asx announcement

mesoblast
the regenerative medicine company

Boardroom Radio Interview with Mesoblast Chief Executive

Audio link - http://www.brrmedia.com/event/120127

BRR **Today at Boardroom Radio (BRR) we're once again joined by Mr Silviu Itescu, who is Managing Director of Mesoblast. Silviu welcome back to BRR.**

SI Good afternoon, thank you.

BRR **Silviu, Mesoblast has just announced Phase 2 disc repair results; could you give investors and listeners an overview of these results?**

SI Yes, look we're very excited by the results we've just presented. There's a tremendous unmet need. Patients with degenerating intervertebral discs of moderate to severe severity have very few options, despite failing interventions like steroids and use of opioids, the only other alternative to these patients is surgery. So we initiated a trial of 100 patients following positive results and preclinical studies in sheep where a single injection of our off-the-shelf allogeneic Mesenchymal Precursor Cells resulted in in improvement in the intervertebral disc structure and an increase in the matrix of the disc, the proteoglycan. Following that we initiated this Phase 2 trial evaluating in a randomized blinded fashion one of two doses of mesenchymal precursor cells injected into the disc, into the intervertebral disc, versus one of two placebo controls either saline or hyaluronic acid. And the patients have now completed 12 months of follow-up, and at the 12-month point what we've seen is that both of the doses of mesenchymal cells have performed significantly better than either of the two controls in both sustained reduction in pain, improvement in function, reduction in opioid use and reduction in the need for additional procedures. So on the basis of these exciting results we will be talking with the FDA and other regulatory bodies around the world in moving this program into Phase 3 shortly.

BRR **Silviu could you be a touch more specific just in terms of the results with some numbers?**

SI Sure with respect to the primary problem in these patients which is chronic low back pain, we've received clear views from the key opinion leaders, the physicians, the patients and the healthcare payers and the principle targets that we ought to be aiming for here is a 50% or more reduction in low back pain for at least a 12-month period and with that as an important endpoint we were very pleased to see that in fact the low dose resulted in 69% target achievement, the high dose mesenchymal cells injection at 62% target achievement, whereas each of the control groups, hyaluronic acid 35%, and saline only 31%, the difference between the treated and the controls was highly significant at P equals 0.009 and P equals 0.038. Achieving that kind of a target in this very rigorous patient population in our view is a major accomplishment, but then when we looked at a different approach, in other words which patients not only had at least 50% reduction in back pain but

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what proportion in fact had minimal pain, minimal residual pain altogether which is really the objective of the treatment, what we found was that 52% and 42% of each of the treatment arms versus 18% of each of the control arms achieved that very important target, again p was 0.01 and 0.05 respectively. To accomplish that kind of an endpoint in this very recalcitrant population with chronic low back pain is in our view incomparable to any other treatment that's out there. In addition to that we saw about a 42% reduction in chronic opioid use in the treated population and a very significant reduction in the need for additional non-surgical interventions over a 12-month period, again statistically significant reduction between the two treatment arms which were similar and the saline treated controls. Finally we had evidence by radiographic means that we were improving the structure of the disc, and we used multiple parameters here we were able to demonstrate radiographically an increase in disc height between six to 12 months in both treatment groups whereas disc height was reduced in both control groups, and that's a very important observation radiographically. And secondly by some very sophisticated analyses we were able to demonstrate an improvement in disc stability in both treatment groups as compared to both control groups and again, disc stability is a fundamental issue in a degenerating disc and when you prove disc stability by reducing its motion of one vertebrae over the other, what you're really seeing is a structural improvement of the disc such that presumably there is more proteoglycan matrix being deposited and the structure of the disc more closely resembling the normal disc structure.

BRR **That's fantastic news. And what are the implications for the patient population?**

SI As I said this is a very large patient population, an unmet need. In the United States alone there are about 3.5 million people suffering with moderate to severe low back pain from degenerating intervertebral discs. At least 600,000 every year in the United States will undergo interventions such as multiple steroid injections. For these patients really none of the treatments do little more than give them a little bit of pain relief and provide no sustained benefit, so there is nothing out there other than invasive surgery. We believe that if we are successful in Phase 3 we will have a minimal invasive injectable product that will provide the kind of long term sustained benefit that is needed for this very debilitative population.

BRR **And Silviu, Mesoblast has just announced quarterly results which detailed around $250 million of cash on the balance sheet. Will this be a sufficient amount of capital to take the disc through to market essential?**

SI Yes we're very well resourced and cashed up to complete the Phase 3 trial of intervertebral disc repair on our own and have allocated the funds necessary for that. In addition, obviously the $250 million that we have in the bank is sufficient for a number of Phase 2 programs that are currently in train as well as to ensure that we scale up and get our manufacturing to commercial grade in anticipation of commercial launch of multiple products. In addition to the Phase 3 for disc repair, which we hope we'll be in a position to commence by mid-year, we have recently acquired a mesenchymal stem cell product termed Prochymal®, which is currently being used under expanded access in the United States for the treatment of severe graft versus host disease in

children, which is a complication that potentially results in 90% mortality, and the treatment with Prochymal® has reduced that mortality to approximately 30%. So that we think is a very exciting product and we will be having discussions with the regulators in the short term about the path to product launch in the United States. It has already received conditional approval in Canada and in New Zealand and a portion of our current funds will be used towards commercial launch of that product. And of course, our commercial manufacturing operation will underpin both the commercial launch of this Prochymal® product as well as our disc repair and other products which are in Phase 3.

BRR **Silviu, finally besides the spine disease, what other advanced clinical programs?**

SI So I've just touched on the Prochymal® product for graft versus host disease in children and in addition to that we expect to have at least three other programs in Phase 3 during the course of this 12-month period. We have a Phase 3 trial for congestive heart failure which is actively recruiting and is in partnership with Teva Pharmaceuticals; we're very excited about that program as it rolls out across North America during the current year and we have a Phase 3 program that is actively enrolling Crohn's Disease that has the objective to complete enrollment of approximately 330 patients; that program has successfully passed through two interim analyses, including a futility evaluation. The objective of that program is to in a multi-dose approach with our cell therapy product to induce early remission in patients with very severe Crohn's Disease not responsive to other biologics. It's a major area again of unmet need. And in addition to these programs, we have a number of Phase 2 trials that are ongoing in the areas of inflammation and immunity, notably diabetic kidney disease and rheumatoid arthritis refractory to biologics.

BRR **Silviu, thank you very much for your time today.**

SI Thank you.

About Mesoblast

Mesoblast Limited (ASX:MSB; USOTC:MBLTY) is a world leader in the development of biologic products for the broad field of regenerative medicine. The Company's proprietary technologies include its highly purified, immunoselected Stro-1/Stro-3 positive Mesenchymal Precursor Cells (MPCs), culture-expanded Mesenchymal Stem Cells (MSCs), Dental Pulp Stem Cells (DPSCs), and expanded Hematopoietic Stem Cells (HSCs). Mesoblast's protein technologies are based on factors derived from its proprietary cellular platforms, including Stromal Derived Factor-1 (SDF-1). Mesoblast's allogeneic or 'off-the-shelf' regenerative medicine products are being developed for the treatment of conditions with significant unmet medical needs. Product development focus is in four major and distinct areas - systemic diseases with an underlying inflammatory and immunologic etiology; cardiac and vascular diseases; orthopedic diseases of the spine; and improving outcomes of bone marrow transplantation associated with oncology or genetic conditions. www.mesoblast.com

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