90
		Max	86.9
	Week 48	n	4
		Mean	107.95
		SD	37.32
		Min	67.2
		Median	106.80
		Max	151.0
	Week 52	n	15
		Mean	61.75
		SD	10.69
Min		44.6	
Median		62.50	
Max		81.4	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
1,25(OH) ₂ D (pg/mL)	Week 64	n	15
		Mean	60.35
		SD	12.43
		Min	42.8
		Median	59.70
		Max	89.3
	Week 76	n	15
		Mean	62.67
		SD	11.69
		Min	43.7
		Median	63.40
		Max	80.3
	Week 88	n	13
		Mean	60.84
		SD	11.55
		Min	41.7
		Median	62.50
		Max	89.3
	Week 100	n	15
		Mean	64.05
		SD	14.98
Min		38.2	
Median		59.70	
Max		91.2	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
1,25(OH) ₂ D (pg/mL)	Week 112	n	14
		Mean	63.00
		SD	17.53
		Min	39.5
		Median	62.10
		Max	92.9
	Week 124	n	3
		Mean	59.60
		SD	20.16
		Min	40.4
		Median	57.80
		Max	80.6
	End of study	n	5
		Mean	80.90
		SD	14.69
		Min	61.7
		Median	87.60
		Max	94.8
	End of treatment	n	14
		Mean	53.61
		SD	10.68
Min		30.2	
Median		55.30	
Max		69.6	

Parameter (unit)	Visit	KRN23 (paediatrics)	
		N=20	Actual
1,25(OH) ₂ D (pg/mL)	Withdrawal	n	1
		Mean	87.20
		SD	-
		Min	87.2
		Median	87.20
		Max	87.2

KRN23-003 and KRN23-004 (paediatrics): Incidence of treatment-emergent adverse events (TEAE) in patients with self-administration

PT	KRN23 (paediatrics) N=20			
	TEAE		Drug-related	
	n	(%)	n	(%)
Any TEAE	17	85.0	2	10.0
Adenoidal hypertrophy	1	5.0	0	0.0
Arthropod sting	1	5.0	0	0.0
Astigmatism	1	5.0	0	0.0
Beta haemolytic streptococcal infection	1	5.0	0	0.0
Blepharitis allergic	1	5.0	0	0.0
Blood 25-hydroxycholecalciferol D	1	5.0	1	5.0
Bronchitis	1	5.0	0	0.0
Chalazion	1	5.0	0	0.0
Chronic sinusitis	1	5.0	0	0.0
Conjunctivitis	1	5.0	0	0.0
Constipation	1	5.0	0	0.0
Contusion	1	5.0	0	0.0
Croup infectious	1	5.0	0	0.0
Dental caries	7	35.0	0	0.0
Diarrhoea	2	10.0	1	5.0
Dizziness	1	5.0	1	5.0
Eczema	1	5.0	0	0.0
Enterocolitis viral	1	5.0	0	0.0

KRN23 (paediatrics)
N=20

PT	TEAE		Drug-related	
	n	(%)	n	(%)
Epistaxis	1	5.0	0	0.0
Erythema infectiosum	2	10.0	0	0.0
Foot fracture	1	5.0	0	0.0
Gastroenteritis	1	5.0	0	0.0
Hand-foot-and-mouth disease	1	5.0	0	0.0
Headache	1	5.0	1	5.0
Hordeolum	1	5.0	0	0.0
Impetigo	2	10.0	0	0.0
Influenza	6	30.0	0	0.0
Malocclusion	1	5.0	0	0.0
Nasopharyngitis	8	40.0	0	0.0
Nausea	1	5.0	1	5.0
Otitis media	3	15.0	0	0.0
Periodontitis	2	10.0	0	0.0
Pharyngitis	3	15.0	0	0.0
Pyrexia	1	5.0	0	0.0
Rash	1	5.0	0	0.0
Rhinitis	1	5.0	0	0.0
Rhinorrhoea	1	5.0	0	0.0

