Dr. Long-Jyun Su, CEO, LuminX, Taiwan "A Pharmacokinetic Platform for Preclinical Evaluation of Therapeutic Cells"

LuminX is a Pharmacokinetic Platform for preclinical evaluation of Therapeutic Cells. Cell Therapy is used to treat human diseases.

[Our Technology]

We have developed LuminX GPS. Our Cell tracking kits are ready to use for a lot of cell types. For example, MSC or iPSC and CAR-T. If the cell could be labeled with our kits, then we can track it and check the cell's location in small animals, big animals and a lot of different kinds of animal disease models. It's means that LuminX Tracking kits can help our customers to save lots of RD time.

Our technique is a spin off from the academia SINICA in Taiwan. We published the paper in nature nanotechnology to optimize the material production. We also published the review paper in this year. We use our technique and answered the Mesenchymal stem cell mechanism, systemic safety, and bio-distribution for the clinical applications.

Our products can label such as MSC (Mesenchymal stem cell), iPS cells and T-cells. And we also provide the service platform to our customer, especially for the background-free cellular imaging or cell bio-distribution in PK, PD analysis.

[Our Business Model]

To sell the kits is one of our business models. We also can support our customers to do the experiment design. Our customer are Hospital, Research Institute, CRO companies or the cell related companies. We already proofed the concept of this basic business models in Taiwan, including the hospital, DCB or some huge CRO company, even the cell therapy industrial companies. LuminX Biotech knows that to use our technique can help them to shorten time a lot.

[Market]

We want to move on the global market from Taiwan. There is a reason that the cell therapy market is a huge and countless market, another reason is currently we focus on the preclinical stage for the cell therapy industry witch we are still developing.

Our go-to-market strategy. Now we have some providers in Japan, Shanghai, and in Vietnam. On the RD part, we are still keep researching and developing the preclinical stage, it's our target, we want to support the whole cell therapy industry in the preclinical/clinical trial on next step.

LuminX Biotech has our special kits and techniques. Now we focus on the preclinical stage. We can provide the cell localizations, cell qualification, and cell quantification. These information can help our customers to save their time to bridge from the preclinical study to the clinical trial, because we can provide more reliable data which can strongly persuade authorities.

We're looking for a business strategy partner, and need to open Japan's market on our next step. We are also looking for investors, we can work together for the best future by our special techniques and professional literacy of Biomedical and your best investment vision.

[Our Goals]

Our goal is to "Become the global FDA approval cell therapy Center, preclinical testing center"

[Q & A]

Q.

What is the target molecule of your reagent? It looks like it is binding to nuclear, right?

Α.

No, our kit will not go inside the nuclear. It will stay in the lysosomes and endosome. So it will not damage the cell in any kind of behavior and Gene label.

Q.

Then why is it so sustainable? The cell, can you explain to me?

Α.

Actually, our material is the artificial diamond and size is 100nm. Then our technic is made it can release fluorescence and forever. So this kit's mechanism is different from the organic dye. Because organic dye is decayed by laser or other external energy such as sun light even the lamp. Our material will not destroy by this external energy, can be stabled forever. So, it's means our custmor got a stable and forever fluorescence from our kits. These Kits can be uptake by multiple cells, and we found that it will not be decayed by mechanism of exocytosis. So it's different from any kind of others nanomaterial. For example, the nanogold, it will be exocytosis maybe more than 50%. So if custmor choose the organic dye or nanogold, of course they can't do the $\[\]$ long-term tracking $\[\]$. But our kits can solve this problem perfectly.

We even can track in the cell such as behavior or morphology for a long long time.

Q.

Do you already have cases in on clinical stage? Or if you haven't, when do you expect to start first clinical trials?

A.

Actually, we didn't have a clinical trial now because it is the nanomaterial. Currently, we focus on the preclinical stage, but in Taiwan, there is a case that one company used our data, they submit to the authority for their pre-IND currently. So maybe 1 to 2 years later we can prove that we are going to and really in the preclinical stage. Otherwise, because we know our bottle neck-go into the clinical stage. So, now we found some way to solve this problem and keep work hard to beat the problems. We are doing now, but currently, our business model is focused on the preclinical part, because preclinical is also the huge market and full of lot of the cell products. They found the IND to the preclinical trial, they want their cell drug production to go into clinical phase I, phase II and let it in the market.

So let's find our very position.

Q.

Probably you have to compete with the isotope use the kind of technology to label the cells. Could start for the pharmaceuticals that were used for the conventional technologies in pharmaceuticals. Do you have any strategy to replace those kinds of technology or strong strengths against them? A.

Actually, the isotope is not a common use in the research institute, it's usually find in the hospital. So our next step, now we have some project cooperate with the expert who do the isotope profession in Taiwan. So, we will combine these two special technique, use their different function and benefit. Back to the question, our technique can perfectly solve the problem about quantify the cell number. So, let's means that we can answer the PK PD and bio-distribution questions that common found in the preclinical stage. But the others technique such as organic dye they cannot do this only by the PCR system. It's lot of uncertainty that they cannot answer the whole organs information and optical hubs of some details in the advantage research. Another one, the MRI have more safety issues by operator or researchers. MRI are also having some disadvantages.

So now we know that our platform can suitable for any kind of cell, then we can provide PK PD and bio-distribution information safely.

Q.

I see Thank you very much. And probably your customer doesn't know that what kind of data will be needed for the approval to talk to the PMDA or FDA. So you have to consult to kind of things. So I guess the probably the CRO could be a good partner for you. And more discussion will be needed. But definitely your article itself will be at their business too.

Α.

Yes. I can echo your comment, there is any company use our platform? We collected some real data and industrial data. So, it is right, we already have the first case in Taiwan. They apply the IND. Then we have some cooperator. Such as a large CRO Company in Taiwan. That's why I know that i should to open the market from Taiwan to neighboring countries, because our target market size is very huge. And now, even we just focus on the [preclinical trial part]. Because I know we can provide lots of reliable data, powerful data which can support our huge customers industry, they can go to next step as soon as possible. The next step is the sale part. So it can provide a can launch the sale product for the patient is much more important. This is why we focus on the preclinical stage currently, it's a huge market size.