Research Update
Paradigm Bio Limited (ASX:PAR)
PARA_OA_008 top line results

Price: $1.345 | Valuation: $3.19 | Implied Return: 137% |05 April, 2023

Investment Summary

Paradigm Biopharmaceuticals (PAR) released 168 day data from its phase 2 trial, PARA_OA_008. The data released showed promising Ostearthritis (OA) disease modifying results with improvement in a reduction in cartilage loss, reduction in bone marrow edema lesions compared to placebo, and reduction of marginal osteophytes compared to placebo group. We also saw a continuation of the trends from the day-56 readout in four key biomarkers (ARGS, COMP, C2C, and CTX-II). While this data does not ensure that PAR treatment, Zilosul©, will be granted disease modifying osteo-arthritis drug (DMOAD) indication it is a positive insight into the potential outcomes when the final data, due in the 2H of 2023, is released. On the back of this final data set, PAR intends to initiate discussions with the FDA on what is a required regulatory pathway for a DMOAD indication. This will lead into the final design in the second stage of the upcoming phase 3 trial, PARA_OA_003.

Key Points:

- 61 participants received iPPS 2 mg/kg once or twice weekly, or placebo (N=20 within each group). PAR today announced 6-month readout and a follow-up period out to 12 months will follow. PAR obtained MRI data to identify any differences in disease progression. Cartilage loss, bone marrow lesions, and osteophyte formation most showed structural changes.
- Once weekly iPPS showed 21% improvement in mean cartilage loss score in the medial femur. Placebo showed a 4% worsening of cartilage loss (p=0.065). Twice-weekly iPPS showed no statistical improvement compared to the placebo group. Cartilage loss is seen as the most important feature of OA disease.
- One weekly iPPS showed an average 38% decrease in bone marrow lesions in the lateral femur. An increase of 47% was seen in the placebo arm (p=0.056). In the lateral tibifemoral compartment a decrease of an average 17% in the once-weekly iPPS while the placebo group increased 56% (p=0.028).
- Marginal osteophytes is an early finding in OA which are bone spurs that form between the cartilage and bone. These increase in size and number as the disease progresses. Osteophytes showed slight decrease or remained stable compared to an increase in the placebo arm.
- WOMAC scores for pain, function, stiffness showed durable responses compared to placebo. WOMAC function showed 50% improvement for 53.3% of twice-weekly iPPS compared to 21.1% of placebo (p=0.067) at day 168. Positive trend or statistical significance shown at day 112 for WOMAC stiffness (p=0.029), function (p=0.059), and overall (p=0.067).
- Importantly, the placebo group used rescue medications 4 times as often as the twice-weekly iPPS group.
- Molecular biomarkers of cartilage degradation were favourable compared to placebo. Synovial fluid and serum samples (ARG's and COMP) showed favourable changes. Serum C2C and urinary CTX II also showed beneficial effects compared to placebo. C2C and ARGS (SF) showed statistical significance (p=0.024) however the remaining biomarkers did not have reported p values.

Recommendation

While the data was promising in showing a consistent trend and further empirical evidence (via the MRI images) it fell short in showing a definitive disease modifying result. However, the study was mainly exploratory to see signals or signs of disease modifying. A larger study will be needed to prove DMOAD. As detailed in the key points the varying reactions between the single and double dose arms as well as the varying statistical p-values fell short of a definitive effect. However, the data set is only at the halfway point and the full 12-month data set could be more definitive. The trial ednpoints, which were change in pain from baseline at day 56 and change in at least one biomarker, were achieved. As such we retain our $3.19 target however we probably wont be certain of DMOAD until the results are published and peer reviewed on the full 12 month data set for PARA_OA_008 which we anticipate will be due sometime between September and November of 2023.

Company Data

Recommendation: BUY
Price (Date 05-04): $1.345
ASX Code: PAR
Shares on Issue: 279.6m
Market capitalization: $376m
Enterprise Value: $292m
12-month price range: $0.85-$2.15

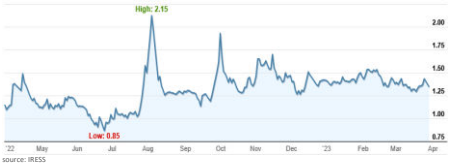
Board Structure & CEO

Paul Rennie: Chairman & Managing Director
Dr. Donna Skerrett: CMO & Executive Director
John Gaffney: Non-Exec Director
Amos Meltzer: Non-Exec Director
Helen Fisher: Non-Exec Director

Major Shareholders

Allianz Asset Management: 5.75%
Kzee Pty Ltd (Kzee Super Fund): 3.78%
Paul Rennie: 3.29%
Total Top 20: 29.14%

Chart



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