KRN23 (paediatrics)
N=20

PT	TEAE		Drug-related	
	n	(%)	n	(%)
Seasonal allergy	1	5.0	0	0.0
Skin laceration	1	5.0	0	0.0
Swelling face	1	5.0	0	0.0
Syncope	1	5.0	0	0.0
Tonsillar hypertrophy	1	5.0	0	0.0
Tonsillitis	1	5.0	0	0.0
Tooth abscess	1	5.0	0	0.0
Tooth development disorder	1	5.0	0	0.0
Tooth fracture	1	5.0	0	0.0
Upper respiratory tract infection	3	15.0	0	0.0
Urticaria	1	5.0	0	0.0
Vascular malformation	1	5.0	0	0.0
Visual acuity reduced	1	5.0	0	0.0

ADULT DATA

KRN23-004 (adults): Baseline characteristics of patients with self-administration

Parameter (unit)		KRN23 (adults) N=4
Sex	Female	2 (50.0)
	Male	2 (50.0)
Age (yrs)	n	4
	Mean	39.3
	SD	21.5
	Min	21
	Median	35.5
	Max	65
	<65	3 (75.0)
	≥65	1 (25.0)
Weight (kg)	n	4
	Mean	51.45
	SD	10.68
	Min	40.1
	Median	49.95
	Max	65.8
Phosphate (mg/dL)	n	4
	Mean	1.98
	SD	0.43
	Min	1.5
	Median	1.95
	Max	2.5
Calcium (mg/dL)	n	4
	Mean	9.40

Parameter (unit)	KRN23 (adults)	
		N=4
1,25(OH) ₂ D (pg/mL)	SD	0.36
	Min	8.9
	Median	9.50
	Max	9.7
	n	4
	Mean	37.23
	SD	9.64
Parathyroid hormone, intact (pg/mL)	Min	25.1
	Median	37.80
	Max	48.2
	n	4
	Mean	78.0
	SD	34.8
	Min	46
TmP/GFR (2-hour urine) (mg/dL)	Median	77.0
	Max	112
	n	4
	Mean	1.6173
	SD	0.3348
	Min	1.282
	Median	1.5690
Max	2.049	

KRN23-004 (adults): Summary of drug exposure of patients with self-administration

Parameter (unit)		KRN23 (adults) N=4
Duration of treatment (week)	n	4
	Mean	102.05
	SD	3.90
	Min	100.1
	Median	100.10
	Max	107.9
Dose per 4 weeks	n	4
	Mean	46.973
	SD	26.739
	Min	9.35
	Median	52.960
	Max	72.62

KRN23-004 (adults): Serum phosphate over time of patients with self-administration

Parameter (unit)	Visit	KRN23 (adults)	
		N=4	Actual
Phosphate (mg/dL)	Baseline	n	4
		Mean	1.98
		SD	0.43
		Min	1.5
		Median	1.95
		Max	2.5
	Week 8	n	4
		Mean	2.15
		SD	0.45
		Min	1.8
		Median	2.00
		Max	2.8
	Week 16	n	4
		Mean	2.33
		SD	0.43
		Min	1.9
		Median	2.25
		Max	2.9
	Week 24	n	3
		Mean	2.30
SD		0.44	
Min		2.0	
Median		2.10	
Max		2.8	

Parameter (unit)	Visit	KRN23 (adults)	
		N=4	Actual
Phosphate (mg/dL)	Week 32	n	4
		Mean	2.20
		SD	0.61
		Min	1.6
		Median	2.10
		Max	3.0
	Week 40	n	4
		Mean	2.05
		SD	0.45
		Min	1.7
		Median	1.90
		Max	2.7
	Week 48	n	4
		Mean	2.13
		SD	0.59
		Min	1.3
		Median	2.25
		Max	2.7
	Week 56	n	4
		Mean	2.35
SD		0.47	
Min		1.9	
Median		2.35	
Max		2.8	

Parameter (unit)	Visit	KRN23 (adults)	
		N=4	Actual
Phosphate (mg/dL)	Week 64	n	3
		Mean	2.47
		SD	0.74
		Min	1.9
		Median	2.20
		Max	3.3
	Week 72	n	4
		Mean	2.13
		SD	0.58
		Min	1.5
		Median	2.05
		Max	2.9
	Week 80	n	4
		Mean	2.28
		SD	0.78
		Min	1.6
		Median	2.05
		Max	3.4
	Week 88	n	4
		Mean	2.10
SD		0.48	
Min		1.8	
Median		1.90	
Max		2.8	

