

ASX RELEASE

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Phase 2b Osteoarthritis Clinical Trial Ahead of Schedule with 80% Recruited

Highlights:

- Paradigm's phase 2b clinical trial in knee osteoarthritis and concurrent sub-chondral bone marrow lesions is now over 80% recruited, remaining well ahead of schedule
- Paradigm expects recruitment to be finalised over the coming month with the pivotal results **read-out by Q4 CY2018**
- 260 osteoarthritis patients have now been treated by their doctors with pentosan polysulfate sodium, via the TGA Special Access Scheme, an almost doubling of the number of patients from 6 weeks ago showing real patient need for new OA treatments
- Phase 2a, clinical trial in participants with viral arthralgia (Ross River virus) is currently over 75% recruited and with recruitment numbers improving following seasonal recurrence of the disease - **Expected read-out Q4 CY2018**

Melbourne 16 May 2018 Paradigm Biopharmaceuticals Ltd (ASX: PAR) today provided an update on the progression of their phase 2b clinical trial confirming that pivotal, commercially valuable phase 2b randomised double-blind placebo-controlled data will be available in Q4 CY2018, earlier than previously expected.

Phase 2b - Osteoarthritis / Bone Marrow Lesions – 80% Recruited

A phase 2b, randomised double-blind placebo-controlled multicentre study to evaluate the effects of pentosan polysulfate sodium (PPS) on pain in participants with knee osteoarthritis and concurrent subchondral bone marrow lesions

Recruitment Status

- Trial is ahead of schedule, with over 80% of participants recruited to date
- All six sites are operational and are recruiting as expected
- Recruitment continues to be strongly supported by positive public referrals from patients treated by their doctors via the TGA Special Access Scheme

Paradigm is very pleased with the strong momentum that the clinical trial has been able to maintain. Injectable PPS has the potential to be a 'break-through' in the treatment of osteoarthritis (OA), where current therapies do not have adequate pain-relieving effects, provide no protection for the degenerating joint structures and are also associated with significant adverse side effects.

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It is estimated that the size of the market is US\$5 billion per annum and this figure could potentially be multiples higher if new, effective, patented treatments such as PPS are commercialised.

OA also remains the most common form of joint disease globally. In the US alone, it affects over 30 million adults, whilst in Australia, arthritis affects around 3 million people. In both countries, the condition is a leading cause of pain and disability among the elderly and a cause of life-years lost due to disability.

The results from this phase 2b clinical trial are expected in Q4 CY2018.

Click here for Clinical Trial Details:

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=373400&isReview=true>

TGA Special Access Scheme

Paradigm is pleased to announce that in excess of 260 osteoarthritis patients have either been treated or approved for treatment by their doctor via the TGA Special Access Scheme ("TGA SAS"). This is a increase of almost double since Paradigm last report from six weeks ago and is a strong indication of the positive effect PPS treatment is having on patients. All SAS patients are symptomatic with OA pain and have failed current standard of care, which involves treatment with analgesics, NSAIDs (non-steroidal anti-inflammatory drugs) or corticosteroids.

Patients are treated under the same dosage protocol as the current Phase 2b osteoarthritis / bone marrow lesion clinical trial. Paradigm is currently evaluating the data provided as feedback from Doctors treating their patients treated under the TGA SAS, which the Company looks forward to releasing to the market once completed.

Phase 2a - Viral Arthralgia – Ross River Virus - Update

Phase 2a, randomised, double-blinded placebo-controlled pilot clinical trial treating a total of 24 participants across five trial sites in Victoria and Queensland. Patients with Ross River virus (RRV) induced arthralgia (painful joints) are being evaluated for safety, tolerability and effects on disease symptoms of PPS subcutaneous injections.

Recruitment Status

- The clinical trial is currently over 75% recruited
- Recruitment rates are starting to improve again after recent wet weather events in Queensland following a slow period caused the changeable prevalence of the disease, which is spread by mosquitoes.
- All five sites are operational and are recruiting as expected

Paradigm remains confident that the trial will recruit fully and will complete within budget. Paradigm hopes that the phase 2a trial will demonstrate the potential of PPS as an effective treatment for patients with persistent joint symptoms following Ross River virus infection, where a treatment is desperately needed.

Looking forward it is hoped that positive results from the RRV Phase 2a trial will provide the foundation for a commercial opportunity not only on RRV within the Australasian region but also for Chikungunya virus, potentially with the United States Department of Defense.

The results from this viral arthralgia phase 2a clinical trial are expected in Q4 CY2018.

Mr. Rennie, Paradigm's CEO said "the speed at which the OA trial is recruiting is very encouraging as it is quite rare for clinical trials to recruit ahead of expectations. We view this accelerated recruitment as an indication of not only the pain and discomfort that OA sufferers are under but also the dire need for new treatments that are safe and effective. Separately, the dramatic increase in patients being treated with PPS by their Doctor under the TGA Special Access Scheme is very encouraging. We believe it shows that the patients are achieving results that doctors are suitably impressed with to warrant doctors applying for access for other their OA patients."

ENQUIRIES:

Paul Rennie

Director & CEO

Paradigm Biopharmaceuticals Ltd

Email: prennie@paradigmbiopharma.com

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