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Immuno Cure has a unique approach to the failure-ridden field of HIV vaccine development: focusing on a therapeutic vaccine for already infected individuals rather than a preventive vaccine. Founders Tom Lau and Dr Xia Jin explain the companyâ??s origins as a spin-off from the University of Hong Kongâ??s AIDS Institute in 2015; how its leadership team brings extensive experience in corporate finance and scientific research, particularly in HIV and vaccine development; and how the company is leveraging resources across the Guangdongâ??Hong Kongâ??Macao Greater Bay Area for clinical trials and manufacturing. With Immuno Cureâ??s DNA-based vaccine showing promising results in preclinical and Phase 1 trials, Lau and Jin outline their plans to proceed to Phase 2 and to potentially partner up with Big Pharma in the coming years.

How did Immuno Cure come into existence, and what are the backgrounds and roles of its co-founders?

Tom Lau: Immuno Cure began as a spin-off from the University of Hong Kong (HKU) in 2015, specifically from the AIDS Institute of HKU. This institute was founded in 2007 by Professor Chen Zhiwei, a senior researcher trained under Dr David Ho. DrHo is a highly respected figure globally in the HIV research community, known for inventing the cocktail therapy that drastically reduced AIDS-related mortality and morbidity in the mid-1990s.

My background spans over 40 years in multinational corporate development, finance, and management across various sectors, including infrastructure, resource development, construction, and engineering services. I have been instrumental in steering Immuno Cureâ??s growth by leveraging my extensive experience in corporate finance and project management. Our company focuses on developing innovative DNA vaccines and antibodies, utilizing our patented PD-1-Enhanced DNA Vaccine and Anti-Î?42PD1 Antibody platforms. These platforms are designed to combat infectious diseases, such as HIV, and various cancers.

Initially, our operations were conducted in Professor Chenâ??s lab at the AIDS Institute at HKU. As our research and development efforts expanded, we recognized the need for additional expertise, which led to Dr Xia Jin joining our team.

Dr Xia Jin: Before joining Immuno Cure, I held several prominent positions, including Chief Scientific Officer and Vice Geneaal Manager at a public company (688863) Shanghai Serum Bio-Technology Co., Ltd. in Shanghai. My academic journey began with obtaining a Medical Doctor degree from Peking Union Medical College, followed by a PhD in Life and Biomolecular Sciences from Open University under the mentorship of Professor Sir Patrick Sissons of Cambridge University.

My postdoctoral training was conducted under Dr Richard A. Koup and Dr David Ho at the Aaron Diamond AIDS Research Center in New York. I started running my own lab after postdoctoral training at Rochester University, New York, initially as a tenure-track assistant professor, and then as an associate professor. During my time in the United States, I served as Principal Investigator or Co-investigator on numerous research grants from the National Institutes of Health (NIH) and the Bill & Melinda Gates Foundation. I also participated in several NIH study sections and served as an international expert reviewer for research agencies in the Netherlands, Hong Kong, Taiwan, and Singapore.

My roles have included Professor and Principal Investigator at the Shanghai Public Health Clinical Center, Director of the Vaccine and Immunology Research Center at Fudan University, Distinguished Professor at the Chinese Academy of Sciences, and Principal Investigator and Executive Director of the Vaccine Center at the Institut Pasteur of Shanghai. My research has focused on HIV and dengue virus immunology and vaccine development, resulting in over 140 published scientific papers in journals such as Science, Journal of Experimental Medicine, Journal of Clinical Investigation, and Journal of Virology.

When Tom approached me about joining Immuno Cure, I was deeply impressed by the companyâ??s innovative technology and the potential impact of our research on global health. Over several months of discussions, Tom shared his vision for Immuno Cure, which resonated with my passion for translational research. Our combined expertise in HIV vaccine trials and translational research, along with our shared history with Professor Chen, who has been a close friend and collaborator for many years, laid a strong foundation for our partnership. Together, we aim to develop world-class therapies to address critical health challenges, focusing particularly on HIV and cancer vaccines. Our work at Immuno Cure is driven by a commitment to advancing scientific innovation and improving health outcomes worldwide.

