Charles Chen – Vice Chairman & CEO, Medigen Vaccine Biologics Corp. (MVC)

At MVC we have chosen a tried and tested technology platform as novel vaccine technologies face novel challenges

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Charles Chen of Taiwanese firm Medigen Vaccines Biologics Corp (MVC) shares his career journey, the company's COVID-19 vaccine strategy, and what MVC's competitive advantages are.

Charles, could you start by introducing Medigen Vaccines Biologics Corp (MVC) and yourself as CEO to our international audience?

I am the CEO and co-founder of MVC, and concurrently I am also a Distinguished Adjunct Professor of Bio-innovation at Temple University in Philadelphia, USA, and Chair Professor of Industry-Academia Collaboration at National Yang-Ming University in Taiwan. I have been in the vaccine business for nearly 40 years, working with both animal and human vaccines.

Regarding our company’s history, in 2009, three Taiwanese companies, Medigen Biotechnology Corporation (MBC), Schweitzer Biotech Company (SBC) and CESCO Bioengineering established a team to develop human vaccines; the entity was spun off in 2012 as MVC. MVC is the first cell-based vaccine manufacturer in Taiwan with solid R&D capabilities to develop and manufacture vaccines and biosimilars.

MVC is involved in several human vaccine developments, including H7N9 pandemic vaccine, H1N1/H5N1 pandemic flu vaccine, and vaccine against the EV71 virus that causes hand-foot-and-

mouth disease (HFMD) for children under the age of six. We have also obtained a license for a dengue vaccine and an S-2P protein subunit adjuvanted COVID-19 vaccine from the National Institutes of Health (NIH) in the USA.

We were listed on the Taiwan OTC stock exchange in 2018. That same year, we received PIC/S GMP certification for our vaccine manufacturing plant.

MVC focuses on cell culture vaccines. What advantage does this have over other vaccine development and manufacture platforms?

An often used technology is egg-based vaccine production. This platform has a number of challenges. For example, during an avian virus pandemic, the egg supply may be limited. In contrast. a cell bank will ensure a stable supply of key biomaterial components. Furthermore, as our cell culture technology platforms use serum-free media and employs a ‘single use’ closed manufacturing system, we have no risk of contaminants like Bovine Spongiform Encephalopathy. Cell-based production is also rapidly expandable and scalable, and cell culture is usable for many different types of vaccines such as seasonal flu vaccines, dengue and HFMD.

While it was challenging to develop this technology, we had expertise that helped us along the way. Having been involved in animal vaccines for decades, we were familiar with the cell culture technology platform, as most swine vaccines are produced from cell cultures. Taiwan also has a number of renowned academic and research institutions such as the National Health Research Institutes (NHRI) and Academia Sinica.

Another challange was funding; we wanted to build a PIC/S GMP compliant plant and that required a lot of resources. Finally, we also needed biomaterials such as recognised cell lines. We obtained both cell lines and virus locally and other needed materials from international organizations such as the World Health Organization (WHO), however the validation process and studies we did ourselves.

MVC has a COVID-19 vaccine too, as you mentioned. What progress have you made here?

Many parts of Asia had to deal with the Severe Acute Respiratory Syndrome (SARS) crisis in 2003, including Taiwan, and it left a strong impression with significant mortality and a society in lock-

down. We also saw a repeat with MERS in 2012 although it did not affect Taiwan to the same extent as SARS. When COVID-19 hit us, we did not know if it would be similar to SARS, but we immediately saw how serious things could become. We spoke to public health experts as early as February 2020 to brainstorm ideas on the development of a vaccine or a therapeutic option. We contacted the U.S. NIH and learned that they had a vaccine candidate that was being developed in partnership with the U.S. biotech company Moderna. We obtained a license for the gene sequence and started producing a stabilized COVID-19 spike antigen and began our own preclinical investigations.

Due to its quick pandemic response, Taiwan did not have many COVID-19 patients, and we had to use extensive animal studies to explore formulation and dosages. We also established a partnership with a US-based Dynavax to use their CpG 1018® adjuvant in our vaccine. We completed our preclinical trials at the end of September 2020 and have now entered Phase 1 human trials with 45 subjects. The Taiwanese government has indicated that they would like to use our Phase 2 trials as a basis for Emergency Use Authorization (EUA) approval, so we expect to have 3000 subjects in our Phase 2 trials as opposed to the normal 200-300. We expect to enter Phase 2/3 trials by the end of this year.

We know that many companies are in the COVID-19 race, and a lot of the R&D has been done in a very short period of time. Modern vaccine technology has improved significantly over the past few decades, and today’s vaccines can be produced faster without compromising safety. Determining vaccine efficacy is still a major challenge, however, and this step takes time.

There are many companies that are testing new technologies, which is exciting. At MVC we have chosen a tried and tested technology platform as novel vaccine technologies face novel challenges. For example, mRNA vaccines will require very low storage temperatures (-20 to -70C) and thus face transportation and logistical barriers that may limit their distribution. It may turn out that these type of vaccines are only feasible for the developed countries which have the cold chain infrastructure needed for storage and distribution. Other COVID vaccines under development such as those based on adenovirus vectors, may have problems with booster doses. I believe that with our technology, our adjuvanted vaccine will be able to meet the needs of countries without sophisticated logistics infrastructure and may even be suitable as a booster shot for other vaccines (e.g, adenovirus-based vaccines).

Finally, our adjuvanted subunit vaccine may allow us to adjust the formulation to create a single-dose vaccine, which would be more economical and convenient.

What is MVC's commercial strategy for the vaccines you are developing?

We have a local, regional and global approach. Our COVID-19 vaccine will first be manufactured to meet the local needs. Taiwan has 23 million people so it has a significant market, and the government would very likely be our initial and most important customer. Already, the Taiwan government has demonstrated its willingness to financially support the development and production of COVID-19 vaccines.

Beyond Taiwan, we see our neighboring countries in Asia as important secondary markets. Countries like Vietnam, Thailand and Indonesia do not have cell culture production facilities, so these countries are potential markets. Japan and South Korea only have a couple of vaccine companies that use cell culture production. These countries are potential collaborators for us. We have already pursued a partnership with GC Pharma of South Korea for the import of their QIV.

From a global perspective, other markets also exist for us in Latin America and Africa. Of course, we also hope to address vaccine needs in developed countries since we have a PICS/GMP manufacturing facility that meets EU EMA and US FDA requirements.

The vaccine market is dominated by a couple of Big Pharma companies. What do you see as MVC's competitive advantage in this sector?

Taiwan is not part of the WHO, so for us, it is important to establish bilateral, regional and international collaborations with other entities. We have to be nimble and work with both local and foreign partners.

I think we have a very strong pipeline and R&D activity, especially since many of our technologies and vaccines have been licensed from top institutions like the U.S. NIH. Some of the diseases we are targeting like the seasonal flu and dengue fever are global challenges; others are more regional. In some areas like HFMD, we are working in markets where Big Pharma is not involved.

Any final message you would like to send to the global vaccine community?

Vaccine companies need to collaborate, not just compete. Preventative vaccines are essential to public health and I would like to see more regional, as well as global collaboration. After all, even if

you solve a problem in your own country, if your neighbors are struggling with the same disease, you are still at risk.

MVC’s goals are to serve local public health needs, build regional trust and alliances, and actively participate in meeting global needs.

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