Paul Stoffels – CEO & Chairman, Galapagos

The complexities of conditions like cancer demand a revolutionary solution. That is where CAR-T cell therapy could be a potential game-changer

19.07.2023

Tags: Belgium, Galapagos, Biotech, Oncology, CAR-T, Cell & Gene Therapy

Back home in Belgium after a stellar stint in Big Pharma, Dr Paul Stoffels is now looking to reshape the future of cancer care with the biotech he helped co-found in 1999, Galapagos. In an exclusive conversation with PharmaBoardroom, Dr Stoffels outlines his excitement about a new CAR-T delivery model that brings the production process closer to patients and for translating scientific discoveries into tangible improvements in patients' quality of life.*

What is your primary motivation for developing innovative medicines and how did your path intersect with the journey of Galapagos?

My passion to develop innovative medicines began amidst the devastating HIV pandemic. It was while working as a physician in Africa during that period that I witnessed firsthand the urgent need for effective treatments. The profound impact on patients' lives pushed me to make a meaningful difference in the world.

Guided by this goal, I embarked on a path that led me to join forces with the visionary Dr Paul Janssen at Janssen Pharmaceutica. Together, we focused our activities on groundbreaking HIV research and the discovery of new medicines. In the mid-1990s, I seized the opportunity to co-found two Belgian biotech companies, Tibotec and Virco, which would go on to play pivotal roles in revolutionizing HIV treatment.

Imagine a world where HIV, once a fatal disease, is transformed into a manageable, chronic condition. This dream became a reality through the tireless efforts of the teams at Tibotec and Virco, who spearheaded the development of revolutionary diagnostics testing and new medicines for multidrug resistant HIV. The landscape of medicine shifted and gave hope to many patients worldwide.

But my journey didn't stop there. In 1999, I co-founded Galapagos, a joint venture between Introgene (now Crucell), a Dutch gene therapy company, and Tibotec, whose vision was to harness the power of gene, viral, and cell technologies to develop novel medicines. Even in those early days, before a complete deciphering of the human genome sequence was achieved, Galapagos forged ahead fearlessly.

As Galapagos grew, so did its capabilities in drug discovery. We advanced multiple promising drug candidates, including treatments for debilitating conditions such as rheumatoid arthritis and ulcerative colitis, into clinical trials. Multiple collaborations were established with industry leading companies such as GSK, AbbVie, and Gilead, amplifying our collective impact on patients' lives.

After the acquisition of Tibotec-Virco by Janssen/J&J in 2002, I continued to spearhead the R&D efforts for infectious diseases at Janssen, focusing on HIV, HCV, TB and vaccines. In 2008, I took over the leadership of Janssen R&D, with a focus on transformational medicines to address unmet medical needs. Together with our dedicated teams, we launched 25 innovative medicines, with 7 of them being listed on the World Health Organization's (WHO's) essential medicines list. Following the principle of "The World is your Lab", we established an extensive innovation network in collaboration with universities and biotechs to source breakthrough science. One of the key initiatives has been the creation of J-labs, which has led to the creation of incubators worldwide and has provided a platform for hundreds of start-ups, many of which have flourished into successful biotech companies.

Throughout my journey as a physician, researcher and entrepreneur, my focus has always been on challenging the status quo to bring transformational innovation to patients worldwide.

Fast forward to the present, Galapagos is now a fully integrated independent biotechnology company. Our first medicine for rheumatoid arthritis and ulcerative colitis is now available for patients in Europe and Japan.

Today, Galapagos focuses its commitment on the key therapeutic areas of immunology and oncology. We leverage our profound scientific expertise in various drug modalities, ranging from small molecules to cutting-edge cell therapies. Our ambition is clear: to push the limits of medical

intervention, save lives, and improve patient outcomes.

Having now returned to the company you co-founded in 1999, can you tell us about its focus on CAR-T and your view on the impact it can have on healthcare?

When we founded Galapagos in 1999, our focus was primarily on novel mode-of-action small molecule drugs targeting a broad range of indications. However, in the field of cancer treatment, we realized that a different approach was needed. The complexities of conditions like cancer demand a revolutionary solution. That is where CAR-T cell therapy could be a potential game-changer.

