

# What Can China Teach Us About CAR-T?

## Moderator

Shailesh Maingi, Founder and CEO, Kineticos

## Panelists

Bill Farley, VP of Business and Corporate Development, Sorrento Therapeutics

Anil Goyal, Chief Business Officer, MimiVax

Michael Catelani, Chief Operating and Financial Officer, Anixa Biosciences

**Kineticos:** We've talked about pricing and market access, autologous vs. allogeneic approaches, as well as solid tumors. Let's now talk about how they are thinking about CAR-T in China. They seem to have embraced this idea of CAR-T and I'm interested in hearing everyone's thoughts on the current state of these therapies in China particularly.

**AG:** There is no regulation in China like the US regulations on clinical trials. You have 300 or so trials, any hospital can start a trial. There is a lot of investment, but I haven't seen any data. Also, there has been some concern regarding data generated by a certain company. However, from what I hear, they have addressed the issue. Broadly speaking, we as a country, need to talk about STEM education. There is so much human capital that is present in China, in terms of science and technology, the US is falling behind. I think we need to continue to invest in science and technology education to compete with what's happening in China.

**BF:** CAR-T now is like where we were with antibodies 5 years ago. If you had a dollar and a dream back then, you had an antibody company. The same thing is going on right

now with CAR-T. There are serious concerns about real corruption in the clinical prosecution related to data, patients, and being able to translate this into the west. The great things about China are the robust patient population, willingness, usage of a labor arbitrage, and IP, but the major challenge with doing this in China is that there are strict controls on moving samples in and out of the country. You cannot take anything that translates into the human genome out of China. Until that changes, it will continue to be a challenge because you can't take a tumor sample out of China - you have to bring in resources and set them up there.

Prior to joining Sorrento, I spent 6 months in China. It is a great, wild frontier, but there needs to be a better way to do things globally, particularly with human samples that we can translate. There may be opportunities to do manufacturing there, from a labor arbitrage standpoint, like what Wuxi has successfully done. Setting up in tax-free zones and having sample partitions that you bring in and out is an approach, but you are not allowed to access the local population. You can access the data, but you cannot access the sample. Not being able to reproduce or do the same experiment is always challenging for a scientist.

**MC:** The regulatory environment is flexible in China. A lot can be done there, but even with these advantages, China has been generally unable to overtake the rest of the world in biotechnology. Without some change in regulatory and business practices, this trend will continue with every new technology in China.

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**Kineticos:** There are things that China can learn from us with patient safety and rigorous regulations. Are there things that we can learn from China?

**MC:** It is a difficult balancing act, but our regulatory structure can be overly restrictive. It's about trying to find a sweet spot in between the wild west and bubble wrapping everything we do in the US. There has to be some middle ground where we can find greater efficiencies without

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risking patient safety.

**AG:** We need to, as a country, set big vision goals. China has set up a goal of ‘Made in China 2025’. They can rally their education system, corporations, etc. to help with that vision. We have to invest more in our science and technology aspects of the country. Hampering immigration into the US is going to limit us from being competitive as well. Quite a bit of scientific discoveries have been made from folks who immigrated from outside the US. We have to look at our strength as a country in the diversity and ability to create new opportunities for people.

**Kineticos:** If the immigration policies become any stricter, you and I would not have been able to get into this country 50 years ago.

**AG:** The reason for me coming to the US was to contribute to the human growth through stopping disease, specifically cancer. I couldn't have done that research or helped companies back in India.

**Kineticos:** I completely agree. Bill, is there anything that we can learn from either a public

policy, regulatory, or education perspective?

**BF:** We can leverage some of the learnings from China's industrialization. We should take note of these lessons so that we don't suffer the same consequences. Some open market, like China, is good. One must understand the Chinese medical system too. It is not a point-of-care system like we have here. The data have to be looked at through a different lens. If you have a presence and understanding of your goals there, it can be a prudent investment to leverage, both from a financial standpoint and moving assets forward in a cost-effective way. Being able to look at the development aspects and gather data with the caveat of being very cautious about your IP is a great opportunity that can be capitalized on.

**Kineticos:** I am reminded of Tom Friedman, who writes for the NY Times. Tom used to talk about being in China for a day and being in America for the rest of the days. He was implying it would be nice to say these are our big priorities, but then our messy capitalist structure is more efficient at understanding how to fully capitalize on these priorities. It is a mixture of what China can learn from us and what we can learn from them all while keeping an ambitious vision for our country.

Any final comments anyone would like to make?

**BF:** CAR-T is at the tip of the iceberg with living drugs and using the whole immune system and beyond. Addressing solid tumors by looking at TILs or TCRs, which are also now at the forefront, could provide distinct advantages over CAR-Ts from a compatibility standpoint. I am a big fan of this mystery that we have opened up and I'm excited we've moved into the next revolution in biotech. We had the first one where we were able to clone something, the second where we were able to make antibodies, the third when we completed the genome, and now we have gone into engineering cells. It is going to fuel our environment for the next decade to come.

**MC:** This is such an exciting time to be in oncology research. There is so much happening and so many new things being discovered. It will be interesting to see how history looks back at what we are doing today.

**AG:** We can finally start talking about a cure for cancer. We are not there yet, but we can start talking about it. We are seeing the effects. The investment is the most exciting piece because people and companies don't just throw money at any idea or technology. I have seen cancer from early age, and I wish I had the technology that we have today for the family and friends I know that have passed away. This is a great future direction and I hope we all continue to invest our time into all diseases.

**Kineticos:** We start by talking about technology but as we all know, technology by itself is meaningless. It is only what the technology can do to help patients and reduce suffering in patients, and friends and family of patients. The reasons we do this, in the end, is to make a difference in the lives of patients.

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