CJ Wang – CEO, Frontier Biotech, China



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Dr CJ Wang, CEO of Frontier Biotech, shares his exciting ten-year journey with Frontier and their distinctive focus on HIV drug development, with their flagship compound, Aikening®, launched in China in 2018; their ongoing efforts to develop more novel therapeutics; their ambitious internationalization strategy to bring their therapies to patients globally; and their imminent plans to IPO!

CJ, Frontier Biotech is one of the few exceptional Chinese biotechs to have developed and marketed a novel drug! Could you start by sharing the story of how Frontier was established?

The story of Frontier Biotech was founded on the serious unmet medical needs in HIV. This sets us apart from the majority of Chinese biotechs that focus on cancer. In Chinese, we have a saying ‘□□□□□□□ ’ – translated in English, it’s ‘thousands of troops crossing a solitary wooden bridge’, which means significant resources being invested on a single challenging and competitive path. We want to become a fully integrated research-based biopharma with global competitiveness.

We are one of the very few Chinese biotechs to have completed the difficult journey from molecule to market. Frontier was first established in Chongqing in 2002 by Dr. Dong XIE, an expert in HIV drug development. Our flagship drug, albuvirtide or Aikening® was initially discovered by him, and

he took it to IND stage in 2008. Back in the 2000s, pharma companies were focused on developing oral drugs for HIV because the prevailing commonsense then was that patients would prefer to take a pill instead of an injectable. However, Dr. Xie saw the potential in developing a long-acting injectable HIV drug that could meet the needs of HIV patients. Today pharma companies have realized the benefits of long-acting injectables for HIV/AIDS, but in 2002, Dr. Xie and Frontier were at the vanguard of this change.

I came on board in January 2009 and our third cofounder, Dr. Rongjian (RJ) LU, joined in October 2009. Together, we took the drug all the way from Phase I to approval. In 2013, we moved the company to Nanjing because of the great ecosystem here and now we operate in Beijing, Chengdu and Shandong as well.

We are very proud that our flagship drug, Aikening®, the first innovative HIV drug developed by a Chinese company, was approved on 23 May 2018 by the Chinese regulator, the National Medical Products Administration (NMPA), and has been on the market since 2 September 2018. We were honored that the China Pharmaceutical Innovation Research and Development Association (PhIRDA) Executive President Dr. Song Ruilin attended our product launch event.

Aikening® is the first long-acting HIV fusion inhibitor, effective against most HIV-1 strains including drug-resistant strains, administered by intravenous infusion on a weekly basis. It is a peptide drug with a good safety profile and no predictable drug-drug interactions.

As an industry veteran yourself with extensive US experience, what made you decide Frontier was the right company for you?

I am a scientist by training and started my pharma industry career in 1990, but I made the transition from R&D to marketing and business development in 1996. For over a decade, I worked for five biotech/pharma companies in the US working on marketing and product management, licensing and M&A. As a BD executive I had completed several significant deals including the divesture of Evamist® by Vivus in 2007 and Merck’s (MSD’s) acquisition of Abmaxis in 2006. After that, I wanted to do something different and coincidentally, around that time, Dr. Xie reached out to me through a mutual friend. I still remember our first meeting, on a snowy December evening in 2008 at Washington Dulles International Airport, where he pitched me Frontier. I realized that HIV was an extremely meaningful area to work in, and it was very positive that the compound had already received IND approval. From my prior experience, I thought that the ‘druggability’ of this compound was pretty high so even though it was a risky endeavor, we stood a good chance of

success. All these reasons motivated me to join Frontier Biotech in January 2009.

HIV is a disease that carries a lot of stigma. Could you briefly outline the unmet medical needs in this area within China?

Whether you look at it from a socioeconomic or personal perspective, HIV is a hugely significant therapeutic area with highly unmet medical needs. Globally, nearly 40 million people live with HIV and the number is still growing. In China, the official numbers are ~1.25 million but the true figure could be higher. Each year, around 100,000 new HIV cases are discovered in China, and in 2018 the figure was actually closer to 150,000. It is obvious that the awareness of and attention to this area needs to be raised significantly.

A major challenge is the perception of HIV as a “poor person’s disease” or associated with drug use or unsafe needle practices. In China, 20 years ago, HIV was highly associated with certain predominantly rural populations with unsafe needle practices, such as drug users or those that sold blood for money. However, today nearly 95 percent of HIV transmission occurs through sex. Current estimates place the gay community in China at ~30 million with the positive HIV rate estimated at ~8 percent. What is even more alarming is that nearly half of newly discovered infections are late-stage patients with comorbidities that need to be hospitalized to receive treatment for HIV/AIDS as well as other bacterial/fungal infections.

The Chinese government offers a free drug program that benefits around 700,000 people today. In addition, eight HIV drugs are on the National Reimbursement Drug List (NRDL) and another ~10 percent of patients are covered by the private sector. However, given the current situation, more still needs to be done to address this issue in China. The United Nations has established a 90-90-90 goal for HIV: 90 percent diagnosed, 90 percent of that on treatment, and 90 percent of *that* with successfully controlled viral loads. The world and China are still far from meeting that goal.

