PARADIGM BIOPHARMA

BELL POTTER HEALTHCARE CONFERENCE 2023

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Summary

Paradigm Opportunity

Globally harmonised phase 3 OA program.

- Recent capital raising to fund the company through to mid CY25 (without additional licensing revenue)[1,2].
- Extensive clinical data and Real-world evidence of iPPS effect in OA:
  - Phase 2 PARA_OA_005 (121 patients)
  - Phase 2 PARA_OA_008 (61 patients)
  - TGA special access scheme (over 600 patients)
  - US FDA approved Expanded Access Program (10 ex-NFL Players).
- FDA Fast Tracked phase 3 OA program. Stage 1 completed, randomising over 600 patients across 120 sites in 7 countries.
- Opportunity for expedited approval in Australia through TGA Provisional Approval prior to the completion of the global phase 3 program.
- Recent results indicate treatment effect on OA beyond just the relief of symptoms supports iPPS as a blockbuster opportunity.
- Strong IP and patent protection for iPPS.
- Commercial scale manufacturing capabilities completed.
- Strategy to partner clinical assets.

1. $69.4m includes cash balance and R&D Refund provision as at 30 September 2023 and assumes A$28.5m proceeds from capital raising (excluding costs of the Offer),
2. $103.2m includes cash balance and R&D Refund provision as at 30 September 2023 and assumes A$28.5m proceeds from capital raising (excluding costs of the Offer) and full exercise of all Options.

Blockbuster market opportunity

Zilosul® aims to meet a significant unmet need in osteoarthritis.

FDA Fast Track Designation

Market size potential US$10B+ p.a.[4]

People affected by OA in 2020[3]

72m+

People affected by OA by 2030[3]

120m+

Markets: US, EU5, Canada and Australia.

In the US alone, OA is predicted to increase by 86% to 67 million by 2030.[3]

Knee and Hip (Global)

69%

of all OA

OA patients dissatisfied with current treatments[1]

81%

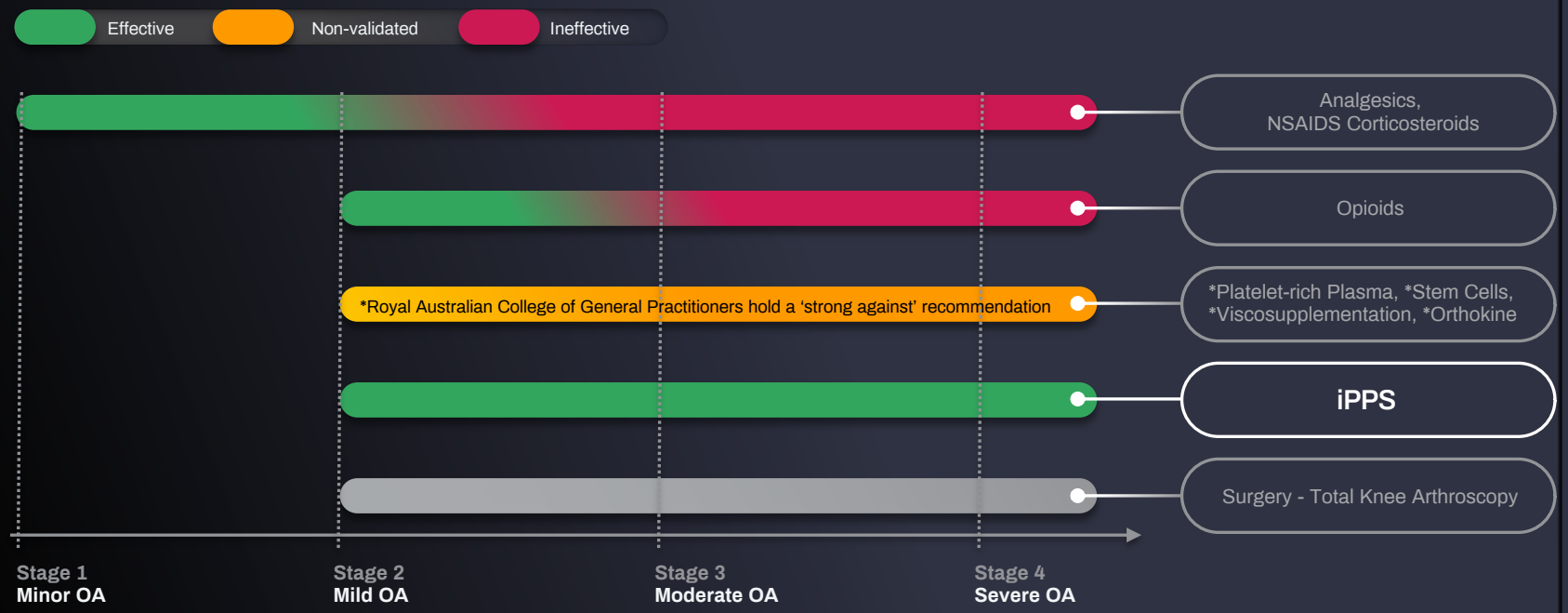
Target uptake: 10% dissatisfied market[1]

