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Moving Forward With Cartilage Regeneration: Q&A With Regentis CEO Dr. Alastair Clemow

By Laura Miller

GelrinC, developed by Regentis Biomaterials, is a new biomaterial solution for cartilage repair that can be used during orthopedic procedures. The material is a combination of a synthetic biomaterial and fibrinogen, which enables the material to degrade in a unique fashion.

"Unlike other polymers, in the body GelrinC degrades from the outside in and it is this feature which makes it and ideal cartilage repair material," says Alastair Clemow, Ph.D. "We inject the GelrinC into the cartilage defect as a liquid and then solidify it using ultraviolet light. It then becomes a soft, slippery, clear hydrogel. Over time, the hydrogel allows the repair of new cartilage into the defect."

Here, Dr. Clemow discusses GelrinC's progress and where it could fit into the market in the future.

Question: How is GelrinC different from other solutions being used or tested right now?

Dr. Alastair Clemow: We are different from other systems being investigated because most systems use a cell based approach. This means that they must extract cartilage cells in one operation, expand those cells in a lab and finally re-implant them in a second procedure. The problem is that the treatment is extremely expensive and requires two procedures. As a result, the cell-based systems haven't taken off because of the cost and inconvenience.

Most surgeons today perform a procedure called microfracture for these patients. In this small holes are made at the defect site to allow blood to come in. It's a simple procedure, but its potential to regenerate quality cartilage is low. GelrinC has the advantage that it does not need cells and so it can be implanted in a single procedure which is obviously less expensive and preferred by patients. We are unique among cartilage repair companies in that we put the material in as a liquid and then convert it into a solid. This allows us to completely fill the defect regardless of its size or shape. It is not possible to

know what shape the defect is before treating the patient and the last thing you want to do is to force the patient to fit the implant instead of having the implant fit the patient. That's how we have an advantage compared to the competition.

Q: What types of patients are treated with GelrinC?

AC: Most of the patients who are suitable have traumatic injuries. In cartilage repair, you aren't going after osteoarthritis patients who have a misshapen knee and other problems. We deal with traumatic injury, typically among young people. If you do nothing for these patients, the person is in pain and can't exercise. If this defect is left alone, it fills in with weak tissue which often leads to arthritis.

If you can remove the pain, the patient can return to sports and you can also help prevent arthritis in the long run. In the sports world, people with knee injuries tend to get arthritis more quickly because of instability in their knees.

Q: What is your goal for the company and technology going forward?

AC: Our goal right now is to develop and generate as much clinical evidence of efficacy as possible. We have been conducting a pilot study in Europe for the past two years, and we are excited about the data coming from that since it indicates that GelrinC offers excellent results for the patient. It is this combination of ease of use, coupled with good clinical data, which will be the basis for the company in the coming years. We plan to expand and develop the European study to obtain more data on the product.

We have also filed for a CE Mark and will work with leading surgeons to figure out how best to market the product within Europe. Once that is complete, the plan is to really develop a regulatory plan for the United States. We will then apply for an investigational device exemption from the Food and Drug Administration to begin the process in the United States.

Q: What challenges are you facing right now and how will you overcome them?

AC: Right now, everyone has the same problem obtaining approvals for a medical device since it seems that every time you move the ball down the field, the goal posts moves further away. This is particularly true for orthopedics, however, we believe strongly that sports medicine is a particularly sweet spot for us. Athletes are typically motivated to get better and since these procedures can be done in an outpatient setting, reimbursement is not the problem that you find with other types of surgery.

Another challenge that is faced by us, as with many new devices, is the learning curve in teaching surgeons a new procedure. However we are particularly fortunate in that what we do isn't a big change from what the surgeon has traditionally been performing. Therefore we are confident that with some extra training, we can get surgeons to enjoy successful outcomes.