In particular, patients with serious conditions (e.g. comorbidities, drug resistance, surgery, impaired kidney and liver functions, etc.) need fast-acting, efficacious and very safe injectables – like Aikening®. In many markets, particularly developing countries including China, this particular group of HIV patients has significant unmet medical needs.

In addition, our drug is believed to be quite suitable for post-exposure prophylaxis (PEP). In terms of mechanism of action, speed of onset and weekly injection Aikening® would be beneficial for at-risk populations.

With Aikening® having been on the market for over a year now, how are the commercial results?

We are proud that Aikening® has been accepted and welcome by the doctors and patients, and is saving lives! Within two months of product launch, Aikening® was added into the Chinese HIV Treatment Guidelines.

Since it is the first long-acting injectable HIV drug on the China market, we are working within a virgin market. We have built a professional marketing and sales team to provide medical education and training to physicians. We need to explain the benefits of our novel drug very well. What has helped is that HIV is a specialty field covered by a relatively small number of hospitals in China. At the moment, our team covers around 40 hospitals in ~30 cities and the coverage is growing quickly. We plan to cover >80 percent of all HIV hospitals in China. We are also in the process of having our product listed on the National Reimbursement Drug List (NRDL). All of these will continue to drive our commercial performance.

Besides Aikening®, what other innovative projects are you working on?

Our second project is a combination therapy with Aikening® and 3BNC117, which we licensed from Rockefeller University in New York. This will be an all-injectable, long-acting combination therapy offering a complete solution with a new mechanism of action. Both drugs are complementary and have synergy, which was why we decided to license 3BNC117. Before we licensed it in, 3BNC117 had already gone through several Phase I and II trials. What caught our eyes was that this antibody was able not only to suppress the viral load/virus but also to elicit an immune response resulting in significantly delay the viral rebound time. This opened a door to HIV immunotherapy, which could ultimately achieve the goal of developing a functional cure.

Being able to offer a combo solution was important. Looking at the success of Gilead, for instance, their HIV franchise really took off after they developed their fixed-dose combination pill, relieving the burden of taking three different pills a day for patients.

We will explore four indications: multidrug-resistant HIV strains, maintenance therapy, immunotherapy and prevention. Immunotherapy is very hot in oncology but with HIV, it is still in its infancy. Effectively, we are exploring the potential of our combo as a functional cure to allow patients to stop taking HIV drugs for a certain period of time. That would change the current

treatment paradigm – and we are pioneering this approach.

Our US Phase II trial of the combo drug is ongoing and we have our IND approved to conduct a Phase II trial for immunotherapy in China by the NMPA. We have also established a strategic collaboration with ThermoFisher Scientific, who will manufacture 3BNC117 at its St. Louis site in the US.

In addition to that, we also have an exciting product in a different area: pain. We are not just a HIV company and we plan to move into new therapeutic areas when the time is right. AB001 is a novel topical pain patch for musculoskeletal pain that I invented. Pain represents a huge market opportunity and topical pain patches offer a superior safety profile compared to that of oral painkillers. We have designed and successfully completed a double-blinded, randomized and placebo-controlled Phase II trial in nine clinical centers in the US for chronic low-back pain and met statistically significant clinical endpoints. Pain clinical trials are difficult due to the existence of a strong placebo effect and the subjectivity of pain, so we have made great progress. We recently concluded a Phase I trial in China to collect safety and PK data in Chinese population, and hope to move directly into Phase III trials in China.

With such exciting and innovative products, what are your plans for commercializing these products in international markets?

Our team’s dream has always been to build an international biopharma company. Having successfully taken our first product to market in China, we are now looking to increase our manufacturing capacity and advance our commercial strategy both domestically and internationally.

For Aikening®, we are already working on entering developing markets where this drug could be highly beneficial to seriously ill patients. Our strategy is to work with leading local and regional pharma companies with experience in commercializing HIV drugs through co-marketing and supply agreements, or similar collaboration models. We have already signed such agreements in over ten countries across Southeast Asia, Africa and South America, and we plan to market the drug in at least 60 countries in the near future. For certain emerging markets, if the size is significant enough, we are also open to licensing deals.

Our combo therapy is first aimed at developed markets such as the US and EU, and that is why we started a Phase II trial in the US first. Of course we will also develop it for China and developing

markets.

For the pain patch, the plan is to develop and commercialize it in China first.

Frontier Biotech has achieved significant results over the past decade. What can we expect from Frontier in the next few years?

We will continue to execute our commercial strategy for Aikening® as well as advance on our clinical development programs as mentioned. We will also enrich our pipeline through internal R&D efforts as well as external deals. We want to bring in a couple more assets within the next year or two.

As a growing biotech, we are also recruiting. We have around 300 employees at the moment and the number is growing quickly. One of the main success factors and differentiators of Frontier Biotech has been the stability and expertise of our senior management team. This is incredibly important. We are all low-key and down-to-earth people that focus on our mission of developing innovative drugs to meet patient needs globally.

Finally, we are currently in the process of IPOing on the newly established Shanghai STAR Board, which would open the capital markets to us and enable us to realize many more of our ambitions.

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