Zilosul® indicative price: US$2500 per year[2]

1. National Institute of Health; Emerging drugs for osteoarthritis; Hunter DJ and Matthews G 16(3): 479–491; 2011 September.
2. Global Pricing Research conducted by Paradigm. EU5: Germany, UK, Spain, France, Italy
3. OARSI. Osteoarthritis: A Serious Disease, Submitted to the U.S. Food and Drug Administration December 1, 2016
4. Calculation based on 10% penetration dissatisfied patients with knee and hip OA in the 72m addressable market, at price of US$2500.

Market Demand

There are no effective treatments for Moderate to Severe OA



"Most patients with OA of the hip and/or knee either initiate on or switch to opioids for long-term management of OA-related pain despite known risks. This highlights the need for new treatments that delay or prevent use of opioids[1]".

1. Source: https://www.tandfonline.com/doi/full/10.1080/03007995.2023.2234727?scroll=top&needAccess=true&role=tab

Precedent OA transactions

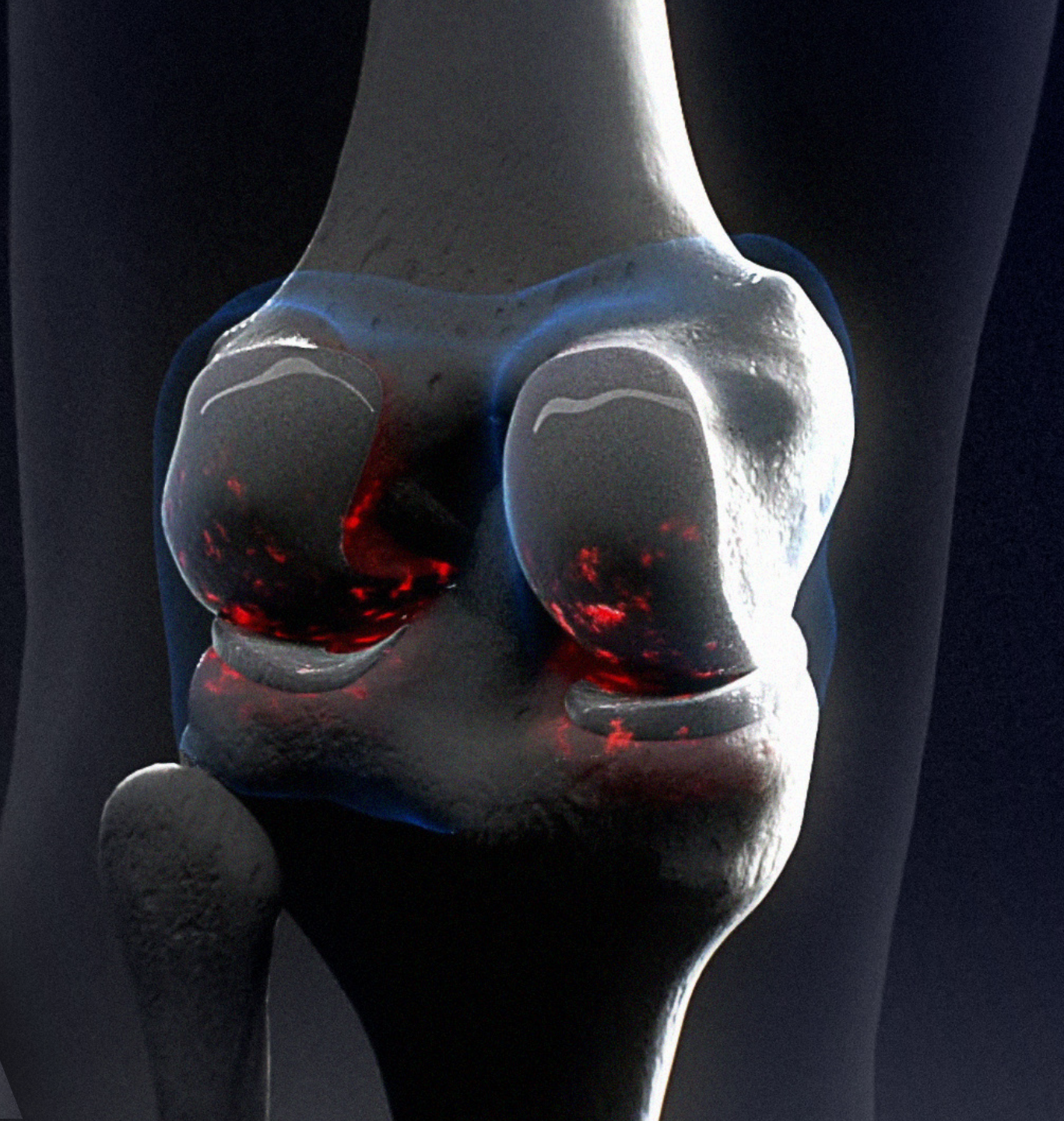
Late-stage OA program potential to unlock shareholder value

