Interview with Stanley Chang, Chairman & CEO, Medigen Biotechnology Corp.

29.06.2010

Tags:

Medigen Biotechnology Corp.

Medigen was created in 1999 and is a listed company. How did the vision for the company come about, and what was it that attracted todayâ??s main shareholders to Medigen?

Medigen was registered at the MOEA in 1999, but the company was actually established in 2000. In the beginning, the founders shared a single vision â?? to help patients. In my past as a medical practitioner, I had found that some diseases are currently totally untreatable. We need new therapeutics for these particular diseases.

In Taiwan, major difficulties are caused by the problem of liver cancer. In Western countries, liver cancer will rank outside the top ten causes of death for cancer, but in this country over the past 20 years it has ranked number one. It was not until the last 2-3 years when lung cancer became the number one cause of death for cancer. The reason for such high levels of liver cancer in Taiwan was hepatitis B. This was why twenty years ago the country started vaccinating against the disease: by immunizing children the carrier rate was reduced from 15% to less than 1%. Because of this achievement, the review paper on all the national data was published in the New England Journal of Medicine ten years ago. After that, most Western countries followed the steps that Taiwan took, recommending vaccinations for Hepatitis B: it has been proven to reduce the instances of Hepatitis B infection, and liver cancer in the long run. 95-99% of patients with a Hepatitis B infection eventually become immune to the virus, but the remaining 1-5% continue to suffer from the infection into chronic phases, eventually leading to cirrhosis of the liver. From this group, one out of twenty will have liver cancer by the age of forty.

In the year 2000, Medigen found that there was still no treatment for liver cancer. Although there were lots of drugs that could be used for treating different kinds of cancer, they could not be used for treating the liver, as the liver is the organ for metabolism. My aim at the time was to help those people if possible. We had a chance to talk to a public company in Australia called Progen. We discussed whether they had a viable project for the treatment of liver cancer, and expressed an interest in working together. We eventually signed a collaboration agreement. Progen specialise in treatments for cancer of Western significance. Medigen was centred on cancers of Asian importance, which begins with liver cancer. That was the vision: to help the patient, treat liver cancer, and get a good return on investment for our shareholders.

We started the collaboration, and our partner in Australia continued working on clinical trials on cancers of Western importance. Medigen looked only at one single indication: liver cancer. In most drug development, if you want to have combination then you need a very large number of samples, because any new drug being tested will have to work alongside existing therapies. But no treatment

is the rule for post-reception of liver cancer. So we were able to trial PI-88, our drug, as a monotherapy. You can have very clear data between two groups: one is control (without treatment) and the other one is with PI-88.

We donâ??t want to play small games. We donâ??t just look at 20-30 patients to see the proof of concept. We want to have comparative studies, so our phase II design at the time was up to 340 patients. We compared two groups, and the result was very successful. The reduction of recurrence at the end of one year improved by 50% and the time to recurrence was extended by 78% between the two groups.

In 2005, Medigen had an end of phase II meeting with the US FDA. Groups of scientists from Taiwan, Australia and from Progenâ??s CRO in the US met the FDA, who reviewed the data from six medical centres in Taiwan. This was a first in Taiwanese history. In the past, Taiwanâ??s clinical data was always part of a global trial: never used singly, but as a package. What was even more exciting was that after reviewing the data, the FDA suggested to us that there was no need to finish the whole of the Phase II trial: that we could stop right away, and start a phase III study based on the data, and invited our partner Progen to go through a SPA (Special Protocol Assessment) and to have one single phase III trial for accelerated approval. It was at this point that Medigen and Progen parted ways: Medigen sold its license for PI-88 back to Progen.

Biotech has very long cooking times. Medigen has offset the long investment period for new drug development with a profitable manufacturing business that is helping you to create revenues on a yearly basis. To what extent is that unique within Taiwan? How is the business growing today?

