DirectorsTalk Highlights » Q&A with Tim McCarthy Non-Executive Chairman at ImmuPharma PLC (LON:IMM)

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ImmuPharma PLC (LON:IMM) Non-Executive Chairman Tim McCarthy caught up with DirectorsTalk for an exclusive interview to discuss their interim results, initiating Lupuzor's regulatory submission, activities for 2017, confidence in announcing top line results and more interest from potential licensing partners

Q1: Prior to the interims announced this morning, you've announced good progress on Lupuzor's trial over the last few days. Firstly, can you summarise where ImmuPharma is with the current status of the Phase III pivotal trial?

A1: Well, we're in this pivotal Phase III study which, just to remind your listeners, is the last stage of clinical development in the whole process of getting a drug to market. We have 200 patients in the study and last week we'd put one of our regular updates out to market which confirmed that the study was all on track, all 200 patients have passed through the 6 months stage, all patients are in this study for 12 months and we have just over a quarter of patients have completed the study i.e. the whole 12 months.

The trial is on track to report in the first quarter next year, 2018, and importantly, we're still seeing a very robust safety profile. So, just to put that in context, all drugs, as I'm sure you'll listeners will appreciate, when they get to the market it's because they demonstrated that they are efficacious, in other words they work in patients and treat the condition or disease but also that they have an acceptable side effect profile. All drugs, being chemicals, being put into your body generally will demonstrate some sort of side effects which patients have to endure in order to get the benefits at the same time.

With Lupuzor, we have quite a unique situation that in all our trials to date, and certainly what we've seen in the Phase III to date, is a completely benign safety profile so we're getting no side effects whatsoever. That's supportive of everything we done previously in clinical study and that's very encouraging to us and everything else seems to be going on track with the study as well.

On that basis, we're looking forward to the results in Q1 of next year and we're looking forward with confidence.

Q2: How important is safety in the Phase III trials?

A2: It's very important in that all drugs have a risk and benefit so, as I just mentioned, if you imagine for the moment that a drug is a chemical so you're putting a chemical into your body and very often your body doesn't like that. The most stark example is when cancer patients have to endure chemotherapy-type treatments, I think everyone appreciates how difficult that is for cancer patients and the side effects which they get as a result of it. That is something which the body doesn't take naturally to have chemicals put into its body so the developer of the drug but also more importantly the regulator who approves the drug for launch, has to look at that risk benefit. So, does the patients receive more benefit in taking that drug, in other words does it alleviate their symptoms, does it in some cases cure their disease or condition, versus the amount of side effects they have to put up with whilst they're taking the drug.

So, if you can have a drug, which we believe we do have with Lupuzor which has no side effects profile whatsoever, now that's an enormous benefit and certainly to date, in all the clinical studies

we've seen Lupuzor perform in, have very very good efficacy, in other words it gives a lot of symptom relief to patients. So, if we end up with a drug which is very effective but with no side effect profile whatsoever then you can see how powerful that drug will be.

Q3: Yesterday you provided the market with a very bullish statement on initiating Lupuzor's regulatory submission and the phrase 'planning ahead in anticipation of the trial's successful outcome' was used. Can you give some detail as to what activities you plan to accomplish over the next few months?

A3: Well, back to what I was just saying about the timing of the results coming up in Q1 next year and the fact that everything we've seen to date gives us a lot of confidence of a successful outcome of that study. One then has to look forward and through that timing to a point when we are putting together regulatory dossier which we then submit to the regulator authorities such as the FDA in the States and the EMEA in Europe to apply for approval for the drug's launch.

Now regulatory dossiers, it's quite a complicated thing and it involves lots and lots of data and information so it will certainly include all the results of clinical studies which we've completed to date plus the current Phase III study. It will include all the pre-clinical data that we have including dosing regimens and administration and all that sort of thing and it also includes manufacture of material for launch.

So, we gave that as an example in the announcement this week that we are just initiating manufacture of what we call the commercial batches of Lupuzor so to apply in the dossier, you have to have three separate batches of manufacture material which are suitable for launch. So, one has to demonstrate what the manufacturing processes are, that they're produced to good manufacturing practice and that they are, what we call stable, in other words they have a good shelf life.

If we're looking ahead with confidence to the results early next year then we have to start doing those sorts of activities now such that we have the dossier ready to submit as soon as we can.

Q4: What activities do you plan for the rest of 2017?

A4: Clearly, the main focus is on completing the study and whilst we go through the next 3-6 months we will be keeping the market updated on all of our activities and regular updates on the progress of the study.

In the background, we are also working on our earlier stage programmes, we have programmes in cancer and diabetes which are at early stages of development so there may well be some updates on those.

Also, we shouldn't forget that we're working still very closely with our collaborator in France, CNRS, and they are putting a lot of time and effort along with ourselves into looking at the potential application of Lupuzor into other autoimmune diseases and this springs off of what we call our P140 platform. So, Lupuzor currently is being trialled in Phase III for Lupus which is a very debilitating, autoimmune disease but there are other autoimmune diseases which we believe we can apply Lupuzor to, Crohns being a very good example.

Q5: How confident are you in announcing top line results for Lupuzor's Phase III trial in Q1 2018?

A5: I think we're very confident and the trial is going absolutely according to plan. In terms of announcing any results in the study, it's not only just about completely the patients through the study themselves but it's about collecting all the data and analysing it and then putting that into some sort of format which we can then deliver what the results are.

So, we're working very closely with our Clinical Research Organisation (CRO), Simbec-Orion, on this and what they are doing is collecting the data from patients as we go along because it does take a little while to process all the information and data which is collected from patients during the study. So, if we were to wait until the end of the study, in other words when the last patient had completed, to process all the data it would take Simbec-Orion a long time. So, that data is being processed as we go along so when the last patient completes their 12 months then we'll only have small amount of data to complete and so we know exactly when the last patient is completing the 12 months. Looking at that and giving a little bit of time to complete the analysis of the data we're absolutely confident we'll get these results out in the first quarter next year.

Q6: With top line results nearing, are ImmuPharma receiving more interest from potential licensing partners?
A6: It's difficult to say we're getting more or less but let me say that for an innovative drug such as Lupuzor which is going into patients that are crying out for medicine, for effective medicine, this is a very attractive asset for a lot of companies in the pharmaceutical industry so yes, we are getting a lot of interest on it.