JosÃ© Eduardo Vidal â?? CEO, CytoImmune Therapeutics

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17.12.2024

Tags:

Puerto Rico, Americas, USA

CytoImmune, founded in 2017 and established in Puerto Rico in 2020, is focused on developing immune-based therapies using proprietary natural killer (NK) cells. CEO Dr JosÃ© Eduardo Vidal discusses the biotechâ??s innovative approach, the access promise of allogeneic NK cells as opposed to T-cell therapies, the advantages of setting up operations in Puerto Rico, and the clinical manufacturing services CytoImmune provides, allowing the company to generate revenues alongside its scientific efforts.

Could you start by introducing CytoImmune and the story behind the company so far?

CytoImmune is a relatively young company, focused on developing immune-based therapies. Essentially, what we do is take cells from the immune system, genetically engineer them to modify their capabilities, and then create a therapeutic solution from human immune cells. That is the core of what we do.

The company was founded in 2017, and we established our presence here in Puerto Rico in 2020. Like many start-ups, we initially operated as a virtual company, raising funds and developing a

pipeline of potential products. In 2020, we moved to Puerto Rico, where we set up a full-scale operation. Now, we have a research facility and manufacturing capabilities, allowing us to manage every aspect of developing, filing, and eventually commercialising new products.

Could you explain a bit more about Track NC cells and how they could potentially redefine cancer treatment?

Track NC cells are a proprietary line of natural killer (NK) cells developed from human umbilical cord blood, which we source through dedicated collection and processing centres. Unlike typical NK cells found in the body, which can kill a target only once, our cord blood-derived NK cells are more aggressive and exhibit superior persistence. These cells can bind to a target, secrete substances to destroy it, then release and regenerate, allowing them to repeatedly kill multiple targets. This enhanced ability makes our NK cells significantly more potent than those derived from peripheral blood, offering promising potential in immune-based therapies.

As for the types of cancers we are targeting, the approach is somewhat agnostic to cancer type. We programme these cells to target specific markers found on the surface of cancer cells. So, in theory, they could target any cancer, as long as there is a distinct marker to recognise. Our first clinical programme focuses on non-small cell lung carcinoma, as the lungs are the first stop for NK cells, making it an ideal setting to test our platform. However, we are also working on treatments for pancreatic, kidney, and prostate cancers, with lung cancer being the most advanced programme.

Given that CytoImmune is pioneering cell therapies through allogeneic approaches, what do you consider the primary scientific and logistical challenges in scaling these therapies, especially in comparison to autologous approaches?

The main challenge when comparing allogeneic and autologous therapies is patient access. Having worked on the development of the first allogeneic T-cell therapy at Atara, I understand the challenges of both approaches. Autologous therapies, which use a patientâ??s own cells, often yield better therapeutic responses but are prohibitively expensive, with costs ranging from USD 500,000 to USD 1 million per patient, limiting access. In contrast, allogeneic therapies allow for the manufacture of larger cell batches to treat multiple patients, reducing costs significantly to around USD 200,000 per patient. However, a key challenge remains maximising cell production from a single batch, as NK cells are difficult to grow. To address this, we are using large-scale bioreactors, similar to those employed by companies like AbbVie and Amgen, to scale up production. The more cells we can produce from each batch, the more cost-effective it becomes for patients. And we are making good progressâ??though it is challenging, we are optimistic that, with our experience, we will achieve success in scaling up the production over the next few months.

Are these the key reasons why NK therapies are more affordable than CAR T-cell therapies?

NK cells are naturally allogeneic, meaning they can be sourced from a healthy donor and used in another patient with fewer compatibility issues than T-cells. While we conduct haplotype matching to avoid immune rejection, NK cells are generally compatible across a wider range of patients. In contrast, T-cells are patient-specific and require careful matching of HLA markers to ensure compatibility. At Atara, we found that a partial match of three markers could cover about 95 percent of the worldâ??s population, making T-cell therapy more feasible and cost-effective.

One of the challenges with T-cells is that they differentiate over time. Initially, they are active and can directly kill cancer cells, then they transition into memory cells, where they essentially â??teachâ?• other cells in the immune system how to respond. The problem with growing T-cells in bioreactors is that, as they differentiate, their function can diminish.

Do you think NK cell therapies will eventually replace CAR T-cell therapies, or do you see them working together as complementary treatments?

