ASX RELEASE 9th November 2021

Paradigm Presentation at the Bell Potter Healthcare Conference

Paradigm Biopharmaceuticals Ltd (ASX: PAR) ("Paradigm" or "the Company"), a clinical stage biopharmaceutical company focussed on repurposing existing molecules for new indications with unmet clinical needs, wishes to share the attached presentation materials to all shareholders, that will be presented at today's Bell Potter Healthcare conference.

Paradigm CEO, Mr Paul Rennie, and CMO Dr Donna Skerrett will be presenting to the Bell Potter Healthcare Conference at 2.05pm. The conference is available to all registered Bell Potter clients.

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals LTD (ASX: PAR) is a late-stage drug development company with the mission to develop and commercialise pentosan polysulfate sodium for the treatment of pain associated with musculoskeletal disorders driven by injury, inflammation, ageing, degenerative disease, infection or genetic predisposition. Paradigm is also investigating proof-of-concept for the use of PPS in respiratory and heart failure indications.

Authorised for release by Paradigm CEO, Mr Paul Rennie

To learn more please visit: www.paradigmbiopharma.com

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PARADIGM BIOPHARMA

BELL POTTER HEALTHCARE CONFERENCE

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This Company presentation contains forward-looking statements, including statements regarding anticipated commencement dates or completions dates of preclinical or clinical trials, regulatory developments and regulatory approval.

These forward-looking statements are not guarantees or predictions of future performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this presentation. Readers are cautioned not to put undue reliance on forward-looking statements. The rate and timing of enrolment of our clinical trials and the timing of top-line results of our clinical trials should be regarded as forward-looking statements and the actual dates could differ materially from the expectations and projections set forth in Company presentations or statements especially during a pandemic.

Executive Summary

Lead program:

Phase 3 global study in Knee OA. Blockbuster potential with 32m+ sufferers in the US alone

Proven Safety and Efficacy: OA Phase 2b trial (n=112) met primary, secondary and exploratory endpoints: Included pain, function, BML and biomarkers

Commercial:

Global Market Research confirmed US$2500 achievable for Zilosul® for indication of pain and function in knee OA.

Pipeline:

Multiple indications in various stages of development:

Clinical Stages: OA, MPS, Alphavirus

Pre-Clinical: Respiratory, Heart Failure.

Protection:

Strong portfolio of IP protection and patents on Zilosul® – patents in all key markets from 2030 to 2039.

Exclusive agreement with only FDA approved manufacturer of PPS, bene pharmaChem, for 25 years from date of marketing approval.

Exclusive agreement covers all major markets.

Phase 3 Company

Global Harmonised Pivotal Trial – PARA_OA_002

United States

- FDA clears IND application investigating Pentosan Polysulphate Sodium (PPS) for the treatment of pain associated with knee osteoarthritis (the Trial) has been cleared by the US FDA
- Approximately 56 sites have been selected.
- Lead investigator confirmed.
- Central Ethics approval received.

