PARADIGM BIOPHARMACEUTICALS LIMITED

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PARADIGM CORPORATE UPDATE: MAY 2019

KEY HIGHLIGHTS

- **MATERIAL REDUCTIONS IN BONE MARROW LESIONS BEING SHOWN IN HIP, KNEE CAP AND ANKLE UNDER TGA SPECIAL ACCESS**
- **MANUFACTURING OF PHASE 3 iPPS COMPLETE, KEY REQUIREMENT OF UPCOMING IND FILING WITH FDA**
- **FIRST 10 EX NFL PLAYERS IDENTIFIED, AND US DOCTORS ENGAGED, SUBMISSION TO FDA FOR COMPASSIONATE USE OF iPPS IMMINENT, FIRST RESULTS LIKELY IN 3Q CY2019**
- **PARADIGM'S MAIN OA COMPETITOR TANEZUMAB MISSES PIVOTAL PHASE 3 ENDPOINTS**
- **CAPITAL RAISING COMPLETED AND REITERATION OF UPCOMING TIMELINES / CATALYSTS FOR REMAINDER OF 2019**

Paradigm Biopharmaceuticals Ltd (ASX: PAR) is today pleased to provide the following update on its clinical programs and commercial progress.

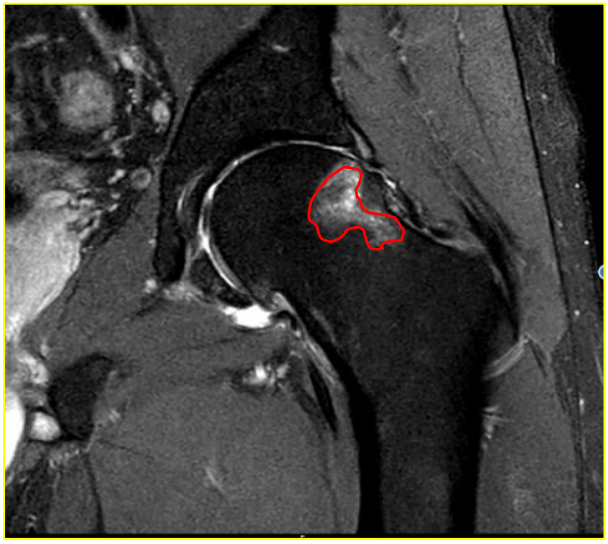
MATERIAL REDUCTIONS IN BONE MARROW LESIONS SHOWN IN HIP, KNEE CAP AND ANKLE UNDER TGA SPECIAL ACCESS

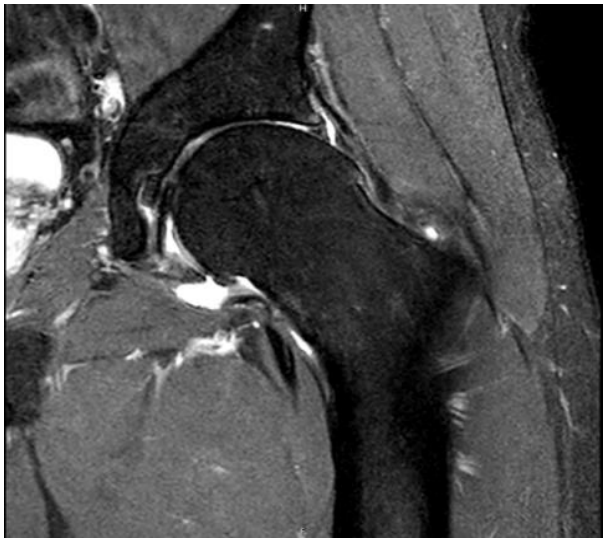
Bone marrow lesions in the subchondral bone of people with knee osteoarthritis (OA) are associated with pain and progression of cartilage loss over time. As previously reported from Paradigm's Phase 2b clinical trial (see prior released results), the group of patients that received injectable Pentosan Polysulfate (iPPS) had a clinically meaningful reduction in BML Grade which was also statistically significant over placebo (p=0.03).