Date	Licensee/Acquirer	Licensor	Phase	Upfront (US$m)	Total Deal Value (US$m)#	Region
Jun-22	Endo International	Taiwan Liposome Company	3	30	140	USA
Apr-22	Juniper Biologics	Kolon Life Science	3	n/a	600	APAC, MEA
Oct-21	Pacira Biosciences	Flexion Therapeutics	Marketed	n/a	579	100%
Sep-21	Haisco Pharmaceuticals	Biosplice Therapeutics	3	20	140	China
Feb-21	Nuance Pharma	Antibe Therapeutics	3	20	100	China
Oct-20	Novartis	Merk kGaA	2	~53	475	100%
Nov-18	Mundipharma	Kolon Life Science	Marketed	~27	600	Japan

 # Including Upfront & Milestone payments and excluding royalties, if applicable.

Top-line Results

PARA_OA_008



Recap

PARA_OA_008

Exploring the durable effects of iPPS on pain, function and OA disease progression.

Biomarker study assessing change from baseline in multiple objective measures associated with disease progression of OA.

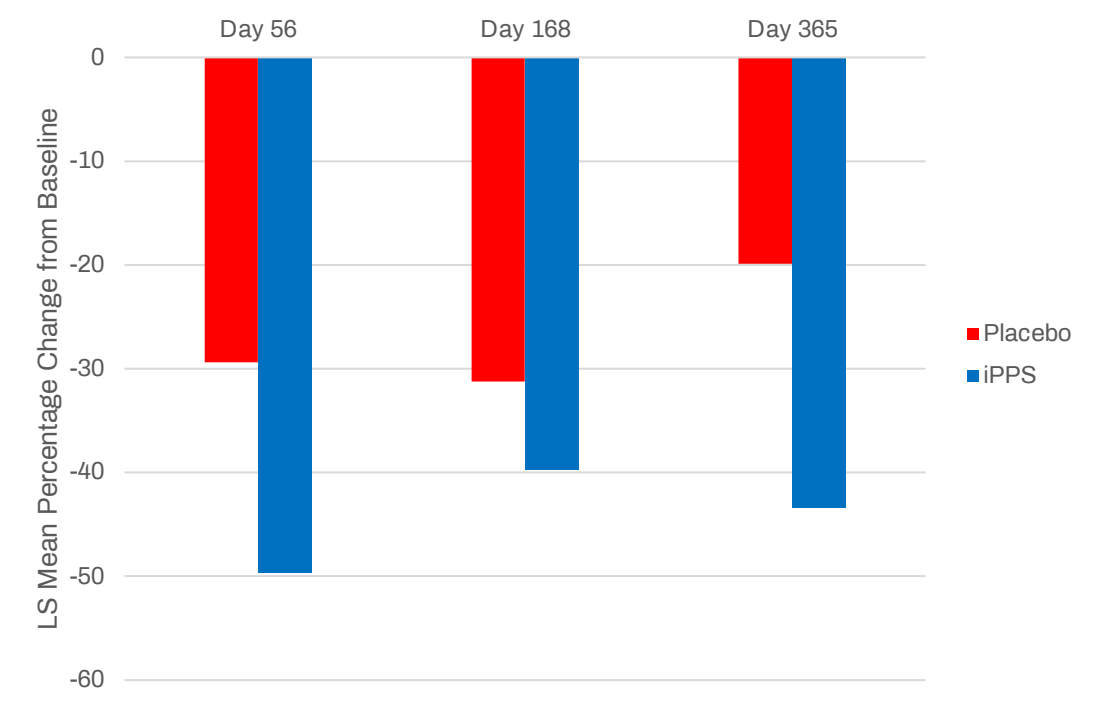
- 61 participants received iPPS once or twice weekly, or placebo.
- Follow-up period out to 12 months.

