Jan-Mou Lee – Founder, FullHope Biomedical, Taiwan

Through close collaboration with KOLs and medical doctors, we will continue to explore the different ways to utilize cell treatment therapy

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Dr

Jan-Mou Lee, founder of FullHope Biomedical, shares his story of how he came to establish his company after a realization about the loss of impact that occurs when critical research is never transferred outside of the laboratory. Dr Lee goes on to explain his Full Hope's revolutionary platform that is leading Taiwan's cell therapy sector as well as his views on the key trends of the field within the country and region.

Can you please introduce yourself and elaborate on how you came to found FullHope Biomedical?

I had been a scientific researcher for most of my career up until founding FullHope Biomedical. An important turning point for me was discovering a new breakthrough in cell therapy that promised to have a strong benefit to patients. Typically, when scientists find important data during their researchers, they simply write their finding and report it to a scientific journal and what I had found was very exciting, so I was sure I could submit the finding to a very prominent journal. The samples we had collected were from a cancer patient and because I was so excited, I wanted to give my gratitude to the relatives of this patient. When I tried to explain the breakthrough that we had discovered I was shocked because the patient's family told me it did not matter – the patient had passed away two days before. It was then that I realized what is the significance of research findings if they are not able to help patients in the end. Rather than submitting my findings to a

publication for the purpose of building my scientific reputation and advancing my research career, I decided to translate this data and found Full Hope Biomedical (FHB) as a way to ensure that this important breakthrough would be able to directly impact the lives of patients.

Joining the entrepreneurial world was a big challenge and something I was not used to. Unlike in academia, we have to find ways to raise capital and fund the research we are doing. After five years of difficult adjustment, I am proud to say that FHB is one of the leading companies in Taiwan within the field of cell therapy. Six years ago, when we began, the cell therapy space was very barren and not many stakeholders had experience in immunotherapies. However, working with the Centre for Drug Evaluation (CDE) we were able to determine how to properly design a formal cell therapy clinical trial in Taiwan. Furthermore, the government has passed new regulations to allow the use of six cell therapies in Taiwan. Under the new “Regulations Governing the Application of Specific Medical Examination Technique and Medical Device”, stem cell therapies are able to be applied to patients one phase I trials are complete. In fact, I was one of the consultants to help develop this amendment.

FHB is collaborating with several major medical centres such as National Taiwan University Hospital and Taipei Veterans General Hospital to conduct cell therapy clinical trials. Our development strategy is to take advantage of our innovative research power and translate our lab findings to the clinic while collaborating intensely with leading key opinion leaders in the fields of oncology and autoimmune disease. We are currently working on a cell therapy protocol with the government, in addition to the recent regulations and if all goes well we will have over 150 KOLs in cell therapy collaborating with FHB.

Tell us more about FullHope Biomedical’s comprehensive immune function detection and analysis platform.

Our platform is focused on conducting precision diagnosis before preparing personalized immune cell therapies. This immunoprofiling platform uses a patient’s blood sample against over 600 monoclonal antibodies, we can successfully identify over 1,700 cell therapy options. This platform has been Taiwan Accreditation Foundation (TAF) certified for quality insurance of immune cell products. After, we have created a database from the blood samples of subjects of different gender and age groups which we are comparing with different disease models such as cancer and autoimmune disease. In the immunoprofiling, we can design patient-specific regiments that best fit their disease condition, such as combination treatments using both targeted medicine, chemo, or

PD-1 plus cell therapy.

In addition to immunoprofiling , we also conduct clinical trial services. For example, we established a predictive biomarker in a 12-week trial for PD-1 inhibitor drug. We profiled the patients before, during, and after the treatment regimen to conduct a retrospective analysis on the PR (partial response) and DP (disease progression) groups of patients. This way, we were able to determine the patient immune difference and identify biomarkers which can predict patient response to the treatment.

How would you describe the environment in Taiwan when it comes to these innovative treatment methods?

Many doctors in Taiwan were in opposition to the cell therapy reform. They had not seen the clinical data and to them, cell therapy is very unsafe – but they do not consider the efficacy of the treatments. That is why FHB is participating in the partner studies to inform health professionals and we carry out the screenings so we can find the correct target populations to use correct treatment methods.

Through close collaboration with KOLs and medical doctors, we will continue to explore the different ways to utilize cell treatment therapy. Thus far in Taiwan, FHB has completed 6 pilot studies of which 60 percent of patients responded to the treatment. We are working to convince doctors that cell therapies are viable methods of treatment for patients and we currently have 2 cell therapy protocols under review by the government.

What is FullHope Biomedical’s contribution to cultivating Taiwan’s cell therapy landscape?

As we are a company, it is difficult to deal directly with patients. However, because we have the technology, our goal is to set up a clinical institute which will allow us to apply our R&D to the cell manufacturing facilities and review the clinical use of products. Since cell therapies are not reimbursed at the moment, patients pay out of pocket and FHB and deliver them the service and quality that they would not get in standard hospitals. As a specialist only working in cell therapies, FHB will be able to guarantee the safety of these procedures, making them a very viable treatment option rather than an unknown theory. Moving forward, our ambition is to market these services to other strategic markets such as China and Japan for medical tourism, ultimately making FHB in

Taiwan a regional hub for cell therapy.

Taiwan despite being very small, highly emphasizes the rights and safety of patients. Can Taiwan's take on the role of establishing a highly regulated, safe cell therapy environment – ultimately making it a regional leader in the area?

Absolutely. All stakeholders – government, industry, physicians, researchers – we all want Taiwan to pave the path for the stem and immune cell field. We are willing to build a cell therapy model that can be followed worldwide. For example, in the US these treatments are still not available to the public. In Japan, cell therapies have been existent for three decades yet still, not a single cell technology has been approved by the Ministry of Health, Labour and Welfare (MHLW).

In Taiwan, phase II clinical study protocols must be followed when administering cell therapies to patients. All details of the treatment must be recorded, and annual study reports must be filed annually, therefore creating a pool of viable data in the field. This is good not only because it allows companies to make revenues to fund their R&D while having access to a network of data, but the entire sector can also benefit from sharing experiences and ultimately drive the field forward.

What is your strategy to position FullHope Biomedical on an international scale?

In 2017, we passed the certified for accreditation of foreign cell processor by the MHLW of Japan, and concluded a cooperation contract with the Tokyo Immunotherapy Professional Clinic. We have already established collaborations with hospitals and medical centres, and several physicians are interested in our offering. My hope is that we can gather more clinical data from Japan and create more partnerships with the cell therapy sector in the country.

We are of course also looking towards the US for future expansion. FHB has already submitted applications for phase I/IIa clinical trials to the FDA. By the end of this year, we are hoping to obtain approval so that we can begin running trials in the Boston area.

What vision do you have for establishing FullHope Biomedical and a leader in immune-cell therapies?

My vision is for FHB to be a global company with our innovative research in Taiwan and our market development in Japan. We are also hoping to be able to build our clinical data in the US. Additionally, my aim is to establish a joint venture company in China.

When people hear about our company, I want people to be full of hope. What we will do in the future is follow in a direction to bring health back to our patients.

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