BG Rhee – CEO, SCM Lifescience, South Korea

The difference between SCM and other stem cell companies is that we have the highest purity stem cells thanks to our different manufacturing scheme

21.01.2019

Tags: Korea, Regenerative Medicine, Biotech, SCM Lifescience, Cell and Gene Therapy

Dr BG Rhee, CEO of SCM Lifescience discusses their patented proprietary subfraction technology to extract high purity cell cultures, and the impact this will have on the efficacy, cell differentiation ability, and cost of stem cell treatments. Dr Rhee also provides his assessment of the regulatory framework for stem cells in Korea, and some of the challenges the smaller companies are encountering when looking to globalize.

Can you provide us with some background into Korea's stem cell industry and its performance?

Ten years ago, a special committee was set up in Korea to establish the direction for the bio health industry in Korea. The bio health Industry is the least globalised industry in Korea – only 1.5 percent of the global market. This committee sought to determine the areas of biopharmaceuticals which Korea could lead in. They concluded that Korea could excel in biosimilars and cell therapy.

Due to the existence of large manufacturing companies such as Samsung Biologics and Celltrion, biosimilar production was able to get quickly off the mark. Conversely, with cell therapy, the majority of the stem cell firms were small companies; when they look to expand to the USA, they require additional clinical trial data with larger patient numbers. This is very expensive, and these companies are small scale, thus struggling to compete at the global level. The original strategy was for Korean stem cell companies to go global and by-pass Korea completely. Yet, this strategy

cannot work as firms cannot shoulder the costs of international clinical trials.

What is the regulatory framework like in Korea for stem cell treatments?

We are currently in discussions with the Korean government with the aim of amending the laws relating to advanced biopharmaceuticals and regenerative medicines. In Japan, which is now very aggressive in the field of stem cells and regenerative medicine, their laws were amended in November 2014, so that after phase I trials there is conditional approval, and the next seven years are spent collecting the data from the patients for phase II and III trials. In the worst case, there is no efficacy, but the product is safe then the product will be left on the Japanese market.

In Korea, rather than phase I trials, conditional approval may be granted only after phase II trials. Currently there are 6-7 stem cell products on the global market. Four of them are Korean products. This is thanks to the special committee which helped small companies such as Medipost to receive conditional approval.

What is your business model?

Since I joined SCM Lifescience in May 2018, we have raised 40 million USD. We have more than 50 patents and are involved in a number of clinical trials. SCM is mainly focused on the immune-related diseases, and we are now moving to new indications – liver cirrhosis and diabetes.

The difference between SCM and other stem cell companies is that we have the highest purity stem cells thanks to our different manufacturing scheme. Other stem cell companies use centrifugation. When they extract the stem cells from the cord blood or bone marrow, there are many other cells present. Hence, the efficacy is low as the concentration of the specific stem cells is low.

SCM developed a new method called the subfraction culturing method. We collect the single colony which display the best characteristics for a particular indication. From that colony, we culture the stem cells, so it is very pure. Our method also offers a much more concentrated variation of cells compared to the traditional method. Each disease has a different potency marker that we can find. Next, we select the cell lines which have more expression potential for that potency marker. Thus, it is very customised.

Another area we are looking into is tissue engineering. This is in collaboration with the University of Utah CSTEC (Cell Sheet Tissue Engineering Center). This is because one of my former colleagues is based there and has very good polymer science. We are combining their polymer science with our stem cells to develop a product treating ailments of the kidney. 660,000 Americans have kidney failure. 470,000 are receiving dialysis treatment, and a further 190,000 require a kidney transplant. We supply our high purity stem cells with the polymer film from the CSTEC, and together we make our film. When you apply the stem cell filler and place it on top of the kidney, transplantation works at almost 100 percent. We are testing this for both kidney fibrosis and regeneration from scarring, for example following a C-section procedure.

We are still in the early stages and not yet in commercialisation. We have our own GMP facility in order to create the cultures for clinical trials only. Now is the time to search for better global level manufacturing facilities, be it through a partnership, or through upgrading our own facilities. In addition, large Korean players such as Samsung and LG have decided to move into stem cell therapies, so there is potential for collaboration in that regard too.

You mentioned that most Korean stem cell companies focus on Korea and not globally. What are your global operations?

We are focusing on a number of overseas markets including Japan and Australia. Thus, we are conducting simultaneous clinical trials. Although the Korean market is small, it is good to prove the efficacy of stem cell products. We are conducting our trials in Korea together with all of the key hospitals and medical centres, such as SNU, Samsung, and Yonsei.

Recently we have decided to hold acute GvHD trials in Japan because of economic issues – there are too high clinical trial costs for such a small potential market size.

For atopic dermatitis, we have also published all of the pre-clinical work. Last year in the USA, Sanofi had a monoclonal antibody treatment approved for this. It is a very expensive treatment, costing around $40,000 per year and it requires an injection every two weeks. Our stem cell treatment will require only one injection per six months to one year.

In addition, we are expanding trials for stem cell treatments into Liver cirrhosis – a very big market in Korea and China. Many patients are currently waiting for transplants, but there is a long waiting time in Korea. The doctor asked for hepatic artery injection of stem cells for the patient that are full of ascitic fluid. After 3 injections over a two week interval, the patient is still surviving after five

years.

We will conduct this trial in China, simply due to the market size available. We require more pre-clinical work because of different routes of administration. It will not be easy to move to China, and it is impossible without a local partner. We are still looking to find a capable partner for this operation but are in talks with a number of large Chinese players, particularly for pre-clinical work.

You have accrued 55 million USD in investments to date. How important is international investment compared to local investment in Korea?

If we can receive more investment internationally this would be more beneficial, as they are able to introduce SCM to their other global partners. Until now, it has been a struggle to find international investors; indeed, most of our investment to date is Korean in origin and 5 million USD came from Malaysia.

This is a new area for investment, which has a high return, and some risk involved. However, nowadays, it is more secure – even without 100 percent efficacy in an indication, it is still possible to find good and promising data.

What are the potential strengths and opportunities for Korea to be a global player?

An assessment by McKinsey found that Korea cannot be a leading global bio-pharma player. Firstly, the science is not strong enough, although now it is much improved compared to 10-15 years ago. Secondly, there is an ocean between the R&D spending of global pharma such as Roche, and local pharma companies; Korean pharmaceutical companies spend only around 100 million USD on R&D, compared to 10 billion USD for Roche. This is 100 times the scale. Consequently, we cannot compete with companies which are 100 times bigger.

Moreover, in Korea M&A is very difficult. Often small companies are held in the family, passed from generation to generation. There is a cultural element where owners do not want to sell to someone else.

Consequently, Korea must carve out for itself a very niche area where it can be a global leader. In my opinion, this could well be the regenerative medicine field, including stem cell treatment.

See more interviews