Outstanding top-line results:

- **Primary Endpoint Achieved** - change in one or more synovial fluid biomarkers associated with osteoarthritis disease progression at Day 56.
- Statistically significant improvements in pain and joint function at Day 56 (primary end point of the phase 3 OA program).
- Significant improvements out to 12-months in pain, function, stiffness, and overall WOMAC scores for twice-weekly iPPS compared to the placebo arm.
- Positive structural changes in the knee as measured by quantitative MRI analysis. At Day 168 iPPS treatment demonstrated:
  - increased cartilage thickness and volume indicating cartilage preservation,
  - reduced bone marrow lesions,
  - reduced synovitis.

PARA_OA_008: Clinical Endpoints

DAY 365 TOP-LINE RESULTS – CHANGES IN WOMAC PAIN FROM BASELINE

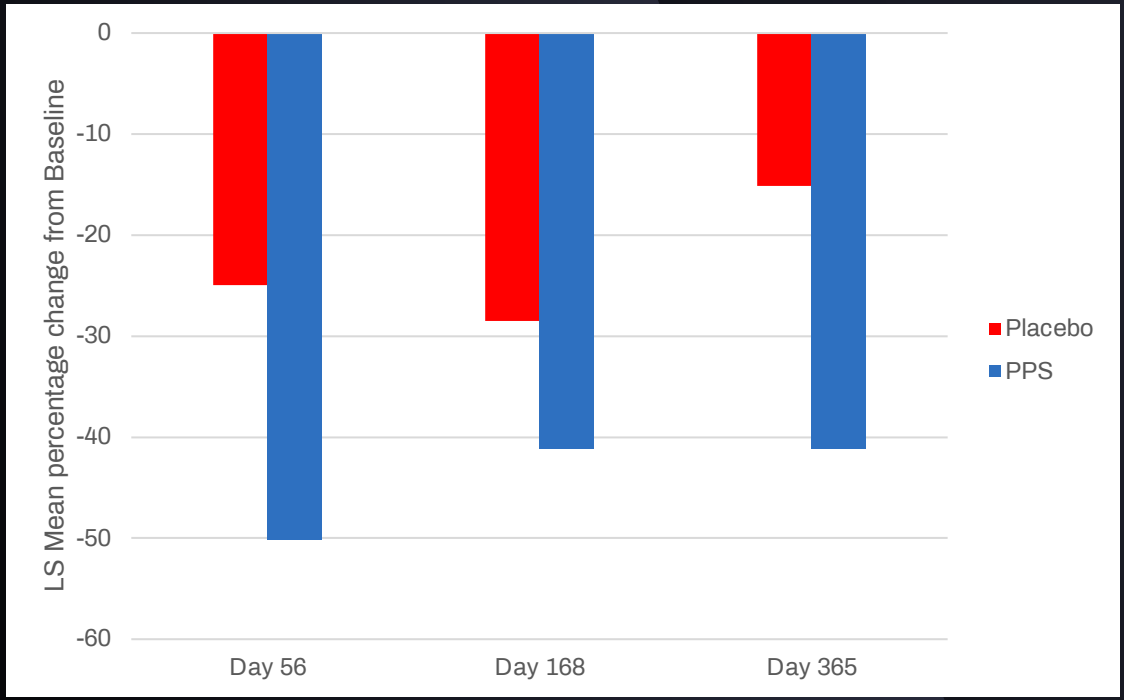


Adjusted LS mean % change in WOMAC pain from baseline at Day 56, 168 and 365 of participants treated with twice-weekly iPPS versus placebo

- Twice-weekly iPPS treatment showed significant improvement at Day 56 (p=0.045) and Day 365 (p=0.054) in WOMAC pain compared to the placebo arm.
- iPPS treatment demonstrated clinically meaningful response to pain.
- The proportions achieving a clinically meaningful ≥30% improvement in pain in the twice-weekly group were 54.5% compared to 33.3% in the placebo group.

