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PARADIGM REPORTS OSTEOARTHRITIS PAIN REDUCED BY 50%

Key Highlights:

- Paradigm reports a 50% reduction in pain (on average), from 45 patients with osteoarthritis after treatment with the injectable Pentosan Polysulfate Sodium (PPS).
- In the 45 patients treated, 84.4% responded with both a reduction in joint pain and an improvement in knee function.
- 50% reduction in pain scores observed with PPS is considered superior than the typical 15% pain reduction scores reported for opioid treatments for chronic pain in OA of the knee and hip.[2]
- These patients were treated under a similar dosing regimen as Paradigm's current Phase 2b Osteoarthritis randomised double-blind, placebo-controlled, clinical trial, which is expected to release results in Q4 CY 2018.
- OA is a blockbuster indication, a condition with a significant unmet medical need: therapeutic market size is US$5bn p.a., whilst the total economic burden in the US alone, is estimated to be US$128bn[1].

Paradigm Biopharmaceuticals Ltd (ASX: PAR) is pleased to announce that in the 45 patients treated, 84.4% responded with both a reduction in joint pain and an improvement in knee function.

Patients, self-reported pain scores were reduced by 50% (on average) from baseline pain scores in 45 patients with knee osteoarthritis (OA) and concurrent Bone Marrow Lesions (BML). Patients were treated by their doctor with injectable Pentosan Polysulfate Sodium (PPS) under the Therapeutic Goods Administration's (TGA) Special Access Scheme (SAS).

The 50% reduction in pain scores observed with PPS in knee OA demonstrates superiority over the "15% pain reduction scores reported for opioid treatments for chronic pain in OA of the knee and hip"[2].

The comparative effects of PPS therapy against opioid treatments implies that the patient-reported data have provided evidence of clinically meaningful improvements in chronic pain. "Clinically meaningful reduction of chronic pain has been defined to be between 25-30% pain reduction"[2].

These patient-reported outcomes from 45 patients precedes the read-out from Paradigm's Phase 2b randomised, double-blind, placebo-controlled, multicentre, clinical trial, which is expected in Q4 CY 2018. By Q4 CY2018 the Phase 2b clinical trial data (n=100) will be supplemented with an additional 150 RWE patients.

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[1] National Institute of Health; Emerging drugs for osteoarthritis; Hunter DJ and Matthews G 16(3): 479–491; 2011 September.

[2] Seghal N, Colson J and Smith H; Expert Rev Neurother. 2013;13(11):1201-1220

Details of case study patients and outcomes

These data pool the patient-reported effects of injectable PPS on painful OA. The 45 patients are a pool of the results from 24 patients which were reported in October 2017 (First Group) and an additional 21 patients who have been treated and assessed between November 2017 and February 2018 (Second Group).

The 21 patients [10 males and 11 females, median age of 57.8 years (range 34 to 78 years)] had been clinically diagnosed with OA and subchondral BMELs (as determined by multiple MRI). At the onset of PPS treatment:

- All patients were symptomatic with OA pain for at least six months and had failed current standard of care which involved treatment with analgesics, NSAIDs (non-steroidal anti-inflammatory drugs) or corticosteroids.
- 60% of the patients had moderate to severe BMELs with a size ranging from five millimetres to more than 20 millimetres in diameter.
- 40% had lesions less than five millimetres in diameter.

Patients were administered with two injections of PPS per week for three to six weeks depending on the severity of the BMEL (a total of 6 to 12 injections). Patients were followed up at four weeks following the last treatment. During the course of PPS treatment, patients did not receive NSAIDs or corticosteroid treatment.

Clinical knee pain outcome measures after the initiation of PPS treatment were as follows:

- 18 out of 21 - (85.7%) patients showed a reduction in pain;

Clinical knee function outcome measures after the initiation of PPS treatment were as follows:

- 19 out of 21 - (90.4%) patients showed improvement in knee function;

Mr. Paul Rennie, Paradigm's Chief Executive Officer said: *"We are very pleased to see the second group of Real World Evidence patients report results that are consistent with the first group of patients we treated under the program.*

Of great importance to us is that Paradigm now has data on 45 patients being successfully treated with PPS for OA associated BMELs. It is a significant positive outcome that all these patients have on average, a clinically meaningful reduction in pain of 50%. Given these patients have a very similar treatment regimen to subjects being treated under the current Phase 2b Osteoarthritis randomised, double-blind, placebo-controlled, clinical trial and these patients have failed current therapies to treat OA, we remain confident of a positive clinical trial outcome, with the expected release of top line results for that trial due in Q4 CY 2018."

About injectable PPS

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.

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