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PARADIGM'S GLOBAL MARKET RESEARCH INDICATES PRICE FOR ZILOSUL® AS A THERAPY TO REDUCE OSTEOARTHRITIS PAIN AND IMPROVE JOINT FUNCTION

KEY HIGHLIGHTS

- Global market research conducted to better understand willingness-to-pay and willingness-to prescribe Zilosul® for osteoarthritis (**OA**) of the knee (**kOA**).
- Research indicates projected price of US$2-3K p.a likely for Zilosul® as a therapy to reduce pain and improve function.
- If future data support a DMOAD label extension by the US Food and Drug Administration (**FDA**) then price per year of therapy in the United States could increase to US$6K p.a. and potentially higher.
- With projections of 50% of patients likely to be offered Zilosul® as a therapy to manage the pain and functional impairment of kOA, and even higher uptake if used as an earlier intervention for disease modification, this research confirms the blockbuster potential for Zilosul®.

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, is pleased to present top-line findings from its recently completed global market research for Zilosul®.

In 2021 Paradigm conducted market research in 4 major markets, the United States (**US**), Germany, France and the United Kingdom, to better understand willingness-to-pay and willingness-to prescribe Zilosul® for kOA. As is customary with market research, the product characteristics of Zilosul® were presented but neither the product nor company were identified. The research findings for the US market are presented here.

The research conducted through global market intelligence and research organisation Decision Resources Group (now Clarivate), explored 3 key pricing and uptake questions via in-depth interviews with specialist physicians and public payers:

1. How is the proposed product profile of Zilosul® perceived by key physicians and public payers?
2. How will Zilosul® fit in the treatment algorithm and how will physicians use it?
3. How much will public payers pay for Zilosul®?

Responders were asked to consider the above questions for two potential approved indication scenarios for Zilosul®:

1. Reduce pain and improve function in kOA
2. Reduce pain, improve function and prevent progression of disease in kOA

Overall, physicians and payers regarded the proposed product profile for Zilosul® positively. Assuming sustained efficacy and robust safety data, physicians and payers consider Zilosul® will provide high value to the treatment of kOA by covering some important unmet needs; specifically, by providing an alternative treatment to reduce pain and improve function in kOA patients, whilst preventing common side effects of currently available therapies, and potentially, preventing disease progression (subject to collection of supporting data).

Physicians' positioning of Zilosul® in the OA treatment algorithm would depend on its approved indication and funding in each market. With approval for reduction of pain and improvement in function, physicians would likely use Zilosul® as a second line therapy, that is, after nonsteroidal anti-inflammatory drugs (**NSAIDS**) and in-line with intra-articular therapies. Specialist physicians estimate that up to 50% of patients would be offered treatment with Zilosul®.

However, with a disease modifying indication, physicians would consider Zilosul® much earlier in the therapeutic algorithm. In this scenario, Zilosul® would be used in line with, or if label and funding restrictions permit, prior to NSAIDS. Payers in the US suggested funding for Zilosul® as a therapy to reduce pain and improve function in kOA would likely be acceptable at a price of US$2,000 to US$3,000 per year of therapy.

If approved by the FDA with a disease modifying label then price per year of therapy in the US could increase to US$6,000 and potentially higher.

The results from this market research confirm that our earlier estimates of US$2,500 per year for Zilosul® are achievable, and indicate the potential for a higher price for disease modification. With up to 50% of patients likely to be offered Zilosul® as a therapy to manage the pain and functional impairment of kOA by specialist physicians, and even higher uptake if used as an earlier intervention for disease modification, this research further confirms the blockbuster potential for Zilosul®.

Market Potential in Osteoarthritis

OA is the most prevalent form of joint disease, affecting up to 16% of the population in the developed world, with more than 72 million people in the US, EU5, Canada and Australia suffering from OA.[1]

OA has a significant impact on day-to-day functioning and, although the levels of pain and disability may fluctuate, it has no known cure or spontaneous remission and is associated with irreversible structural damage and progression over time. Presently, there are no drugs approved that can prevent, stop, or even restrain progression of OA. Moreover, the available medications available to mitigate the pain of OA have numerous risk/benefit considerations and market research indicates that only 19% of kOA patients are satisfied with currently available treatments.[2,3]

The prevalence of OA is increasing in line with the ageing population and increasing rates of obesity. By 2030, the number of people suffering from OA in the US alone is predicted to increase by 86% to 67 million.[3] If we assume a similar increase across the other markets defined above, even allowing for lower rates of obesity in non-US markets, it is plausible that more than 120 million people will be suffering from OA by 2030.

About injectable PPS

Pentosan polysulfate sodium (**PPS**) is a semi-synthetic polysaccharide derived from beechwood that has been used as a medication in humans for over 60 years. Injectable PPS has previously been approved in European markets, where it is registered as an antithrombotic agent. In Australia, injectable PPS for human use is not currently available for sale. Injectable PPS is available via a Paradigm sponsored clinical trial or under the TGA Special Access Scheme to physicians for individual patients who satisfy strict criteria and is subject to approval from the TGA. Elmiron (the oral formulation utilised for interstitial cystitis) is the only PPS product approved in the US. A subcutaneous injectable formulation of PPS is currently being evaluated by Paradigm for the treatment of OA and other inflammatory diseases in the US and other major global markets.

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals LTD (ASX: PAR) is a late-stage drug development company with the mission to develop and commercialise PPS 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.

Forward Looking Statements

This Company announcement 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.

References:

1. Global Health Data Exchange, Institute for Health and Metrics Evaluation, University of Washington. Accessed June 2021 http://ghdx.healthdata.org/gbd-results-tool
2. OARSI. Osteoarthritis: A Serious Disease, Submitted to the U.S. Food and Drug Administration December 1, 2016
3. Matthews GL, Hunter DJ. Emerging drugs for osteoarthritis. Expert Opin Emerg Drugs. 2011;16(3):479-491. doi:10.1517/14728214.2011.576670

Authorised for release by the Paradigm Board of Directors.

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

To learn more please visit: www.paradigmbiopharma.com

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