

UNDER THE BONNET We explain what this company does

Why Lupus treatment is a potential game-changer

Drug in development could have blockbuster potential for ImmuPharma



BROKER SEES MULTI-BILLION POTENTIAL FOR LUPUZOR

Lupus was recently thrust into the spotlight after singer Selena Gomez cancelled her world tour to deal with the autoimmune chronic inflammatory disease, which currently has no cure.

Drug developer ImmuPharma (IMM:AIM) has a pivotal year ahead as it undergoes its Phase III trial for its lead treatment Lupuzor to help treat lupus. The drug has been tipped to have blockbuster status.

Management expects to provide incremental updates on the trial ahead of reporting top line results in the first quarter of 2018 as the final step before filing for marketing approval with the US Food and Drug Administration (FDA).

WHAT IS LUPUS?

The disease causes the body to make antibodies that attack healthy tissue. Typical symptoms include rashes, fatigue, joint pain and swelling, but it can be fatal as kidney failure can occur.

Currently lupus is treated through low-dose steroids, immunosuppressants, anti-malarials and high-dose steroids.

HOW DOES IMMUPHARMA PLAN TO TREAT THE CONDITION?

Lupuzor is a drug that works on the immune system of lupus patients by modifying the behaviour of certain key cells involved in the development of

the disease. It is 100% owned by ImmuPharma.

The drug suppresses the symptoms without any side effects recorded so far as the Phase IIb trial demonstrated significant efficiency and safety.

The symptom-free nature of Lupuzor is achieved by not activating t-cells that can trigger auto antibody production. This is a typical response when new drugs are introduced into the body.

It has also shown potential in treating other conditions such as rheumatoid arthritis, Crohn's disease and asthma.

WHAT IS THE COMPETITIVE LANDSCAPE?

Over the past 50 years, there

has only been one approved drug: Benlysta owned by GlaxoSmithKline (GSK). However, this is only marginally effective and carries significant side-effects.

If ImmuPharma can get its treatment approved, it would not have much competition in what is essentially an area of unmet medical need. An estimated 5m people worldwide suffer from lupus.

The FDA recognises the potential of Lupuzor as it has received fast-track designation, which means the review of the drug will be expedited. It has also been granted the gold standard special protocol assessment by the FDA.

This means if ImmuPharma adheres to the same protocol as its Phase IIb study and delivers positive results, the federal agency will not request a further trial with different endpoints. It also means different outcomes will not have to be pursued in further trials, which should reduce costs.

'BLOCKBUSTER POTENTIAL'

Northland Capital Partners analyst Vadim Alexandre believes the shares are grossly undervalued. He has a target price of 171p, which is more than three times ImmuPharma's current share price of 50.7p.

Vadim says: 'The drug has been looked upon favourably by US regulators, which have deemed it a priority treatment. 'Should the drug be approved, we estimate it could achieve multi-billion dollar annual sales.'

It is important to highlight that despite its side-effects, GSK's Benlysta reached sales of over



AN ESTIMATED FIVE MILLION PEOPLE WORLDWIDE ARE AFFECTED BY LUPUS

\$400m in 2015 with annual sales predicted to hit \$1bn by 2020.

Lupuzor has demonstrated it is safer and more effective than Benlysta in its Phase IIb trial, and may benefit from higher uptake by lupus sufferers if it is approved.

Management anticipates that Lupuzor will also be cheaper than its competitor, which is currently priced at around \$30,000 annually per person.

WHAT ARE THE COMMERCIALISATION PLANS?

ImmuPharma plans to commercialise the drug through licensing deals with big pharmaceutical companies that need new drugs in their pipeline to keep delivering profit growth.

The company will receive royalties on sales from its global licensees.

Currently, management estimates a 95% gross margin.

Either a partner or the company will work with the manufacturer to make Lupuzor

on a large scale. Marketing costs are expected to be low as management will target rheumatologist clinics

that specialise in treating lupus sufferers. ImmuPharma's market for Lupuzor is initially the US and wider North American continent with potential to expand to Europe and Japan.

These are important markets for ImmuPharma as approximately 1.5m people suffer from the most severe form of lupus known as Systemic Lupus Erythematosus in Europe, the US and Japan.

The condition can involve various parts of the body and is more likely to affect certain ethnic groups and women. (LMI)

SHARES SAYS: ↗

Although there are always risks in drug development, ImmuPharma looks attractive as Lupuzor has strong potential to treat a disease that currently has few effective treatment options.

BROKER SAYS: 2 0 0