Australia

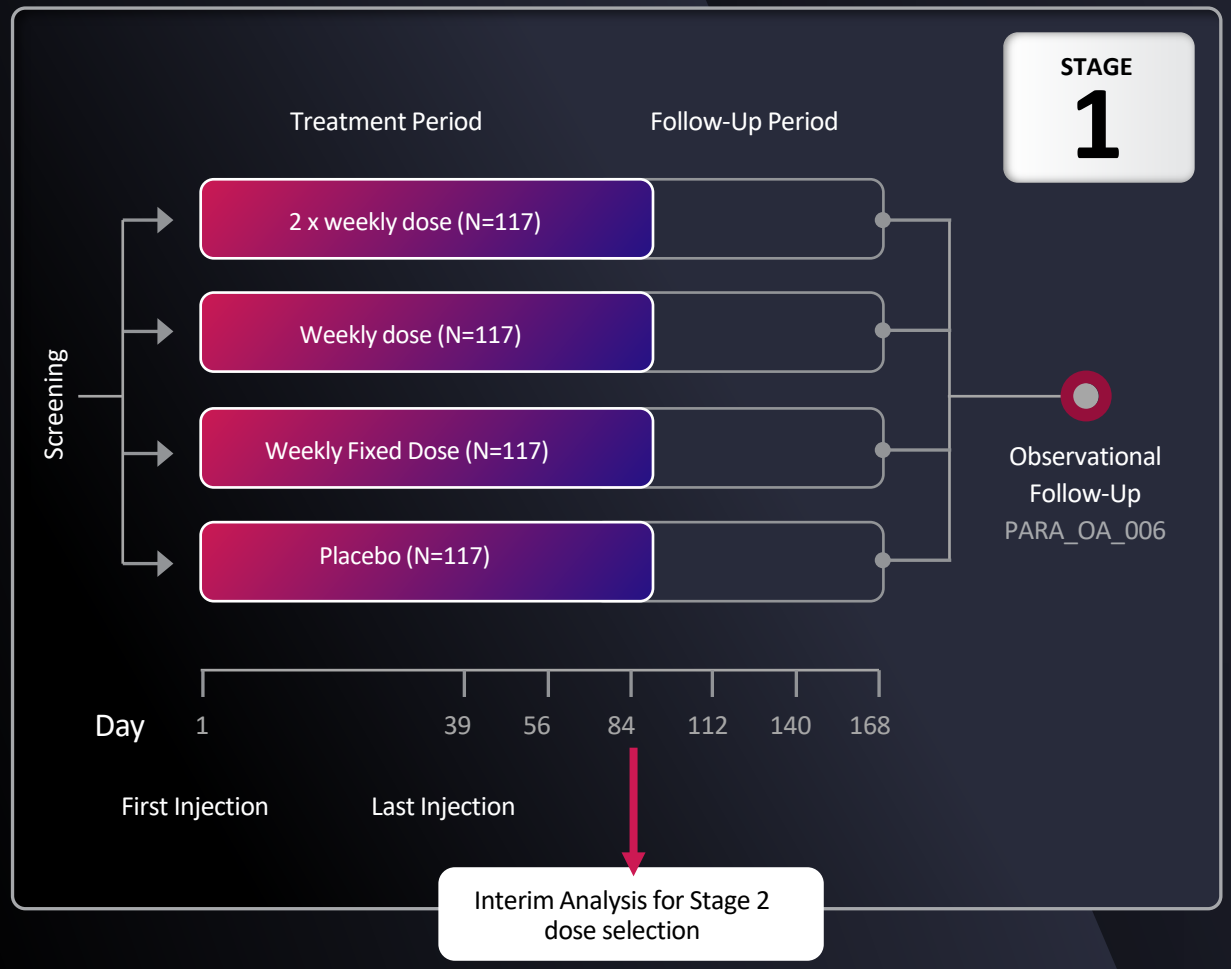
- Eight (8) sites have been selected.
- Protocol has received ethics approval.
- Paradigm has begun contracting sites in WA, Victoria, NSW, SA and QLD.
- First 4 sites in Australia have initiated screening participants
- Lead investigator confirmed.