Drawing from my experience as a doctor and a researcher, I understand the significance of constantly pushing the boundaries of medical progress. Just as we advanced from multiple pills a day to a single daily pill in HIV treatment, CAR-T therapy has undergone a magnificent transformation over the past 15 years. It has shown remarkable results in treating severe hematological cancers, extending patients' life expectancy by years.

Although CAR-T treatment holds immense potential to save lives, it also comes with challenges today. The true essence lies not only in the effectiveness of the therapy but also in its accessibility, flexibility, and the expansion of its benefits to encompass a broader spectrum of life-threatening diseases. That is where pioneering research and groundbreaking manufacturing solutions could play a significant role.

In 2022, Galapagos acquired CellPoint and AboundBio. What was the rationale behind these deals and how do you expect these investments to help improve your capacity to bolster access to CAR-T therapies?

To realize our ambition to accelerate the development of groundbreaking medicines and transform the landscape of patient care, we actively seek collaborations and external breakthroughs that have the potential to revolutionize treatment paradigms. The acquisitions of CellPoint and AboundBio are an excellent example of this approach as through them we gained access to an innovative, scalable, decentralized, and automated point-of-care CAR-T delivery model as well as a next-generation fully human antibody-based therapeutics platform. Combined and supported by our capabilities and resources as a fully integrated biopharma, they have the potential to deliver life-saving medicines to more patients, faster and more efficiently.

Despite the tremendous potential of current CAR-T therapies, long lead times, highly manual central manufacturing, and complex logistics remain the limiting factors for large-scale capacity and broad patient access. To address these limitations, CellPoint developed, in a strategic collaboration with Lonza, a novel point-of-care supply model, which is designed to enable clinicians to administer fresh CAR-T cells within seven days of leukapheresis, without complex logistics or cryopreservation. The proprietary platform consists of Cell-Point's end-to-end xCellit workflow management and monitoring software, and Lonza's Cocoon® Platform, a functionally closed, automated manufacturing platform for cell therapies.

Currently, we have implemented the Cocoon® Platform in clinical settings across three countries – the Netherlands, Belgium, and Spain – as part of two ongoing Phase 1/2 clinical studies with our CD19 CAR-T candidates, GLPG5101 in patients with non-Hodgkin's lymphoma, and GLPG5201 in patients with relapsed/refractory chronic lymphocytic leukemia. We reported promising initial Phase 1 safety and efficacy results from the first 7 enrolled patients in each of the studies. The data also demonstrated that a seven-day vein-to-vein, leukapheresis to infusion time, is feasible. In addition, using non-frozen cells seem to result in a promising safety and efficacy profile of the CAR-T therapy.

We are looking forward to further expanding our oncology portfolio, and it is our ultimate goal to bring novel CAR-T therapies to patients, thereby improving their lives and making a lasting impact on society.

How do you expect healthcare stakeholders to react to this new CAR-T cell therapy delivery model?

The concept of bringing CAR-T cell therapy and its production process close to patients, in or near the hospitals, presents both opportunities and challenges in terms of regulatory oversight.

One notable advantage of this approach would be the potential to administer CAR-T therapy faster and more efficiently to patients who have limited life expectancies, particularly those in the advanced stages of their diseases. These patients, who are in critical condition, often experience delays in receiving CAR-T therapy due to current manufacturing limitations. However, with our innovative point-of-care delivery model, we could significantly reduce the waiting period from months to days as we have demonstrated in our early clinical trials. And although the preliminary data from these trials show promise, it is crucial to validate these findings through pivotal, larger-scale clinical studies.

The regulatory landscape will play a key role in shaping the acceptance and implementation of our innovative approach in cell therapy. We are fully committed to collaborating closely with regulatory authorities to demonstrate the safety, efficacy, and feasibility of our innovative method. By working hand in hand with these governing bodies, we aim to ensure that all necessary requirements are met and that this groundbreaking approach to CAR-T therapy receives the recognition and support it deserves.

How have you been finding the integration of two new companies and two new sets of professionals?

The integration of CellPoint and AboundBio, along with their exceptional teams, has been an exciting and transformative journey for Galapagos. It brought new perspectives, skills, and expertise, strengthening our capabilities and expanding our reach in the field of oncology. By assimilating the CellPoint and AboundBio teams' profound knowledge of cell therapy manufacturing, disease understanding, and clinical trial experience, we have not only reinforced our existing teams but further improved our full end-to-end capabilities.