My view is that both therapies will work together. CAR T-cells and NK cells have different but complementary roles in cancer treatment. CAR T-cells, like other T-cells, have a very specific purpose, while NK cells can complement that by offering additional functionality. There are also other cell types, such as tumour-infiltrating lymphocytes, that are being explored.

I do not think we will see a â??one-size-fits-allâ?• approach. We have not yet seen many combination therapies that use different cell types, but we are actively designing treatments that could integrate multiple cell lines for a more tailored approach.

Moving on to the location of your operations, CytoImmune is a relatively young company, founded in California in 2017, and then you moved your manufacturing facilities to Puerto Rico in 2020. What made you choose Puerto Rico, and what advantages does the island offer for biopharmaceutical manufacturing?

We chose Puerto Rico for several key reasons. The island has a long history in the biopharmaceutical sector, providing a robust infrastructure for biopharma operations that has developed over decades. While the sectorâ??s growth may have slowed, the foundation here remains ideal. Puerto Rico also boasts a wealth of expertise, with hundreds of highly trained scientists specialising in process transfers, troubleshooting, and continuous improvement. Additionally, the strong local education system has created a large pool of talent that works in biopharma globally. Many of these professionals were eager to return, and over 50 percent of our team is made up of Puerto Ricans who have repatriated, allowing us to build a skilled, dedicated team committed to our mission.

How do you think operating in Puerto Rico will ultimately contribute to the efficiency and accessibility of NK cell therapy?

Puerto Rico is playing a crucial role in enhancing the efficiency and accessibility of our NK cell therapies. Scientifically, we are not only focusing on our core TRACK-NK cell line but also expanding into other areas, such as developing NK-based treatments for autoimmune diseases and exploring applications for longevity. We have demonstrated that our NK cells can persist longer and act like younger immune cells, which is key for overall immune health. The expertise available on the island has been invaluable, enabling us to attract talented Puerto Rican professionals from abroad, many of whom have returned to work with us. This talent, combined with a strong scientific infrastructure, creates an ideal environment for advancing our therapies. Additionally, the synergy between biopharmaceuticals and other high-tech sectors, such as big data and AI, is driving innovation. We collaborate with experts in these fields to manage and process the vast genetic data we generate, using AI and deep machine learning to model experiments and accelerate research. This reduces development time, allowing us to bring therapies to patients faster. Puerto Ricoâ??s scientific

expertise, advanced technology infrastructure, and skilled workforce make it a strategic hub for biopharmaceutical innovation, enabling us to shorten development timelines and improve patient access worldwide.

You have mentioned collaborations with other industries, could you elaborate on how these collaborations are advancing your work and contributing to your research and development efforts?

Puerto Rico has a strong foundation in biotech manufacturing, but when we arrived, we identified gaps in the infrastructure needed for developing new therapies. Specifically, we required pre-clinical studies, including in vitro testing and animal studies, before submitting a drug for FDA approval. To address this, we partnered with the University of Puerto Rico and the MSRC, leveraging their animal research facilities for preclinical studies. This collaboration has since expanded, with us now occupying space in their ASTRE programme, where we conduct in vitro studies. This partnership fosters an innovation-driven ecosystem, combining scientific expertise with practical skills, and offers the added benefit of training students and professors in real-world therapy development, ultimately building a pipeline of future talent.

CytoImmuneâ??s facility in Puerto Rico also supports not just your internal pipeline but also offers clinical manufacturing services to other biotech companies. How does this service model foster collaboration within the industry, and what role does it play in advancing cell therapy globally?

Our facility in Puerto Rico has evolved into a hub for partnering with companies, particularly in the early stages of cell therapy development. The strong talent pool and infrastructure we have built here have made us an attractive partner for those facing challenges in developing their therapies. Many companies approach us for expertise in cell platforms, vectors, or specific cell lines. We collaborate by testing their targets on our platform, and if successful, we develop candidates together. What started as informal collaborations has now grown into a formal service offering, with our reputation for delivering results. Initially focused on NK cells, we now work with multiple cell lines, addressing a wider range of diseases. We are also integrating diverse technologies such as gene regulation, mRNA, and epigenetics into our therapies. We are exploring exciting possibilities, including longevity, where we aim to create therapies that not only target cancer but improve overall health. Puerto Rico has become the ideal base for this innovation, combining local expertise and infrastructure in a collaborative ecosystem that drives transformative therapies. The future is incredibly promising.

How has CytoImmune been funded so far, and what are your plans for securing the financing to reach the next milestones and continue on this successful track?