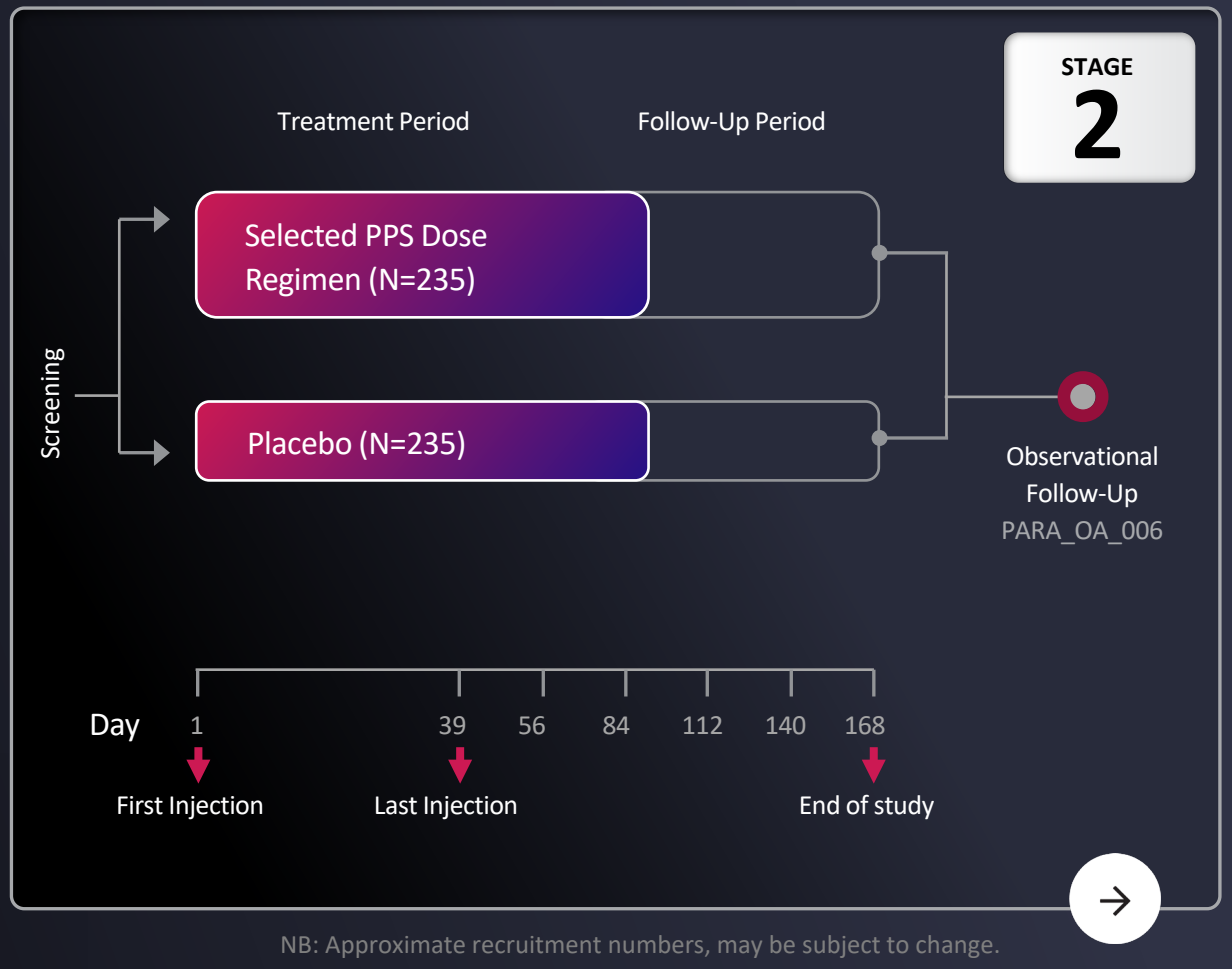
Europe and UK

- Twelve (12) sites to be initiated
- Paradigm is finalising discussion with the lead investigator.
- Site initiation and screening to commence in CY2022

Phase 3 Trial Design

Trial Design





NB: Approximate recruitment numbers, may be subject to change.

Blockbuster market opportunity

Zilosul® aims to meet a significant unmet need in osteoarthritis

Total prevalence of OA in key markets

72 M+

and growing

USA | CAN | EU5 | AUS

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

Knee and Hip

69%

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

Global Market Research

› In 2021 Paradigm conducted market research in major global markets, with physicians, funding decision makers (payers) and patients to better understand willingness-to-pay and willingness-to-prescribe Zilosul for osteoarthritis of the knee (kOA)

› The research centred around 3 key questions in two scenarios:

1. Zilosul registered for pain and function (P&F) only
2. Zilosul registered for pain, function and disease modification (DM).