How do you remain optimistic about developing a successful HIV vaccine, given the high level of resources already spent on this cause, as yet without result?

Dr Xia Jin: Having been in the field for a long time, I understand why previous attempts at creating a preventive HIV vaccine have failed. The complexity of the virus and its ability to mutate have been significant obstacles. Most efforts, including those by prominent institutions like the NIH and its

supported organization the HIV Vaccine Trials Network (HVTN), have focused on preventive vaccines for which the design is challenging and the mechanisms for protection are not entirely understood. However, our approach at Immuno Cure is different. Supported by Professor Chen and Tom, our research has concentrated on a therapeutic vaccine designed to treat already infected patients who are stable under antiviral therapy but not cured. These patients still risk transmitting the virus, so there is a pressing need for a cure.

Professor Chen has dedicated over a decade to researching this area, publishing numerous papers that highlight the unique properties of our DNA-based vaccine in animal models and generating some of the most exciting data known to exist in the field. Encouraged by the exceptional preclinical results, we performed a large therapeutic phase I clinical trial with 45 subjects, divided into three dosing groups (low, middle, and high), along with placebo controls. The results have been promising, replicating many findings from our animal studies, where vaccinated monkeys have shown prolonged protection against the virus for up to eight yearsâ??results unprecedented in the field over the past 40 years.

Our clinical trials have been conducted at the Shenzhen Third Peopleâ??s Hospital, a leading tertiary hospital and medical center with the largest outpatient follow-up for HIV patients in China, handling around 15,000 HIV/AIDS patients annually. Our phase one trials, approved by the National Medical Products Administration (NMPA) of China, followed stringent regulatory standards. The review process was completed efficiently within 60 working days. Our next step is to proceed with efficacy trials in phase II, aiming to replicate the remarkable results seen in our monkey studies. If successful, we believe we can develop a functional-cure HIV vaccine, offering a breakthrough solution to this global health challenge.

How did the review process for your clinical trials go, and what were the preliminary endpoints you were looking for in Phase 1?

Dr Xia Jin: The review process by the Chinese National Medical Products Administration (NMPA) was incredibly smooth and efficient. Iâ??ve reviewed many clinical trials and papers in my career, and our protocol was reviewed without any delays or issues, which is commendable. In Phase 1 of our trial, we aimed to evaluate the safety and immunogenicity of our vaccine across different dosages. We looked at the immune response, particularly the T-cell response, and sought to determine the maximum tolerable dose. Impressively, participants receiving the middle and high doses showed nearly 100% positive immune responses, with the vaccine demonstrating a strong and specific immune activation. This response was not just of high magnitude but multi-functional, which is crucial for its effectiveness.

Our vaccine uses a mosaic sequence, allowing it to cover the entire Chinese population effectively. With low doses, we saw a response rate of 60-80%, and with higher doses, the response rate reached 100%. This level of responsiveness is highly encouraging.

Moving forward to Phase 2, we plan to conduct a multi-center study in China, involving 200 to 300 participants across six to eight major clinical centers. We have already engaged with chief physicians at these centers, who are very enthusiastic about participating.

What are the specific benefits of conducting Phase 2 trials in China, and have you considered other regions for future trials, neighbouring countries like Australia offer good tax breaks for R&Dâ?¦

Dr Xia Jin: Conducting Phase 2 trials in China provides significant advantages in terms of cost and logistical control. The regulatory environment here is supportive, and we can manage the trials more effectively. While we are open to expanding our trials internationally in the future, including regions like Australia, our current focus is on leveraging the robust infrastructure and expertise available in China.

Additionally, the prevalence of HIV in Asia is increasing, making it a critical region for our research. We have had discussions with leading physicians in Australia, and there is interest in collaborating on future studies, especially for cancer vaccines. However, as a small biotech company, we must carefully allocate our resources, often taking a staggered approach to our projects. The financial and logistical benefits of conducting our current trials in China outweigh those of moving them abroad at this stage.

