ImmuPharma PLC

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ImmuPharma chairman and chief executive upbeat on Lupuzor; industry interest remains strong

If it's been a roller-coaster week for investors in the drug developer ImmuPharma PLC (LON:IMM), the stress doesn't show in the demeanour of its two principals - chief executive Dimitri Dimitriou and Tim McCarthy, the chairman.

"Do we look down in the dumps?" asks McCarthy, before answering his own question. "Of course, we don't."

You'd suppose from the share price action there were more reasons to be fearful than cheerful following the publication of top-line data from the phase III clinical trial of Lupuzor, for the treatment of the autoimmune disease, lupus.

WATCH: ImmuPharma pair confident on drug's future
On the face of it, the result wasn't good as the drug missed its primary endpoint. It was efficacious, just not at a level that could be described as statistically significant; however, the devil was very much in the detail of the trial with a number of positives in the results that suggest the 67% fall in the share price this week was something of a knee-jerk reaction.

WATCH: Analyst gives his reaction to Lupuzor news
And these 'positives' also provide a very broad hint as to why Messrs Dimitriou and McCarthy were fairly relaxed when they joined Proactive 48 hours after the update.

First, there is more than a slim chance that the product will still make it to market and crucially, potential commercial partners are still interested in Lupuzor.

"We are at pains to point out this isn't a failed drug," said McCarthy.

"These are results for a drug that didn't meet its primary end-point and that's a difficult concept for a lot of people to understand."

As mentioned above, the data were nuanced rather than binary. As is normal for trial of this magnitude and importance, the ImmuPharma phase III study was a double-blind placebo-controlled study.

This is a simple concept: the doctors treating patients don't know who is receiving the medication and who is being administered a pill or solution with no medical benefit at all - the placebo. Only at the end is it revealed who had what.

Nuanced results
The ImmuPharma trial was a little different. Patients in each group received the standard of care, which is normally some sort of steroid treatment, plus either the placebo or the Lupuzor.

So, while the response rate among the Lupuzor group was 52.5%, the placebo cohort showed an unusually strong

Price: 38.00404p

Market Cap: £53.32M

1 Year Share Price Graph

Share Information

Code:		IMM
Listing:		AIM
52 week	**High**	**Low**
	193p	**19p**
Sector:		**Pharma & Biotech**
Website:		**www.immupharma.com**

Company Synopsis:
ImmuPharma PLC is a pharmaceutical company listed since 2006 on AIM of the London Stock Exchange (LSE:IMM), focusing on developing novel medicines with high sales potential in specialist markets with serious unmet need. ImmuPharma has five drug candidates in development, two platform technologies and approximately 70 patents.

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response at 44.6%.

The latter number was higher than expected, based on what had been observed in phase II where the number was below 40%.

"If we had the same efficacy as we achieved in phase III and got the lower placebo response we saw in phase II then we would have seen statistical significance. That's the subtle point," said McCarthy.

And remember, patients in the placebo group probably weren't responding to the placebo; rather, they were responding to the ongoing treatment they were receiving.

It is worth pointing out that 153 of the initial 202-strong patient group finished the 12-month course. In that smaller group, the response rate for Lupuzor was almost 70%, compared with 59% for the placebo.

Deep dive into the data
In some cases, where patients possessed certain biomarkers, the response was statistically significant; indeed a small handful of patients went into full remission.

The plan now is to take a deep dive into the data. Then there are also conversations to be had with the regulators, who are likely to be a little more understanding than investors who bailed out.

"We need to have a discussion with the FDA [Food & Drug Administration] and EMA [European Medicines Agency] to see what they think because there have been trials where the end-point strictly speaking wasn't met but the FDA understands what's good for the patient and they understand context," said CEO Dimitriou.

"You could have an optimistic scenario where you have conditional approval to make it [Lupuzor] freely available for the patient without having the formal approval. That's the discussion to be had."

More than 10 NDAs
At the same time, talks with potential industry partners are ongoing, with more than ten having signed non-disclosure agreements with ImmuPharma. The latest results don't appear to have rattled potential collaborators.

"We sent them the top-line numbers to the people who we signed confidentiality agreements with. A lot came back the same day and some that didn't have CDAs [confidentiality agreements] in place sent through CDAs the same day," said Dimitriou.

McCarthy added: "The message to take away is we have done an awful lot of groundwork with these companies before we got these results. Within 48 hours we have shared the data and already had responses back."

Agreeing a licensing deal traditionally takes around a year, though the competition can be a catalyst. And remember, Lupuzor has already been through the validation process having earlier in its history been licensed to Cephalon before the takeover of the US biotech saw the rights handed back.

But just why would big pharma be interested in Lupuzor?

Well, lupus sufferers, of whom there are around 5mln worldwide, are incredibly poorly served. The standard treatment is steroid-based, which has many side-effects, while the GlaxoSmithKline-made Benlysta, the first drug in the space for 50 years, also has significant drawbacks. This and the cost of Benlysta means that probably no more than around 13,000 patients have been treated.

A side-effect free alternative?
Even with that limited group, the GSK drug generated US$400mln of revenues. Imagine if you could get a side-effect-free alternative to market. One would assume the take-up rate would be much higher.

"Lupuzor is still a potential multi-billion dollar selling drug. The trial hasn't done anything to alter that," said chairman McCarthy.

"In fact, if anything it has proven what we have always been saying about its product profile. It does no harm and benefits patients."

And all of this is said with a smile.