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Taiwan's role in the region will be to establish a highly regulated, safe usage of stem cell therapies which will make us the leader in this area

17.06.2019

Tags: Taiwan, Regenerative Medicine, TMU, University, Research, Cell & Gene Therapy

Rita Huang, dean of the Office of Research and Development and the director of the

TMU Research Center for Cell Therapy and Regeneration Medicine highlights the center's unique capabilities and its innovative research projects within the emerging space of stem cell treatments. She goes on to give her insights on the key issues faced by the field and delivers her message about Taiwan's ability to be a regional leader in safety and ethics for such therapies.

Please begin by introducing the Center for Cell Therapy and Regeneration Medicine.

I am the director of the office of research and development here at TMU as well as the director of the cell therapy center. The Taipei Medical University (TMU) Research Center for Cell Therapy and Regeneration Medicine was established in 2015 and the next year we established our GTP laboratory to generate clinical grade stem cells. In Taiwan, we have two tracks for cell therapies and regenerative medicine – cell products for the use in clinical trials and for patient treatment under special management.

In 2017, TMU established its international PhD program for cell therapy and regenerative medicine. This is a truly unique program focused on the incubation of expertise in this field. Our aim is for this

program to enhance both the regulatory environment and clinical use of cells or stem cells.

Additionally, I would like to mention that TMU has six affiliate hospitals, three of which are located around the university's campus: TMU hospital, Wan Fang Hospital and Shuang Ho Hospital. For this reason, we have established a cell therapy center at the university for the treatment of patients using these methods.

TMU is particularly focused on the application of cell therapies in cancer and regenerative medicine. For cancer, we use cytokine-induced cells (CIK) and natural killer (NK) cells, and CART is under basic research conditions. In regard to regenerative medicine, we work with mesenchymal stem cells (MSC) which are harvested from different tissues. The field is very young – only 55 cell therapy products have been approved on world markets. Overall, our mission at TMU is to focus on the developing systemic safety of stem cell products.

What are the key research projects that the TMU Center for Cell Therapy and Regeneration Medicine is undertaking?

We are focused on developing the systemic safety use of stem cell products. Some of our key projects are working with diabetes, diabetes foot ulcers, severe burn, stroke, multiple sclerosis, acute lung injury.

Speaking about tumour risks, there is one possibility that the stem cells will initiate a tumour themselves or the stem cells will promote tumour growth. Currently, how to identify the specific cell products that will promote or suppress the tumour is still not well analyzed. TMU is now working to perform gene profiling and preclinical studies to determine the tumour promotion ability of different MSCs in various cancer types. In a similar way, we also study the underlying mechanisms to determine how diabetes and ulcers can be treated. Currently, we have successfully developed a systemic stem cell product pcMSC for systemic disease treatment. The master cell bank establishment is ongoing, and the clinical trial for acute lung injury will be submitted in late 2019. Another project we are working on is the development of nanodiamond labelled MSCs which we can use for stem cell biodistribution, and, the potential pharmacokinetics and dynamics, which still challenge the current cell therapy.

Additionally, we have another project studying the effect of system stem cell therapies on radiation. When exposed to radiation, it kills the bone marrow in the body. However, in our research, we have seen that system stem cell therapy can raise the survival rate to up to 60

percent. The Research Center for Cell Therapy and Regeneration Medicine is also collaborating with TMU's dental school on a study that uses small blood stem cells in dental implants which is very promising for Taiwan's ageing population. This is currently under phase I clinical trial and will soon move to phase II and special management later this year. Finally, we also have a project ongoing for immunotherapy cancer treatments. One of the therapies under development uses CIK and NK cells for the treatment of lung cancer and is still in phase 1 clinical trial.

In what ways does TMU collaborate with the industry to further develop the center's research and bring it to the clinical trial and translation phase?

In TMU we also have a business department that will help the researchers have their IP rights and build connections with the translational industry. We encourage our professors to have their own spin-off companies. In TMU we already have spin-offs for a small molecule drug and medical devices, and we soon plan on having our own cell therapy company. Not only will we collaborate with the industry here in Taiwan, but also internationally.

The Research Center for Cell Therapy and Regeneration Medicine already collaborates with several companies from China, Japan, and the US in the areas of immunotherapies and degenerative diseases.

Internationally, we cooperate with five US universities and one US company, four Taiwan companies, a Korean university and hospital, two top Japanese universities, and both Hong Kong University and the Duke University-National University of Singapore Medical School.

Where does stem cell regulation stand today?

The most important aspect of translation is regulation. TMU's law department helps the government to establish legislation, for example in special management. In Asia, the regulation for cell therapies is still not harmonized.

In Taiwan, there are two critical associations for the initiation of stem cell research, the Taiwan Association of Cell Therapy (TACT) and the Taiwan Society for Stem Cell Research (TSSCR). The TACT cooperates with ACTO (Asia Cell Therapy Organization) in Japan to help establish regulations for all Asian countries, which TMU is also involved. We are aiming to work in society to coordinate other countries and stakeholders together and move forward cell therapies.

The government has placed a high focus on biomedicine and innovation as drivers in transforming the country's economy and scientific positioning. Do you believe that cell therapy and regenerative medicine is an area where Taiwan can be a regional or even global leader?

Although Taiwan is very small, we highly emphasize the rights of our patients. In Taiwan, transparency is very important and all institutions working with stem cells must report all outcomes. Taiwan's role in the region will be to establish a highly regulated, safe usage of stem cell therapies which will make us the leader in this area.

What final message would you like to deliver to our readers on behalf of TMU Center for Cell Therapy and Regeneration Medicine about this field of medicine?

In the next ten years, cell therapy and regenerative medicine will be a promising and helpful therapeutic area. In addition to traditional treatment, this will be new hope for patients. Currently, the information collected for safety and efficacy must be a priority. It is also critical to select the best cell products and apply them correctly.

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