Tom Lau: Although there are attractive financial incentives for conducting R&D in places like Australia, including tax breaks, Hong Kong also offers favourable conditions. We receive substantial support here, with 300% of our R&D expenditure being tax-deductible. In addition, the Government is extremely generous with their funding for R&D here in Hong Kong; and in particular, those programs supporting innovation and technology under the Innovation and Technology Fund of the Innovation, Technology and Industry Bureau. To name a few, in collaboration with HKU AIDS Institute, we have recently secured significant funding as to HK$100 million under the RAISe+ Scheme of ITF and HK$67 million under the TRS Scheme of the Research Grant Co uncil[for our anti-Î?42PDI antibody for liver cancer and therapeutic vaccine for HIV respectively]. This support is crucial for a biotech company like ours.

Our strategy is to maximize the benefits of our local environment while staying open to international collaborations as we grow. The decision to keep our Phase 2 trial in China is based on a combination of cost efficiency and the ability to closely monitor the trial processes, ensuring the highest quality and reliability of our results.

Our Phase 2 trials for the HIV vaccine are designed to take 2 to 3 years. Unlike preventive vaccines, therapeutic vaccines like ours can be designated as a breakthrough therapy for usage before completing Phase 3, offering a faster path to market. Given the innovative nature of our vaccine, we are optimistic about its potential as a breakthrough therapy. The medical community in China is highly enthusiastic about our work. [Official reports estimate the HIV-infected population in China to be under a million, but unofficial figures suggest it could be two to three million. Accurate data is challenging to obtain, but the need for effective treatments is undeniable.] Our careful approach to development, leveraging both local and outsourced resources, positions us well for future success.

What makes Immuno Cureâ??s vaccine platform unique, and under which business model do you plan to extend its application to other therapeutics?

Dr Xia Jin: Our DNA vaccine platform is unique in its targeting signal design, and it is quite versatile and can be adapted to various targets beyond HIV. For example, we developed a COVID-19 vaccine using this platform and tested it in two clinical studies to demonstrate its safety and immunogenicity. Although the COVID-19 vaccine was more of a proof of concept, our primary focus is on the HIV-1 vaccine. Our platform includes a unique leader sequence that significantly enhances the delivery of the vaccine antigen in dendritic cells, resulting in a stronger immune response. This technology can also be applied to cancer vaccines, and we have several cancer vaccine candidates in our pipeline that have shown promising results in animal models.

Tom Lau: Our business model leverages our research capabilities in Hong Kong while outsourcing manufacturing and clinical trial operations to Contract Research Organizations (CROs), Contract Development and Manufacturing Organizations (CDMOs), and Contract Manufacturing Organizations (CMOs). This approach is necessary because Hong Kong lacks the necessary infrastructure and regulatory framework to support these services. As a result, we focus our market efforts on mainland China, working closely with the National Medical Products Administration (NMPA).

To be financially efficient, our strategy is to prove our concepts within China and then look to out-license our technology in other territories. This allows us to maximize our impact and manage costs effectively. By focusing on the mainland, we can leverage the extensive network and resources available there, ensuring the highest standards of research and development while preparing for eventual commercialization.

How have financial resources and market conditions influenced Immuno Cureâ??s development strategy and future plans?

Tom Lau: We strategically avoided the peak investment rush in 2021, especially concerning COVID-19 vaccines. Many companies invested heavily and are now seeing more commercialisation burden than success, with only a few winners globally. Our prudent financial plan meant we didnâ??t chase the spike, which turned out to be a blessing in disguise. This allowed us to stay focused on our core product, the HIV vaccine, which remains our primary value driver.

Although we have promising candidates in our vaccine platform, developing them requires substantial financial resources. Raising funds has been challenging due to increased competition and a more sluggish capital market, but we remain confident in our mission. Our strategy involves careful resource management and pacing our development according to available funds. While weâ??d like to accelerate our progress, we recognize the need to operate within our means.

What is your partnering/licensing strategy, and how has your work been received by scientific peers and the industry?