1

How is Zilosul perceived by physicians & public payers?

2

How will Zilosul fit in the Tx algorithm & how would physicians use it?

3

How much would public payers and patients pay for Zilosul?

Zilosul's proposed profile was regarded positively

Assuming sustained efficacy and robust safety data, physicians and payers believe Zilosul® will provide high value to the treatment of kOA by covering some important unmet needs

New MoA

Favourable safety profile with no renal, GI, CV side effects or cartilage degradation ★

No drug abuse potential ★

ZILOSUL®

Meaningful pain reduction, functional improvement and potential DM effect ★

Sub-Cutaneous RoA vs. IA injections

Convenient dosing regimen (1 weekly injection for 6 weeks) vs. daily intake

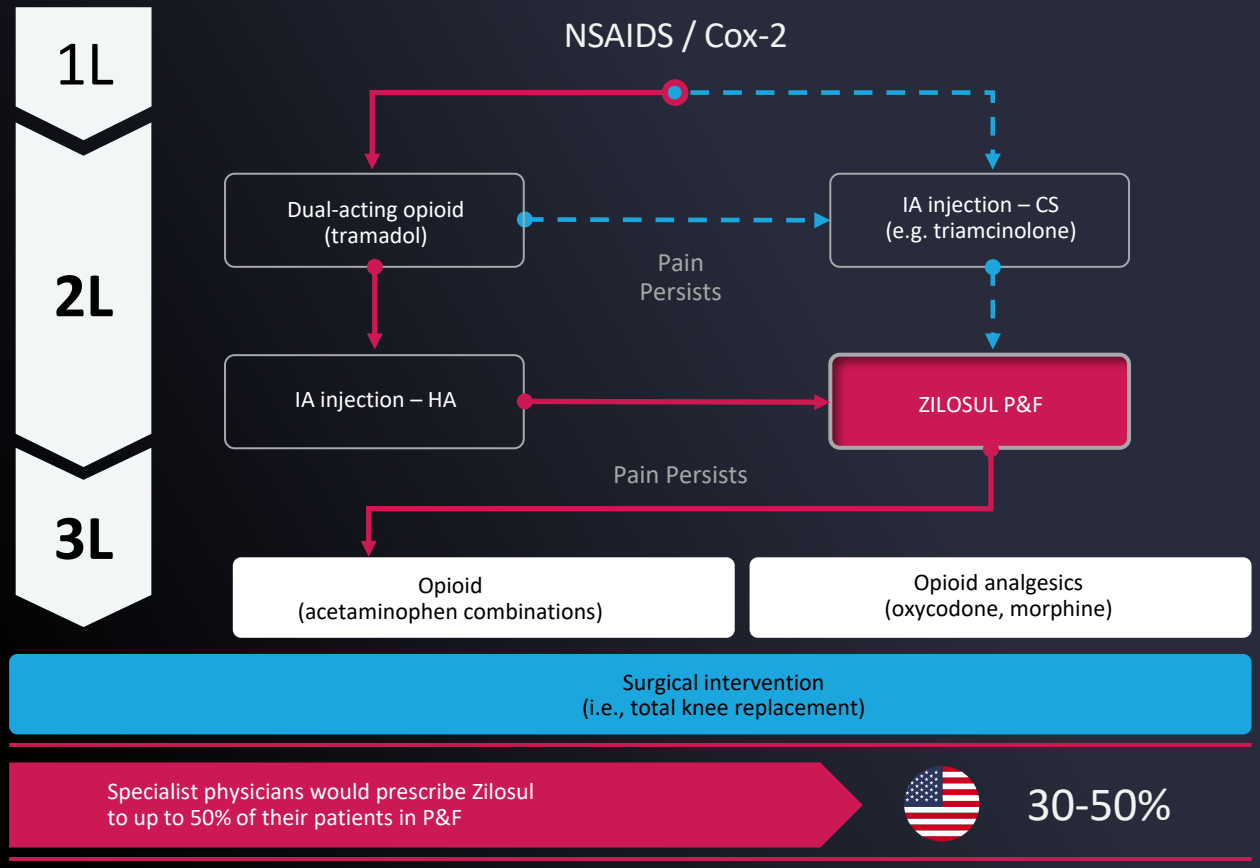
Zilosul is expected to cover the main residual unmet needs highlighted by physicians and payers as it will provide an alternative treatment to kOA patients that is well-tolerated and potentially preserving structural changes in kOA