The company is now pleased to report that it is seeing significant reductions in BML in sites of the body other than the knee using iPPS under the TGA special access scheme. The sites where the Company has seen significant reduction in BML (in conjunction with lower pain scores) include hip, knee cap and ankle. Whilst the Company is focused on the treatment of OA of the knee for its upcoming phase 3 trial, this is further real world evidence of iPPS potential for treatment on all sites of the body effected by BML. The company also continues to observe "whole of body" effect of iPPS, i.e. where a patient has gone for treatment of OA in one site (such as knee), but has then received significant relief in other sites (e.g. hands or back).

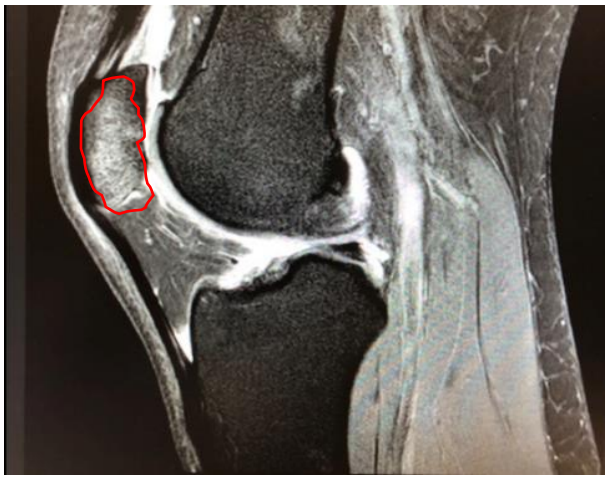
The Company is pleased to provide the following before and after MRI's from patients recently treated under Special Access:

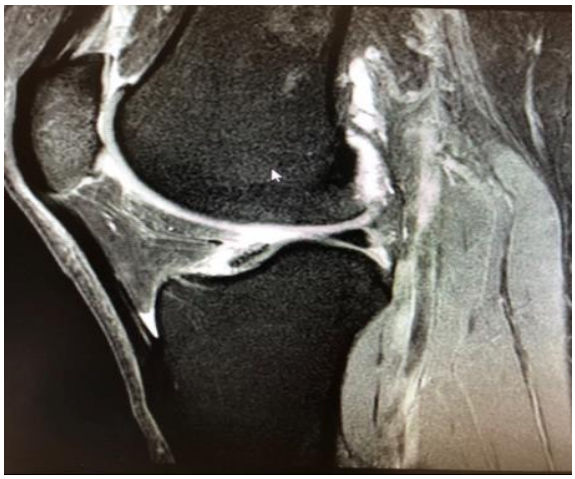
HIP JOINT – close to full regression of BML