PARA_OA_008: Clinical Endpoints

DAY 365 TOP-LINE RESULTS – CHANGES IN WOMAC FUNCTION



Adjusted LS mean % change in WOMAC function from baseline at each visit in participants treated with twice-weekly iPPS versus placebo.

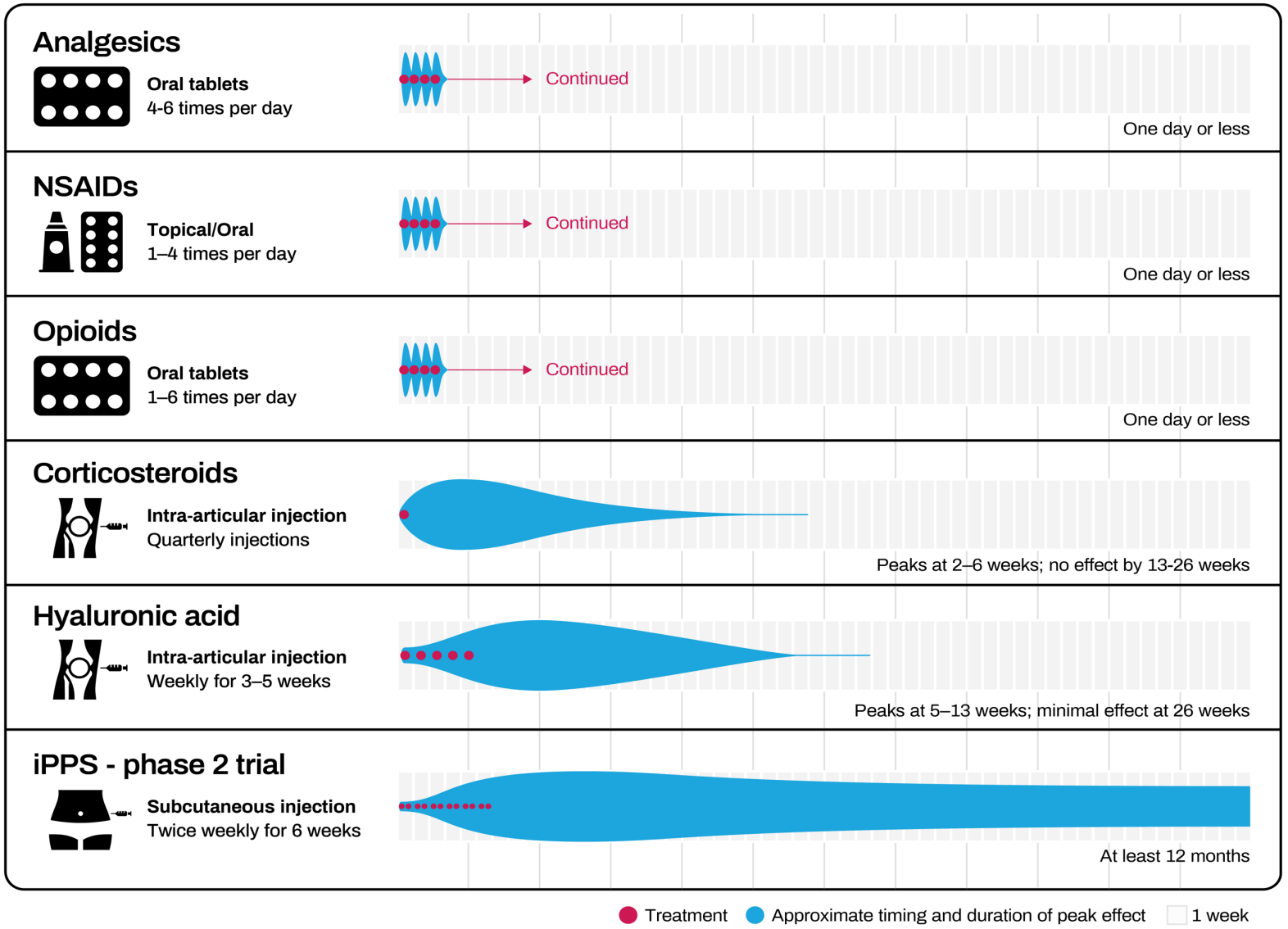
- Significant improvements in function at Day 56 (p=0.017) and Day 365 (p=0.048) in iPPS twice-weekly compared to placebo.
- iPPS treatment demonstrated clinically meaningful response to WOMAC function.
- 55% of participants receiving iPPS twice-weekly reported >50% improvement in function compared to 28% in the placebo arm.

