



ASX RELEASE

Q and A on Hay Fever Program

Melbourne 19 June 2017 Paradigm Biopharmaceuticals Ltd (ASX:PAR) wishes to provide a Q & A on its hay fever program following the receipt of a number of investor enquiries as a result of the trial update announcement lodged on 16 June 2017.

QUESTION

Was the outcome expected?

ANSWER

No. This was unexpected given the very positive preclinical results where PPS was shown to be as efficacious as the corticosteroid, budesonide.

Is this the end of the Allergic Rhinitis (hay fever) program for Paradigm?

No. As previously stated, Paradigm was advised of the top-line results - i.e. the trial did not reach its primary outcome. Paradigm has only received the top-line result from the clinical trial - i.e. drug vs placebo did not reach statistical significance. We have not received the full study report. It is too early to end the Allergic Rhinitis program on the basis of the data received to date. As previously mentioned, once the full data is available it will be reviewed, by an independent expert, and determine next steps.

Should the respiratory indication no longer be valued by investors?

That is not correct. If the analysis determines the problem in the translation of results from the animals to humans the Allergic Rhinitis trial can be re-run at a cost of \$2.0mn and a time-frame of six months. Additionally, Paradigm's respiratory patent also includes Pentosan Polysulfate Sodium (PPS) for the treatment of Allergic Asthma and Chronic Obstructive Pulmonary Disease (COPD). In these indications, Paradigm would need to develop an inhaled version of the drug. This research has been ongoing for the past nine months. At BIO2017, Paradigm will meet with its delivery development partners including 3M Drug Delivery.

Does PPS work in hay fever?

What we know so far is that PPS worked in laboratory experiments used to test drugs in Allergic Rhinitis / hay

fever. Also, PPS was used in laboratory animals and worked very well even compared to the corticosteroid, budesonide. We know the very positive effects in laboratory tests and animal experiments did not translate into humans. The clinical trial was the first in the world to test the effect of PPS in that formulation, in that dose and with that delivery device.

How did the company arrive at the formulation used in the trial?

The Company was advised by various consultants and specialists on the formulation used in this trial. Until we have the full trial report we cannot answer with certainty why this particular formulation did not work as expected.

How common are issues with formulation when companies conduct clinical trials?

Drug formulations are an ever-evolving piece of the drug development process. It is commonplace for a drug formulation to continue to be improved or adjusted right up to the point that regulatory approval is being sought. Companies certainly try to get the formulation right at the start of the clinical trial process but often work is required to optimise a formulation.

Because PPS did not reach the primary endpoints in hay fever will it work in the other indications such as bone marrow edema, osteoarthritis and Ross River?

Yes, the Company believes so. The PPS used in Allergic Rhinitis was an intra-nasal spray. The formulation, device, dose and the route of administration were tested, for effect, in the 'world-first' clinical trial. In Allergic Rhinitis, the mechanism of action was to block the allergic cytokines (IL-4, IL-5 and IL-13).

The bone marrow edema, osteoarthritis (OA) and Ross River use the well-established route of administration (injection), formulation and dose (over 60 years of use in humans).

The mechanism of action for the injectable drug is its anti-inflammatory, cartilage protection and mild anti-coagulation properties. Injectable PPS has been proven to work in at least two clinical trials in patients with advanced OA. Paradigm has also treated over 40 subjects with Ross River, OA or unresolved bone marrow edema with success. All patients have had improved clinical symptoms and those results have guided our clinical trial designs. We expect to report on the bone marrow edema in Q3 CY2017 and commence the Ross River clinical trial in Q3 CY2017.

Does Paradigm need to raise capital now?

Management believes its cash position, including the anticipated R&D rebate in Q3CY2017, is more than sufficient to progress all the Company's current programs, and commence planning for the upcoming osteoarthritis and Phase 2 pilot heart failure clinical trials.

Any final remarks?

Paradigm has continued to use investors funds wisely. Since listing 80% of our spend goes directly to the clinical programs.

Paradigm conducted the Phase 2a Allergic Rhinitis clinical trial to the highest possible quality standards and the trial was professionally executed on budget and on time.

As part of our commitment to deliver on our milestones, Paradigm will now finalize the Phase 2 open label bone marrow edema clinical trial. Paradigm will also now finalize the Ross River Phase 2 clinical trial. So in the two years since listing on the ASX, Paradigm will have completed two Phase 2 clinical trials and commenced its third. In addition, our de-risking strategy continues with new IP being developed or acquired with more details on this front to be provided in future updates. Paradigm is also seeking commercial partnerships for its various programs and as part of BIO2017 and will meet with various pharmaceutical companies.

Paradigm continues to deliver on its development plans but unfortunately, we can never guarantee all results will be positive as that does not happen in the pharmaceutical development industry. However, we can guarantee that the highest proportion possible of shareholder funds will be spent on R&D and drug development and despite this setback, we look forward to updating the market on the positive progress of Paradigm's various programs.

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