Additional File

Safety, tolerability and efficacy of intra-articular Progenza in knee osteoarthritis: A randomized double-blind placebo-controlled single ascending dose study

Additional Table S1
Baseline distribution of semi-quantitative MRI OA Knee Score (MOAKS) markers.

	Placebo (n=4)	PRG 3.9M (n=8)	PRG 6.7M (n=8)
Cartilage morphology			
Maximum thickness score across entire knee			
0	1 (25%)	0 (0%)	0 (0%)
1	0 (0%)	1 (12.5%)	0 (0%)
2	1 (25%)	3 (37.5%)	3 (37.5%)
3	2 (50%)	4 (50%)	5 (62.5%)
No. of subregions with thickness score >0 across entire knee			
0	1 (25%)	0 (0%)	0 (0%)
1-3	1 (25%)	2 (25%)	3 (37.5%)
4-6	1 (25%)	4 (50%)	3 (37.5%)
7-9	1 (25%)	2 (25%)	2 (25%)
Maximum surface area score across entire knee			
0-1	1 (25%)	0 (0%)	0 (0%)
2	0 (0%)	2 (25%)	2 (25%)
3	3 (75%)	6 (75%)	6 (75%)
No. of subregions with surface area score >0 across entire knee			
0-1	1 (25%)	0 (0%)	0 (0%)
2-4	0 (0%)	1 (12.5%)	1 (12.5%)
5-7	0 (0%)	2 (25%)	4 (50%)
8+	3 (75%)	5 (62.5%)	3 (37.5%)
Osteophytes			
No. of locations affected by any osteophyte			
0-2	1 (25%)	1 (12.5%)	0 (0%)
3-5	0 (0%)	0 (0%)	1 (12.5%)
6+	3 (75%)	7 (87.5%)	7 (87.5%)
Maximum osteophyte score in knee			
0-1	1 (25%)	1 (12.5%)	0 (0%)
2	1 (25%)	3 (37.5%)	6 (75%)
3	2 (50%)	4 (50%)	2 (25%)
Meniscus morphology			
Maximum grade across all locations			
0 (normal/signal)	1 (25%)	0 (0%)	0 (0%)
1 (tear)	0 (0%)	3 (37.5%)	3 (37.5%)
2 (maceration)	3 (75%)	5 (62.5%)	5 (62.5%)
BMLs			
No. of subregions affected by any BML			
0	1 (25%)	0 (0%)	0 (0%)
1	0 (0%)	2 (25%)	0 (0%)
2	0 (0%)	0 (0%)	0 (0%)
3	1 (25%)	1 (12.5%)	2 (25%)
4	0 (0%)	3 (37.5%)	1 (12.5%)
5+	2 (50%)	2 (25%)	5 (62.5%)
Maximum BML score in knee			
0	1 (25%)	0 (0%)	0 (0%)
1	0 (0%)	1 (12.5%)	0 (0%)
2	1 (25%)	5 (62.5%)	4 (50%)
3	2 (50%)	2 (25%)	4 (50%)
Synovitis (Hoffa-synovitis score)			
0	0 (0%)	0 (0%)	0 (0%)
1	2 (50%)	5 (62.5%)	3 (37.5%)
2-3	2 (50%)	3 (37.5%)	5 (62.5%)
Effusions (effusion-synovitis score)			
0-1	2 (50%)	1 (12.5%)	3 (37.5%)
2-3	2 (50%)	7 (87.5%)	5 (62.5%)

Data are presented as n (%). BML, bone marrow lesion.

Additional Table S2
Number of patients noted with changes from screening to Month 12 for MOAKS assessments.

Treatment group	MOAKS derived measure	Improved	Unchanged	Deteriorated
Placebo	Number of sub-regions with cartilage thickness score >0	0 (0%)	3 (75%)	1 (25%)
	Maximum BML score in knee	0 (0%)	3 (75%)	1 (25%)
	Number of sub-regions affected by BMLs	2 (50%)	2 (50%)	0 (0%)
	Hoffa-synovitis score	1 (25%)	3 (75%)	0 (0%)
	Effusion-synovitis score	2 (50%)	2 (50%)	0 (0%)
PRG 3.9M	Maximum cartilage thickness score across treated knee	0 (0%)	6 (86%)	1 (14%)
	Number of sub-regions with cartilage surface area score >0	0 (0%)	6 (86%)	1 (14%)
	Number of locations affected by osteophytes	0 (0%)	6 (86%)	1 (14%)
	Maximum BML score in knee	0 (0%)	5 (71%)	2 (29%)
	Number of sub-regions affected by BMLs	1 (14%)	4 (57%)	2 (29%)
	Hoffa-synovitis score	1 (14%)	6 (86%)	0 (0%)
	Effusion-synovitis score	0 (0%)	6 (86%)	1 (14%)
	Meniscus morphology – medial body sub-region grading	0 (0%)	6 (86%)	1 (14%)
	Meniscus morphology – maximum grade across all regions	0 (0%)	6 (86%)	1 (14%)
	Meniscus morphology – patient group	0 (0%)	6 (86%)	1 (14%)
PRG 6.7M	Maximum cartilage thickness score across treated knee	0 (0%)	7 (88%)	1 (13%)
	Number of sub-regions with cartilage surface area score >0	0 (0%)	7 (88%)	1 (13%)
	Maximum osteophyte score across treated knee	0 (0%)	7 (88%)	1 (13%)
	Number of locations affected by osteophytes	0 (0%)	7 (88%)	1 (13%)
	Maximum BML score in knee	1 (13%)	4 (50%)	3 (38%)
	Number of sub-regions affected by BMLs	1 (13%)	4 (50%)	3 (38%)
	Hoffa-synovitis score	0 (0%)	7 (88%)	1 (13%)
	Effusion-synovitis score	1 (13%)	7 (88%)	0 (0%)
	Meniscus morphology – lateral anterior sub-region grading	0 (0%)	7 (88%)	1 (13%)

Data are presented as n (%). BML, bone marrow lesion.