Dr Xia Jin: We have not aggressively pursued partnerships yet because we believe the timing should be right. We plan to start these discussions after we complete Phase 1 of our trials, which will provide us with solid, concrete data for evaluation. This milestone is expected by August this year. At that point, we will be more vocal and aggressive in seeking partnerships. While we are open to others spreading the good news about our progress, we understand that many HIV-focused companies do not have vaccines, and vaccine companies may not have an HIV portfolio. Despite this, we remain optimistic about finding suitable partners.

Our work has been well-received by scientific peers, and we are encouraged by the interest shown by the medical community. We have a strong team of 50 people, with two-thirds based in Hong Kong primarily focused on research and development. Additionally, we have offices in Shenzhen, Shanghai, and Beijing to support various aspects of our operations. In Shenzhen, our team manages clinical trials conducted on the mainland.

In Shanghai, we maintain a medical device necessary for the delivery of our DNA vaccine. This device, known as an electroporation device, enhances vaccine immunogenicity by briefly exciting cells to allow the vaccine to enter before the cell pores close again. This technology is crucial for the

efficient delivery of our vaccine and is the only electroporation device registered in China, with only two similar devices registered in the US. This strategic positioning allows us to efficiently manage our resources and prepare for commercialization.

Our standard regimen involves five injections, administered at 0, 4, 8, and 12 weeks, with a final dose at the 36th week. This intensive initial dosing schedule is designed to ensure maximum efficacy and is based on pre-clinical studies, which have shown it to provide a robust and long-lasting immune response. If successful, this approach could significantly improve treatment convenience and effectiveness for patients. Despite the challenging market conditions and competition for financial resources, we remain committed to advancing our innovative therapies and are optimistic about our future prospects. We believe that with the completion of Phase 1, we will be in a stronger position to attract strategic partners and investors who share our vision.

How has Immuno Cure leveraged the resources of the Greater Bay Area (GBA), and what has been your experience with the level of clinicians and regulatory alignment in this region?

Tom Lau: We have been very successful in utilizing the resources of the Greater Bay Area. Our clinical trials are being conducted in Shenzhen, and our products are manufactured in Guangzhou, both within the GBA. This region offers excellent infrastructure and resources, which we are fully taking advantage of. While Hong Kong is a newcomer in the biotech field, we are very encouraged by the growth and support we are receiving. The Hong Kong government is highly committed to pushing innovations and technologies, which is very positive for our development. We believe that Hong Kong can grow at a faster pace within the GBA, benefiting from its unique position and support.

Dr Xia Jin: Our experience with the clinicians in the GBA has been very positive. We are working with first-class clinicians who were among the first to treat AIDS patients in China with antiviral drugs. These physicians have been trained by experts, including my mentor Dr David Ho, on how to use anti-HIV drugs. They are highly experienced and have a deep understanding of clinical research, which is crucial for their professional growth and promotion within the Chinese medical system. These clinicians are not only skilled but also highly motivated, making them leaders in their field. This has greatly benefited our clinical trials and overall research efforts in the region.

What message would you like to convey to potential partners and major pharmaceutical companies about Immuno Cureâ??s progress and potential?

Dr Xia Jin: For large pharmaceutical companies that have vaccine platforms but lack actual vaccines, we believe our vaccine can fill that gap. Those without a vaccine platform might find it more challenging to see the fit, but we are confident in the unique value our technology brings.

Tom Lau: If weâ??re not on their radar, they should definitely start paying attention to us. While we havenâ??t aggressively reached out to potential partners yet, itâ??s not due to a lack of confidence. We want to ensure we have strong data from our Phase 1 trial before we start discussions. This approach ensures we do not undervalue our work. Weâ??re confident in our therapeutic vaccine and believe that once we present robust Phase 1 trial data, our value will be clearer, making Phase 2 trial an even more compelling stage for collaboration. Our strategy includes leveraging the development efficiencies in China, which will allow us to advance more effectively. We invite everyone to stay tuned for our data, which we believe will demonstrate the significant potential of our innovations.

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