Building a biotech company, particularly in cell therapies, has been a capital-intensive journey. Since we began, we have seen the investment landscape shift, particularly after the â??venture capital winter,â?• which led to a significant pullback in funding. Initially, there was a lot of capital available for new therapies, but as more companies entered the market, the funding slowed. To adapt, we focused on creating a self-sustaining business model, building a revenue-generating line alongside our scientific efforts. The incentives in Puerto Rico have also played a crucial role in sustaining our operations during lean periods. While we remain a private company and have decided not to go

public for now, we are in a strong position financially with a solid cash runway. We plan to approach venture capital again next year, with a more defined strategy for growth and a strong pipeline that we believe will attract investor interest. With momentum behind us, we are focused on delivering results and preparing for the next phase of expansion when we raise capital.

What would you like global readers to know about CytoImmune?

At CytoImmune, we position ourselves as an innovation-driven company, blending scientific expertise with commercial acumen. Our team, with extensive experience in big pharma and biotech, understands how to translate cutting-edge science into therapies that are both clinically effective and commercially viable. Unlike many biotech companies, we focus on ensuring that our therapies are accessible on a global scale, not just successful in clinical trials. Our flexibility is key, with a team spanning research to commercialization, and a partnership model that includes taking stakes in companies like Hemostemics to help scale their therapies.

Puerto Rico, with its rich pharmaceutical history, provides the perfect base for us to lead the next wave of innovation. By collaborating with local universities and research centres, we enhance existing infrastructure, accelerating therapy development while contributing to the islandâ??s innovation ecosystem. The governmentâ??s tax incentive programs, such as the 50 percent tax credit for investments, significantly extend our capital and help us scale faster, providing a powerful advantage for growing businesses. This environment is attracting other companies to Puerto Rico, which will further strengthen the local biotech hub.

Through our efforts, we are not only advancing our own goals but also helping stimulate the local economy by bringing in talented professionals, many of whom are returning to Puerto Rico. While we havenâ??t reached profitability yet, the impact on the community is already evident. With collaboration as our foundation, we are building a positive cycle that will position Puerto Rico as a leading biotech hub, with CytoImmune at the centre of this transformation.

On a more personal note, you have had quite a journey in your careerâ??from working at Amgen to joining Atara, and now being part of this exciting venture at CytoImmune. What convinced you to join CytoImmune?

After my PhD in molecular biology, during biotechâ??s early days I witnessed the rise of therapies like Enbrel, which gave me invaluable insight into the industryâ??s growth. Later, at Amgen, I encountered cell therapies first-hand, and the potential was clear. But I realised that, in a large company, it was hard to bring such innovative work to life. That is when Atara, a start-up focused on FDA-approved cell therapies, came into play. The challenges were immense, but pioneering in this space was thrilling. Once we built a strong foundation, scaling became the next challenge, and that is when I was introduced to CytoImmune.

When I was approached by CytoImmune, the companyâ??s vision to transform patient care and the biotech ecosystem in Puerto Rico was compelling. The timing was perfectâ??I could return home and contribute to the industryâ??s growth.

Within a year, we were breaking ground on our facilities. Being part of building a new industry in Puerto Rico is rare, and we are at a tipping point where CytoImmune is helping shape the future of biotech here. Puerto Ricoâ??s pharmaceutical legacy is evolving, and CytoImmune is at the heart of that transformation.

Is there any final message you would like to convey about CytoImmune?

At CytoImmune, our priority is always patients. Our focus is on giving peopleâ??especially those with no other optionsâ??a fighting chance. For example, in our lung cancer trial, we are offering patients who have failed two other therapies a third option, and we are already seeing incredible results. Some of these patients, who were once bedridden with poor prognoses, are now surviving well past the two-year mark. That is a message of hope, and it is something we are really proud of.

Our platform is designed to bring new hope to people who havenâ??t had that before. But to make it happen, we need to keep expanding our ecosystem. We want to bring clinical trials to Puerto Rico, ensuring that local patients have access to these innovative therapies. We are already working with fantastic partners here to strengthen the infrastructure for these trials. And with groups like TCT Oncology, who are doing ground-breaking work with CAR-T therapies, we are excited to be part of this vibrant, growing community.

Ultimately, it is all about collaboration. We are open to new partnerships that will help us reach more patients and deliver on the promise of these new therapies. It is about making a real difference, and that is the kind of work that makes every challenge worthwhile. That is why we are here, and that is why we are so excited about whatâ??s ahead.

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