CV = Cardiovascular; DM = Disease Modification; GI = Gastrointestinal; IA = Intra-articular; kOA = Knee Osteoarthritis; MoA = Mechanism of Action; RoA = Route of administration

★ *Zilosul addresses the key residual unmet needs identified by payers and KOLs*

Pain & function

Physicians may consider Zilosul® as a second line therapy

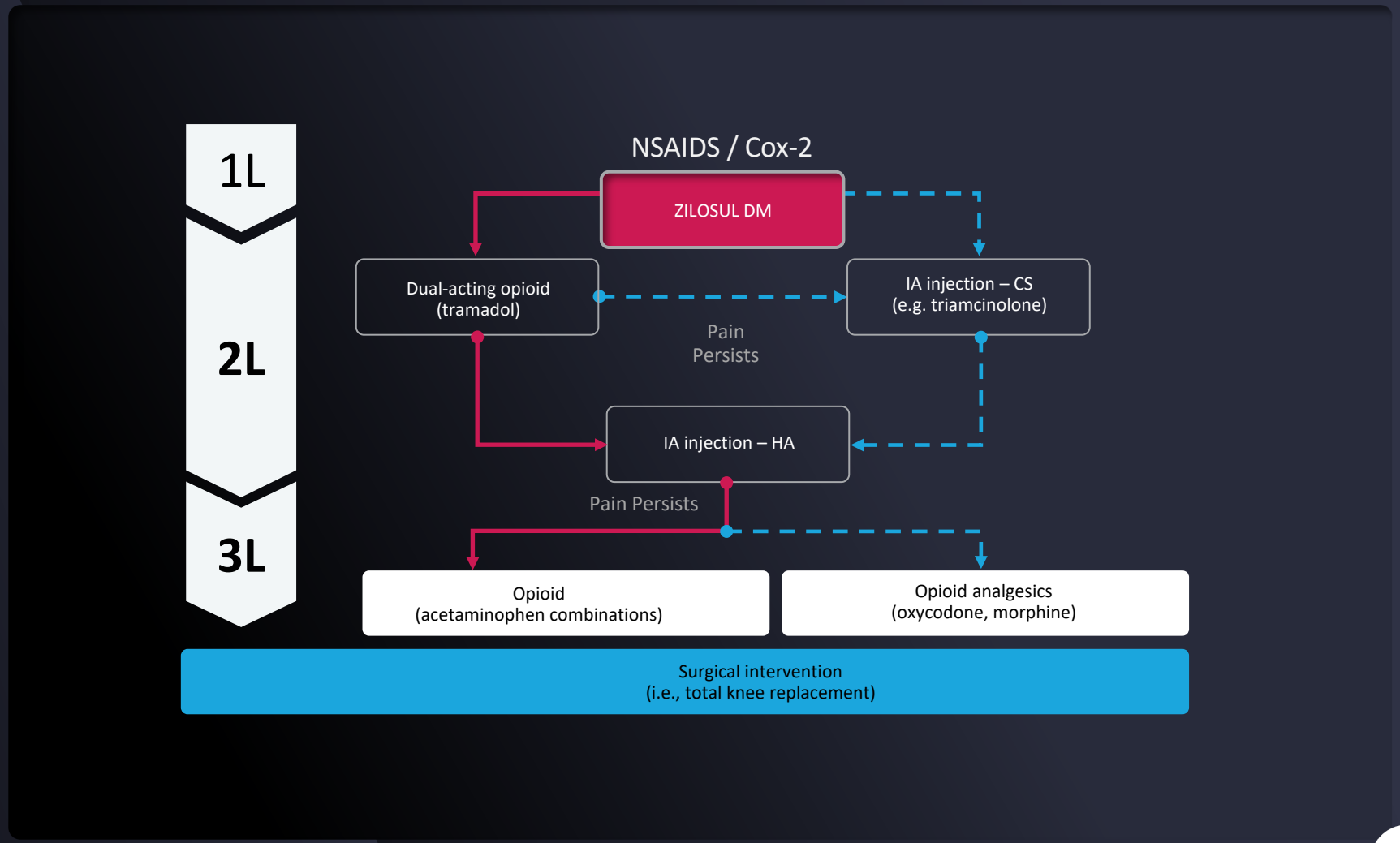


