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ASX RELEASE (ASX: PAR)

### **Paradigm's End of Calendar Year Update**

Paradigm Biopharmaceuticals Ltd (ASX: PAR) is pleased to present an update on its business and clinical development programs.

#### **Clinical Development and Regulatory Milestones**

- Paradigm met with the Therapeutic Goods Administration (TGA) 11 November 2019 to present its case for provisional approval of Zilosul® for the treatment of knee osteoarthritis (OA) with subchondral Bone Marrow Lesions (BMLs).
  - At this meeting, the TGA provided valuable guidance. Based on the feedback received from the TGA, Paradigm is proceeding with the provisional determination assessment process.
- Paradigm will be meeting with the US FDA in Feb 2020 for a pre-IND meeting for its osteoarthritis program in OA knee pain with subchondral BMLs
  - This meeting will provide feedback on the phase 3 clinical program to support regulatory approval
- Paradigm is preparing a scientific advice application for submission to the EMA (Europe) to discuss the knee OA development program in Q1 CY2020. This meeting will provide clarification on the clinical trial design to support regulatory approvals for Europe
- Paradigm is preparing for a combined USA FDA and EMA (Europe) joint parallel advice application for submission to discuss the MPS Phase 2/3 Clinical Trial in Q1, CY2020
  - This meeting will provide for consensus and clarification on the clinical trial design to support regulatory approvals for US and Europe
- Paradigm expects to report on an updated dataset for the SAS program on approximately 400 (cumulative) knee OA patients in Q2 CY2020
  - Evaluated outcomes will include WOMAC, Lysholm Knee Score, PGIC, and NRS outcome assessments.
  - Paradigm plans to use the WOMAC, PGIC and NRS outcome assessments in its Phase 3 knee OA pain with subchondral BMLs clinical trial.
- Treatment program under the Expanded Access Program (EAP) of 10 knee OA with BML patients will commence January 2020.

#### **Key appointments**

- Dr Donna Skerrett joins Paradigm as its Chief Medical Officer based in New York. Dr Skerrett has extensive experience with US FDA IND filings
- Paradigm expands its Investor Relations team
  - Mitch Marrow (US) and Simon White (Australia) will join Paradigm in January 2020. Both have extensive financial industry experience and are high profile ex elite sportspeople

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### Industry Conferences

- Paradigm will be attending the following global meetings in Q1 CY2020:
  - 38<sup>th</sup> JP Morgan Healthcare conference in San Francisco January 2020. Paradigm has already secured a number of meetings with specialist US Biotech or healthcare Funds.
  - 15<sup>th</sup> WORLD Symposium 2020 Lysosomal diseases research and conference – Orlando Feb 2020. The WORLD Symposium is the premier global mucopolysaccharidosis (MPS) meeting, at which Paradigm has been selected to present a poster detailing outcomes from patient research advisory group informing its phase 2/3 clinical trial design.

**ADDRESSABLE MARKET:** Osteoarthritis (OA) is the most common joint disorder in the United States. Symptomatic knee OA occurs in 10% men and 13% in women aged 60 years or older. The number of people affected with symptomatic OA is likely to increase due to the aging of the population and the obesity epidemic. ABOUT 54.4 MILLION ADULTS IN THE U.S. HAVE DOCTOR-DIAGNOSED ARTHRITIS<sup>1</sup>. (Barbour – MMWR [66] 2017). There are over 100 million OA sufferers in the USA, Europe and Japan<sup>2</sup>.

### About injectable PPS (Zilosul®)

Injectable PPS is not currently registered in Australia, but it is registered in four of the seven major global pharmaceutical markets. In those European markets, injectable PPS is registered as an antithrombotic agent. In Australia, injectable PPS for human use is not currently available for sale. Injectable PPS for human use is only available by inclusion into a Paradigm Sponsored clinical trial or via a treating physician applying for its use in patients via the TGA's SAS - Category B.

Zilosul® is a registered Trademark of Paradigm Biopharmaceuticals Ltd (ASX: PAR).

### FOR FURTHER INFORMATION PLEASE CONTACT:

Paul Rennie  
Director & CEO  
Paradigm Biopharmaceuticals Ltd (ASX: PAR)  
Level 2, 517 Flinders Lane, Melb, VIC, 3000, AUSTRALIA  
ABN: 94 169 346 963  
Web: <http://paradigmbiopharma.com/>  
Email: [prennie@paradigmbiopharma.com](mailto:prennie@paradigmbiopharma.com)

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<sup>1</sup> <https://www.arthritis.org/Documents/Sections/About-Arthritis/arthritis-facts-stats-figures.pdf>

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2920533/>

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