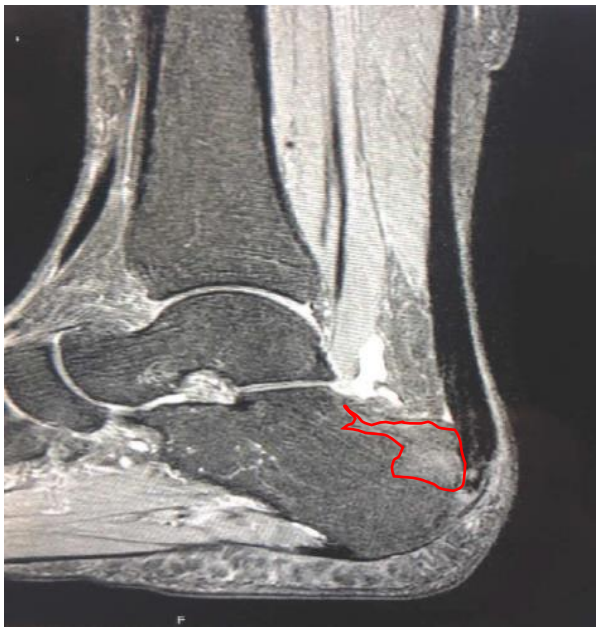


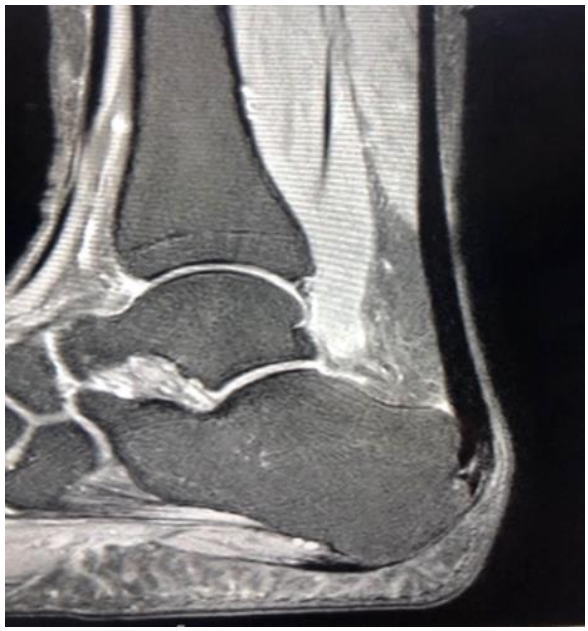
KNEE CAP (PATELLA) – significant reduction in BML





ANKLE JOINT - HEEL BML AND TENDONITIS – almost full regression in BML





MANUFACTURING OF PHASE 3 iPPS COMPLETE, KEY REQUIREMENT FOR UPCOMING IND FILINGS WITH FDA

- The Company has now completed manufacturing of iPPS to support its expected upcoming requirements under its Phase 3 OA and MPS trials and its requirements under TGA special access and FDA compassionate use
- Completion of manufacturing and ownership of batch records are key components of the Paradigm's upcoming IND filings with the FDA
- Improved glass vial presentation replaces current ampoule for ease of use.

FIRST 10 EX-NFL PLAYERS IDENTIFIED AND US DOCTORS ENGAGED, SUBMISSION TO FDA FOR COMPASSIONATE USE OF iPPS IS IMMINENT WITH FIRST RESULTS LIKELY IN 3Q19

- Paradigm expects to submit its application for compassionate use of iPPS to the FDA in coming weeks. If successful, this will enable the treatment of up to 50 past NFL football players in the US.
- First 10 NFL players have agreed to be treated and US based doctors and sites identified
- First results expected late 3Q19

PARADIGM'S MAIN OA COMPETITOR TANEZUMAB FAILS PIVOTAL PHASE 3

One of Paradigm's main competitors for the treatment of Osteoarthritis was nerve growth factor antibody Tanezumab (Pfizer and Lilly). The recent release of its Phase 3 trial results showed that neither of the two dosage levels met all co-primary efficacy goals and both doses fared worse than placebo on safety.

COMPLETION OF $77.9M CAPITAL RAISING AND UPCOMING CATALYSTS FOR REMAINDER OF 2019

The Company has now completed its $77.9m capital raising and is focused on delivering on its pipeline of catalysts for the remainder of 2019:

- Further release of OA pain results under the TGA special access scheme throughout remainder of CY2019. Next batch of patients for release imminent.
- Release of peer reviewed journal paper detailing mechanism of action of PPS via Nerve Growth Factor (NGF) – expected Q2 CY2019
- Appointment of highly regarded US based CMO – Q2 CY2019
- First SAS filing with the TGA for the treatment of MPS patients with iPPS – Q2 CY2019
- Up to 50 ex-NFL players in the US to be treated with iPPS for OA pain - Potential for significant media attention if treatment is successful – FDA approval for compassionate use and dosing to begin Q2 CY2019, first results likely late Q3 CY2019
- File IND for pivotal Phase 2/3 for Mucopolysaccharidosis (MPS) - Q2 CY2019
- File TGA Provisional Approval to sell ZILUSOL® (iPPS) in Australia, potential for near term revenue – Q2 CY2019
- Ross River Phase 2a (safety study) trial results release – Q2/Q3 CY2019
- File IND and meet with FDA re Phase 3 trial in OA - Q3 CY2019
- Possibility of being granted "Fast Track status" for Phase 3 OA trial

To learn more please visit: www.paradigmbiopharma.com

For more information, please contact

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