Main Tx
Alternative Tx

CV = Cardiovascular; DM = Disease Modification; GI = Gastrointestinal; IA = Intra-articular; kOA = Knee Osteoarthritis; MoA = Mechanism of Action; RoA = Route of administration

Disease modification

Zilosul® may be used early in therapy



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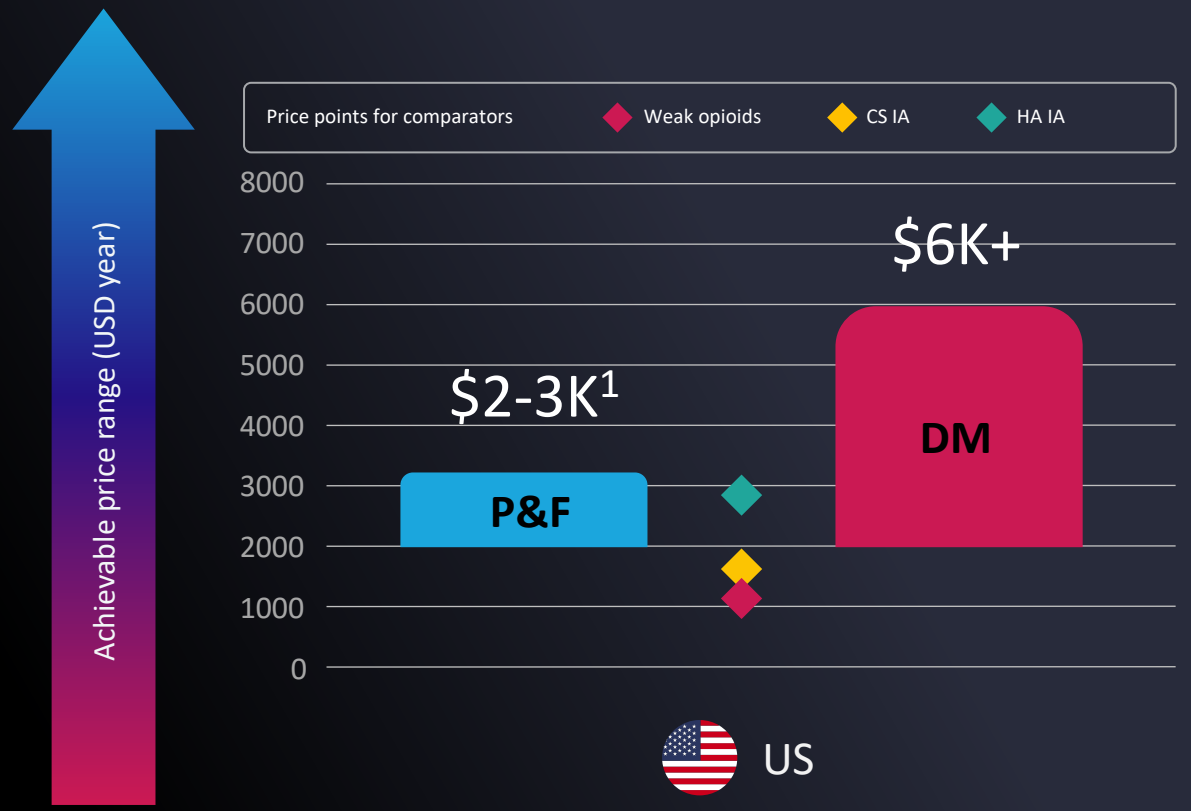
Target pricing