Market Demand

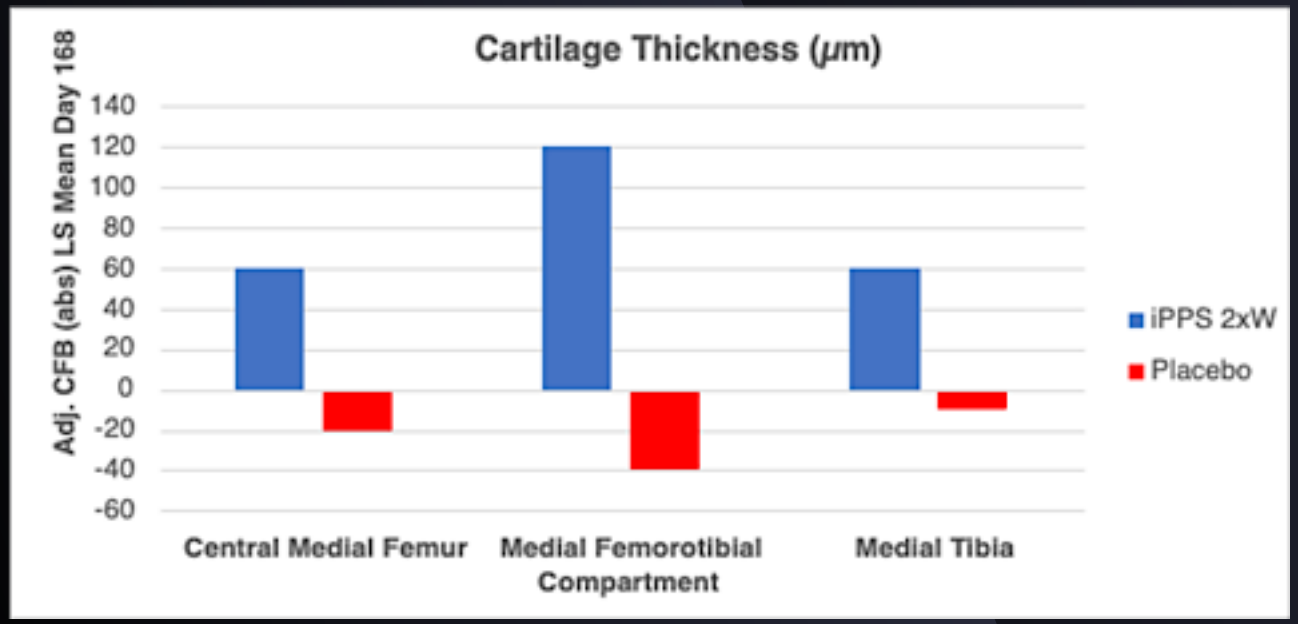
iPPS Durability Compared to Current OA Therapies

Current OA medication effect duration. Representative infographic reflecting current literature on the timing of the peak and estimated duration of treatment effect of currently available OA medications* and iPPS data from the PARA_OA_008 clinical trial.
*References available in Day 365 ASX Release.

