Interview: Frank Douglas â?? CEO, TheVax Genetics, Taiwan

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Frank Douglas, CEO of the TheVax, discusses what he finds so inspiring about innovation in resource-constrained environments, and this Taiwanese biotechâ??s revolutionary SIT specific immunotherapy platform

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The company was founded in 2012 with the mission to focus on the use of immunotherapy to address virus-induced tumors and infections in patients. Could you explain how the company was founded and how you became CEO of the TheVax Genetics Vaccine USA?

While I was a Professor of Practice at MIT, I was visited by Chairman Chang â?? the founder of the company â?? and some of his scientists. We discussed the concept focusing on developing a drug to treat HIV and all difficult diseases. While I became interested in the concept, I learned they owned a veterinary company. Therefore, I encouraged them to test the vaccine concept on a viral veterinary disease before further discussing treatment of human diseases. The veterinary vaccine was successful and the concept was demonstrated; it is now a product, PPRSFREE for the treatment of a significant porcine viral disease. Chairman Chang invited me to become a Scientific Advisor to his main company â?? Healthbanks â?? and we started preparing for filling an IND. In 2010, I was asked to establish an institute in Akron, Ohio, so this temporarily took me away from the effort at Healthbanks. In 2015, as my assignment in Akron was completed, Chairman Chang invited me to join the Board of Directors of TheVax Genetics Vaccine Ltd., which he had founded in 2012. My main responsibility was R&D sector and setting up a branch in the US â?? I am currently CEO of the US branch and am leading the clinical development of the Phase IIa study of our therapeutic vaccine

for the treatment of HPV induced cervical precancerous lesions.

You have been Chief Scientific Advisor of Bayer and member of the Board of Management of Aventis SA (2002- 2004). What challenge motivated you to embark on this new adventure and join this emerging company?

I was on the Board of Directors of a number of biotech companies and grew to appreciate the innovation in these smaller companies. Thus my love for innovation in resource constrained environments drew me to this project. Above all, the Specific Immunological Therapeutic (SIT) approach represents a technology platform with potential for application in several diseases. Coupled with this was my admiration for the entrepreneurship of Mr Chang, the owner, whose commitment to science led him to support the work of a number of scientists in Taiwanese Universities, with the optimism that some of their results would lead to therapeutic solutions for patients. The SIT platform was also congruent with my interest and involvement in personalized medicine. Immunotherapy is the advancing frontier of molecular medicine. In conclusion, a cutting edge technology platform combined with the vision and commitment of Mr. Chang were compelling. I felt the presence of a great and promising technology platform, supported by a leader who was trying to foster science to improve the life of patients.

At the core of the TheVax is its upgraded patented specific immunotherapy technology (SIT) platform. What sets apart this technology platform and makes you confident it can deliver safe and effective products in such a challenging and competitive field as immunotherapies?

Simplicity is the core of this platform that produces therapeutic proteins which consist of three components. I like to think of first component as the vector- the carrier- that will carry the antigen to the antigen presenting cell (APC) and facilitate endocytosis by the APC. The second component is the selected antigen from the virus or tumor, which when processed by the APC will be attached to MHC 1 molecules to be presented on the surface to attract cytotoxic T cells. The final component is a terminal four amino acid peptide which enables further processing of the therapeutic protein prior to presentation on the APC surface.

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The simplicity of this platform also contributes to its flexibility. We can indeed seek to optimize the efficiency of the attraction to the antigen as well as the efficiency of the processing of the antigen once itâ??s released into the cytoplasm. This kind of flexibility allows more opportunities to optimize the innovation. The approach also allows for simple monitoring of the patient. The mechanism of action relies on stimulation of cytotoxic T cells for which there is a well- established assay. Thus one first demonstrates that the vaccine stimulates production of cytotoxic T cells, and secondly, one assesses whether this is associated with a significant clinical benefit. This area of drug discovery is complex and difficult. Therefore, we start by asking simple questions to find an efficient way of drug discovery.

Why did you focus on cervical HPV induced intraepithelial neoplasia?

I use simple and practical approaches when thinking about the desired therapeutic area: testable concepts and readout. HPV has attracted attention- vaccination of young people between ages 13 and 25 is now widely accepted as we recognize that 90% of cervical cancer is due to HPV infection. Unfortunately, there is presently a large number of individuals who did not receive the preventive vaccine and already have pathological changes in the cervix and/or anus. There are surgical approaches to remove precancerous areas of the cervix, however, surgery does provide some risks to women who become pregnant thereafter. A medical alternative, particularly for women of child-bearing potential is needed and our therapeutic vaccine might provide such an opportunity.

When do you expect to complete phase II?

Recruitment for our phase II has been more challenging than anticipated. We are presently introducing a number of approaches to accelerate enrollment and soon will update our projection for end of enrollment.

Letâ??s talk about new indications. Cervical HPV is the first step. Do you have any plans to start a clinical development of drugs in other indications?

Currently, we are in pre-clinical phase in a number of other indications. We have exciting pre-clinical data on hepatitis B, or HBV. The animal data is showing exciting results. Our present focus is on developing reliable production scale of the vaccine for treatment of HBV. A second focus is on invasive cervical cancer- itâ??s more difficult because it requires being done in combination with other therapeutic approaches.

You already have a product that is in Phase II. As the next Phase III is global and requires resources, are you looking for partners? What is your partnership strategy?

We have started some of the negotiations; depending on therapeutic area, partnerships are different. However, in the area of cancer, companies tend to partner after the Phase II results are available. We are looking forward to completing phase II and finding partners. As a small biotech, it is impossible to do Phase 111 alone.

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In terms of drug development, do you have financial resources to start all trials before licensing out the compound in cervical HPV?

Phase IIB will most probably be initiated by ourselves. However, we believe we will find a partner by then.

Our strategy is to focus on completing phase IIA. Afterwards, we will start looking for a partner.. Additionally, we will consider an IPO after earning a solid income.

There are not a lot of international CEOs based in Taiwan. What were your thoughts and assessments on the local industry when you first came to Taiwan?

Many of the biotech companies are founded by Taiwanese people who have worked in the US or Europe. These individuals have an extensive knowledge of the western system that is currently being applied to the Taiwanese market. From an operations perspective, Taiwan is the market where individuals understand the importance of processes and details in the regulatory environment. Secondly, talent pool in Taiwan is impressive. Efficient and successful drug discovery requires hard working and smart people- both of which are present in Taiwan. An unusual opportunity in Taiwan lies in formation of academic-biopharmaceutical industry collaborations to address difficult challenges in drug discovery and development. The collaboration in Taiwan is easier due to small size of the country where everyone is familiar with each other. In conclusion, I believe Taiwan has the opportunity to create real expertise in solving problems that require collaboration of multidisciplinary teams and that will be recognized worldwide.

Where are we going to find TheVax when we come back to Taiwan in five years?

We expect to have major collaborations by then. We will develop our HPV and second generation bivalent vaccine. Further on, our focus and main priority will be developing hepatitis B vaccine.

What do you want our readers to think when they hear the name of the TheVax Genetics Vaccines USA?

An innovative company using its SIT specific immunotherapy platform in order to improve the life and wellbeing of patients.

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