The capital that the company received from Progen allowed Medigen the opportunity to invest in a way that would change the company strategy and allow for constant revenue creation, whilst keeping the companyâ??s main focus on developing new drugs. We needed another business entity to secure constant revenues and support for the company. This is a must for most biotech companies in Taiwan. After some six months of internal strategic thinking, discussing and debating, we decided to go into the NAT (Nucleic Acid Testing) market in China. NAT was new at the time, and for the last five years the segment has experienced double digit growth. We knew that Roche held most of the key patents, and the only large country in the world escaping that kind of IP protection was China. At the time, for Medigen to go from a drug development company to manufacturing or research oriented projects in nucleic acid testing was something very novel, so we needed to acquire the technology. We acquired a company in Texas called Texas Biogen. This company was working on HLA (Human Leukocyte Antigen) and already sold their products in China. The beauty was that this company had all the background research capability for the development of NAT.

Our main market now is pathogen detection with NAT. If you want to release a pack of blood from the blood bank, it has to be very carefully checked for HIV, HBV or HCV. Most Western countries have already shifted their examination kits from Elisa into NAT. The difference is that Elisa checked the antibody of the pathogen, whereas NAT checks the pathogen DNA directly, closing the window of opportunity for a virus to squeeze through unnoticed. This shift has not yet happened in China.

Medigen also integrated some of the research capability from Hepatitis B in Taiwan, and by doing so added another valuable element to this project. We also brought something to China that Taiwan is renowned for: precision machinery. For the blood bank business, you need automation. China is not able to do that. Roche have the capability to develop kits for NAT detection, but they outsource the manufacturing technology. In Taiwan, we have all the strengths and capabilities to combine the two.

The beauty of our China project was this level of international integration: technology from the US, research capability and precision machinery from Taiwan. This was presented to China, and the

Chinese government has now decided to open up the blood bank market. It is a huge market. Medigen is now one of the key players in China along with Roche and Novartis.

Your new drug development has so far all been done in collaboration with other companies. What strengths do you bring to these partnerships?

From the very beginning, Medigen has focused on clinical development, from Phase I or 1 year before IND to all the way to the end of Phase II. We donâ??t work like a CRO: the company owns the right of the project, and we add value. That is the scheme of collaboration and the reason why we need to find partners to inlicense a project or work together on a project to bring it from IND to the end of Phase II.

Our first collaboration was with Progen. The second was with a Japanese biotech company called Oncolys. We worked on a treatment for oncolytic virus, again for the treatment of liver cancer. Our partner in Japan wanted to focus on the treatment for head and neck cancer and also gastric cancer. Again, we put most of our strengths into a project for liver cancer.

You may question why so many liver therapeutics are needed. The reason is very simple. Liver cancer is a disease, but with different stages. For the early stages, you need one particular treatment. This changes in the middle and late stages of the disease. Medigenâ??s goal in terms of new drug development is to defeat liver cancer in the foreseeable future. We want to make Medigen a leading liver-focused specialty Pharma in the world. As long as we can beat liver cancer, we stand a chance of becoming one of the worldâ??s big pharma players, because liver cancer is one of the most important cancers in Asia, and China in particular. With the booming economy in China, I can see that in ten years from now, most of China will be able to afford to receive this kind of medication.

That is the reason that we do not work on discovery projects, but try to inlicense projects from outside. In the past we focused mostly on western biotech or western university-related projects. But as trend is moving to Asia Pacific and Taiwan has built-up momentum in biotech, we are starting to seek good projects from the research institutes in this country. I just set one simple criterion: we will only look at projects that are around 12 months away from IND. Anyone who wants to present their projects will be welcomingly received, but they must be sure that their project has reached this stage, so that Medigen can carry it efficiently into the clinical phase.

Do you have a final message to send to our readers about Medigen?

Medigen has very clear aims and a very clear vision: liver cancer. Itâ??s our plan. If we can succeed in defeating liver cancer, in the future we will expand our pipeline into oncology and liver diseases. That is a very conservative expansion, step by step. We donâ??t want to jump until we have a good story and have accumulated enough resources. We will focus then on other cancers of Asian significance, such as cervical cancer or gastric cancer.

See more interviews