Treatment Response & Duration



PARA_OA_008 | Top-Line Day 168 Quantitative MRI Results

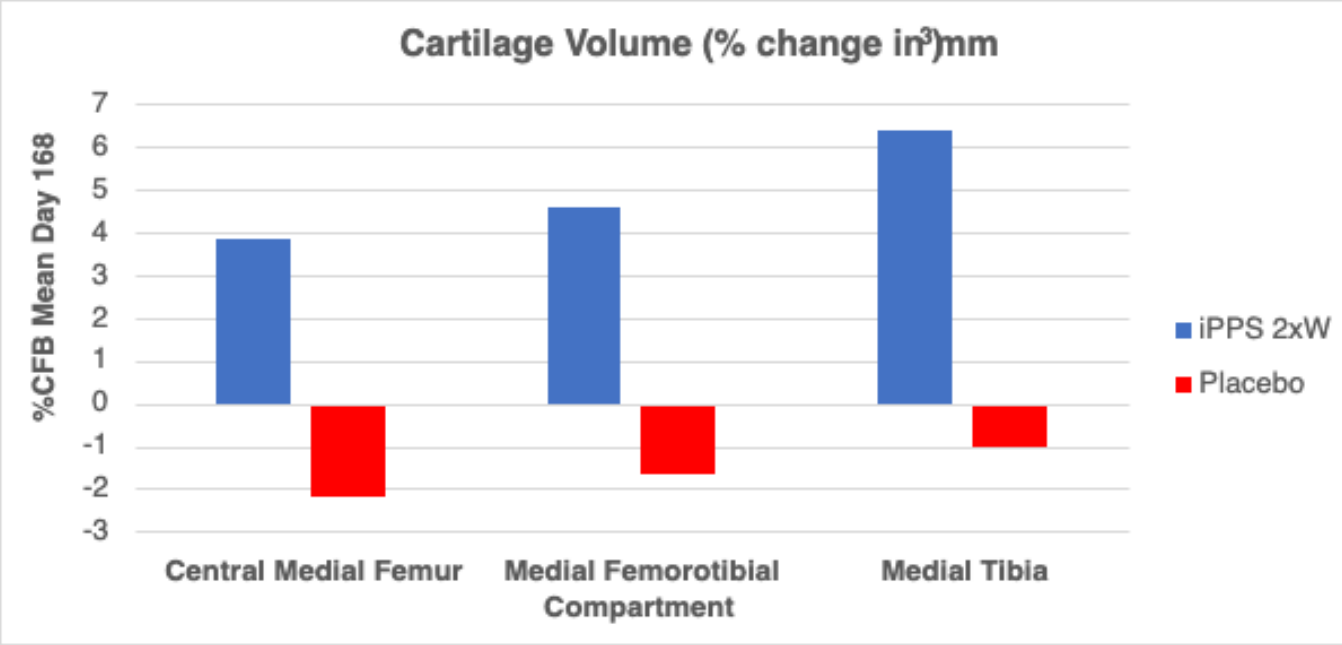


Cartilage Thickness (μm) Adj. CFB (abs.) LSM results by medial region in the knee

Changes in Cartilage Thickness from baseline

- Twice weekly iPPS arm, demonstrated a consistent pattern across regions of cartilage thickening over 6 months
- Placebo showed a loss in cartilage thickness in all medial compartments at 6 months.
- iPPS increased the cartilage thickness in the central medial femur by 60μm (0.06mm) compared to a reduction of -20μm (-0.02mm) in the placebo group at 6 months.
- Placebo consistent with the naturally occurring cartilage loss rate in knee OA progression (-40μm or 0.04mm per year).