Achievable for P&F and a significantly higher price for DM

Pricing potential of Zilosul in P&F and DM compared to price benchmark



1. Reasonable price - higher prices may be achievable but will likely trigger restrictions on use by payers

DMOAD

Current programs to inform of Zilosul® potential as a DMOAD

PARA_OA_008 - Australia

- Biomarker study assessing change from baseline in multiple objective measures associated with disease progression of OA.
- Study will randomise 60 participants to receive PPS or Placebo.
- To date the exploratory clinical trial is 50% recruited.
- Protocol amendments include once weekly dosing regimen, second trial site initiated, extended follow-up period to 12-months.

Canine OA Study

- Dogs with OA of the stifle joint are treated with PPS at a dosing of 3mg/kg (1.7mg/kg human equivalent) weekly for 6-weeks.
- Pain and function will be assessed together with structural changes from baseline as determined by the global OA score measured by X-ray and bone marrow lesions and cartilage volume by MRI.
- Serum samples will also be taken to measure biomarker levels associated with inflammation, cartilage degradation and pain.
- The longer follow up period of 20 weeks (equates on average to a period of 3 years in human lifespan)

MPS

Clinical programs in Orphan designation Paradigm is enrolling

MPS I - Australia

- Open label trial currently enrolling up to 10 subjects. Dosed weekly for 12 weeks then every other week for a total of 52 weeks.
- Women's & Children's Hospital Adelaide.
- Primary endpoint is safety, key secondary endpoints are pain and function, as well as PK.
- 3 subjects currently in treatment: enrolment of additional patients ongoing.
- PPS has been well tolerated.
- Presentation at ICIEM – Congress of Inborn Errors of Metabolism. Nov 2021

MPS VI - Brazil

- A double-blind placebo-controlled trial with 12 subjects. Dosed weekly for 24-weeks.
- Primary endpoint is safety, key secondary endpoints are pain and function.
- The Brazilian regulatory agency, ANVISA, and Brazilian ethics committee CONEP have approved Paradigm's clinical program and study endpoints.
- First patient dosed.

R&D Pipeline

Repurposing of PPS across several acute and chronic medical indications.

Indication / Action of PPS	Stage of Development	Status
Alphavirus induced arthralgia • Anti-inflammatory target: NF-kB • Pain target: NGF • Cartilage degeneration target: ADAMTS-5; MMPs	• Preclinical Proof-of concept for CHIK-V: (Institute for Glycomics; Queensland)	Completed
Heart Failure • Adverse tissue remodeling target: ADAMTS-4 • Anti-inflammatory target: NF-kB • Vascular endothelial inflammation target: CAM (Cell Adhesion Molecules)	• Preclinical Dose translational study: (Center for Heart Failure Research & Institute for Experimental Research, Oslo University, Oslo)	Results Pending
Acute Respiratory Distress Syndrome (viral-induced) • Cytokine storm anti-inflammatory target: NF-kB • Inhibition of Compliment activation	• Preclinical Proof-of-concept study: (Menzies Health Institute, Queensland) • Top-Line results from preclinical mouse model of ARDS mediated by influenza infection	Ongoing

For more information please visit:
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