Parameter (unit)	Visit	KRN23 (adults)	
		N=4	Actual
Phosphate (mg/dL)	Week 96	n	4
		Mean	2.13
		SD	0.74
		Min	1.2
		Median	2.15
		Max	3.0
	Week 104	n	1
		Mean	2.20
		SD	-
		Min	2.2
		Median	2.20
		Max	2.2
	End of study	n	4
		Mean	2.43
		SD	0.47
		Min	2.0
		Median	2.30
		Max	3.1

KRN23-004 (adults): TmP/GFR over time of patients with self-administration

Parameter	Visit		Statistics	KRN23-004 (N=4)
TmP/GFR (mg/dL)	Baseline	Observed value	n	4
			Mean	1.617
			Median	1.569
			SD	0.3348
			Min	1.28
			Max	2.05
	Week 48	Observed value	n	4
			Mean	1.893
			Median	1.955
			SD	0.7453
			Min	0.93
			Max	2.73
	Change from baseline		n	4
			Mean	0.276
			Median	0.410
			SD	0.5977
			Min	-0.51
			Max	0.79

Parameter	Visit		Statistics	KRN23-004 (N=4)
TmP/GFR (mg/dL)	Week 96	Observed value	n	4
			Mean	2.000
			Median	2.116
			SD	0.8019
			Min	0.97
			Max	2.80
	Change from baseline	n	4	
		Mean	0.383	
		Median	0.434	
		SD	0.7116	
		Min	-0.48	
		Max	1.14	
	End of study	Observed value	n	4
			Mean	2.281
			Median	2.137
			SD	0.6764
			Min	1.72
			Max	3.13
Change from baseline	n	4		
	Mean	0.664		
	Median	0.680		
	SD	0.5813		
	Min	0.06		
	Max	1.23		

KRN23-004 (adults): 1,25(OH)₂D over time of patients with self-administration

Parameter (unit)	Visit	KRN23 (adults)	
		N=4	Actual
1,25(OH) ₂ D (pg/mL)	Baseline	n	4
		Mean	37.23
		SD	9.64
		Min	25.1
		Median	37.80
		Max	48.2
	Week 16	n	4
		Mean	51.78
		SD	11.79
		Min	39.9
		Median	49.60
		Max	68.0
	Week 32	n	4
		Mean	68.90
		SD	42.72
		Min	42.5
		Median	50.55
		Max	132.0
	Week 48	n	4
		Mean	47.43
SD		8.06	
Min		38.6	
Median		47.85	
Max		55.4	

Parameter (unit)	Visit	KRN23 (adults)	
		N=4	Actual
1,25(OH) ₂ D (pg/mL)	Week 64	n	3
		Mean	50.70
		SD	19.05
		Min	30.6
		Median	53.00
		Max	68.5
	Week 80	n	4
		Mean	47.03
		SD	18.17
		Min	32.3
		Median	41.25
		Max	73.3
	Week 96	n	4
		Mean	47.78
		SD	13.86
		Min	30.3
		Median	48.90
		Max	63.0
	End of study	n	4
		Mean	45.35
SD		6.34	
Min		37.5	
Median		46.65	
Max		50.6	

KRN23-004 (adults): Overall summary of treatment-emergent adverse events (TEAE) of patients with self-administration

	KRN23 (adults)	
	N=4	
	n	(%)
Subjects with any TEAE	3	(75.0)
Death	0	
Other serious	1	(25.0)
Other significant	0	
Subjects with any drug-related TEAE	0	
Death	0	
Other serious	0	
Other significant	0	

KRN23-004 (adults): Summary of adverse events by System Organ Class and preferred term of patients with self-administration

System Organ Class Preferred term	KRN23 N=4
Subjects with any TEAE	3 (75.0)
Gastrointestinal disorders	2 (50.0)
Dental caries	1 (25.0)
Gastritis	1 (25.0)
Nausea	1 (25.0)
Infections and infestations	2 (50.0)
Appendicitis	1 (25.0)
Influenza	1 (25.0)
Nasopharyngitis	2 (50.0)
Pneumonia	1 (25.0)
Upper respiratory tract infection	1 (25.0)
Musculoskeletal and connective tissue disorders	1 (25.0)
Arthralgia	1 (25.0)
Nervous system disorders	1 (25.0)
Headache	1 (25.0)
Skin and subcutaneous tissue disorders	1 (25.0)
Rash	1 (25.0)