PARA_OA_008 | Top-Line Day 168 Quantitative MRI Results



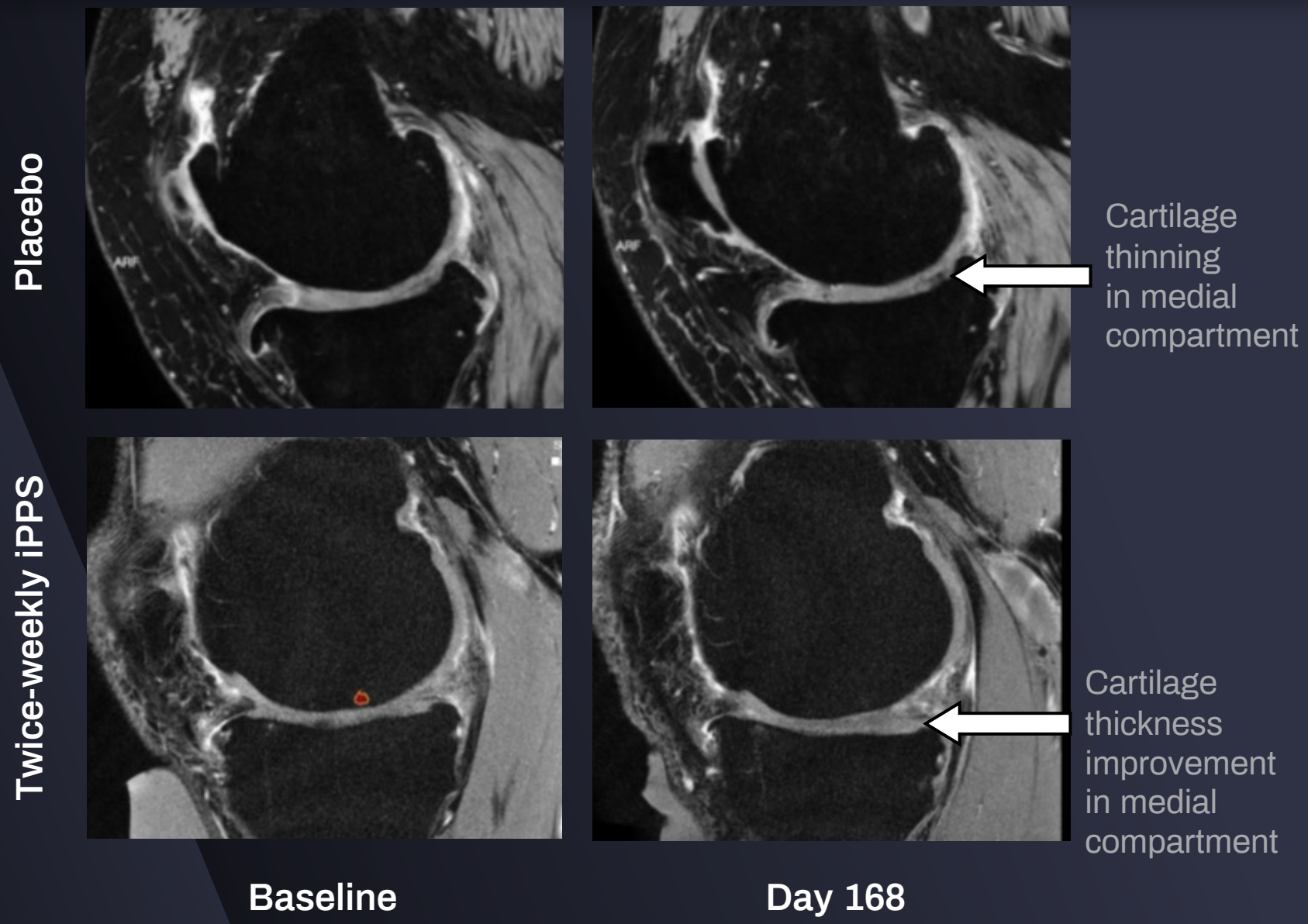
Average percentage (%) change from baseline (CFB) in cartilage thickness (mm) by medial region in the knee.

Changes in Cartilage Volume from baseline

- iPPS showed an average increase in cartilage volume of 4.6%, in the medial femorotibial compartment compared to baseline, whereas the placebo arm showed a loss of cartilage volume of -1.7%.
- iPPS is reversing the breakdown of cartilage at 6 months, compared to placebo which is showing further cartilage volume loss from baseline consistent with the natural progression of the disease (4% reduction in cartilage volume per year).

Cartilage thickness

PARA_OA_008 representative images



PARA_OA_008 | Summary of phase 2 randomised controlled clinical trial

iPPS demonstrated efficacy on both objective and subjective measures compared to placebo

OBJECTIVE DATA MEASURES	Reported
Improvement in synovial fluid biomarkers associated with OA disease progression	Day 56 & 168
Improvement in structural changes in the knee determined by MRI	Day 168

SUBJECTIVE DATA MEASURES	Reported
Significant improvement in mean change from baseline in WOMAC pain, function, and overall scores.	Day 56, 168 & 365
Significant improvement in Patient Global Impression of Change (PGIC)	Day 365

Near-term News flow

Upcoming Catalysts

Event	Target Date
MPS VI phase 2 clinical trials – top-line data.	Q4 CY2023
Phase 3 OA program – FDA protocol review next stage of Phase 3 program.	Q1 CY2024
TGA Provisional Approval OA - submission for next stage determination application.	Q1 CY2024
Phase 3 OA program – Next stage enrollment commencement, subject to regulatory agreement.	H1 CY2024
Regional licensing agreement(s) in OA and MPS	H1 CY2024
TGA Provisional Approval OA - Dossier Submission, pending determination application approval.	Q3 CY2024
The MPS I and PARA_OA_008 – clinical data sets are currently being prepared for peer review and publication.	CY2024
Potential expedited or provisional approval submissions for MPS program (Brazil, Australia)	CY2024

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