To continue to expand in the field of oncology, we are actively seeking and recruiting top talent, attracting exceptional individuals who share our vision. Since the beginning of 2023, we have already expanded our existing teams by over 80 new colleagues, each contributing their unique skills and passion to our shared mission. Furthermore, we are currently in the process of growing our CAR-T point-of-care network in Europe, underscoring our commitment to providing innovative and accessible treatment options for patients.

How does Galapagos' strategy ensure that it both keeps up with its competitors in terms of innovation in the long-term as well as creates value in the short- and medium-term during the lengthy development process?

In 2022, we made a significant shift in our R&D strategy, transitioning from a focus on novel target discovery to a patient-centric, medical need-driven approach in our key therapeutic areas of immunology and oncology.

With a deep commitment to addressing patient needs through transformative innovation, we combine the best science, cutting-edge technology, and next-generation biological capabilities from within our company with external innovation and knowledge sharing beyond our organization.

In addition to expanding our collaborative network, we are also expanding our current capabilities through the exploration of multiple drug modalities, including small molecules, CAR-T cell therapy and biologicals.

Moreover, to streamline our efforts we focus on identifying and prioritizing best-in-disease validated targets within our strategic therapeutic areas. By concentrating our resources on these targets, we can accelerate the development process, significantly reducing the time it takes for our innovations to reach the patients who need them most.

Through our patient-centric, medical need-driven R&D strategy and the combination of internal expertise with external collaborations and advancements in technology, we are confident that our approach will yield tangible benefits and bring transformative solutions to patients in a more efficient and timely manner.

What is your perception of the capacity of the healthcare systems to adopt highly innovative, but also very costly, therapies like CAR-T?

Healthcare systems' capacity to adopt innovation is influenced by a multitude of factors, which encompass the recognition of the added value of the innovation, appropriate reimbursement practices, streamlined regulatory processes, and the ability to bring therapies to market quickly to maintain competitiveness.

From the perspective of biotech and pharmaceutical companies, it is vital for society to acknowledge the transformative impact and added value that innovative therapies can bring to patients. These companies should also be appropriately rewarded for their investments and the risks they undertake in providing potential life-saving solutions. Without fair compensation, companies may struggle to sustain their operations, leading to a lack of investment in future innovations.

Striking a balance is crucial, where the pursuit of higher levels of innovation aligns with the recognition and rewards for that innovation. Insufficient acknowledgment and rewards for the companies' R&D efforts can impede the development of new medicines, hindering progress in the field.

Another critical factor to consider is the speed at which novel therapies are brought to market. Delays in the approval of clinical trials and the progression from Phase 1 to later stage clinical studies can be discouraging and hamper the development of novel therapies, including CAR-T.

Speed becomes a competitive advantage, as being late to the market can result in a smaller eligible patient population and market share.

Furthermore, the regulatory landscape and reimbursement policies play a significant role in the adoption of CAR-T therapies. The willingness of healthcare systems to cover the costs of these therapies and provide timely access to patients is crucial for their success.

By addressing these various factors, healthcare systems can create an environment that facilitates the adoption of highly innovative therapies like CAR-T. Recognizing the value of innovation, implementing appropriate reimbursement practices, expediting regulatory processes, and ensuring timely market entry collectively contribute to the successful integration of these transformative therapies into patient care.

What is your assessment of the state of Belgium's biopharma ecosystem today?

Belgium possesses a thriving and competitive biopharma ecosystem that encompasses the entire value chain, spanning research and development to manufacturing. The industry environment is robust, fostering the presence of both multinational companies and biotechs, with a particular emphasis on biological and vaccine expertise.

This ecosystem thrives on extensive knowledge in pharmaceutical sciences and a pool of experienced professionals. Notably, the biotech sector, especially in the realm of cell therapies, has witnessed significant growth, even comparable to renowned hubs like Boston.

Belgium's biopharma ecosystem is further strengthened by close collaborations among academic institutions, hospitals, spin-offs, start-ups, SMEs, large corporations, and a well-developed logistics network. This collaborative spirit fuels innovation and facilitates the seamless exchange of knowledge and resources, contributing to the overall success of the ecosystem.

At Galapagos, we are fortunate to benefit from a talented workforce of approximately 500 employees in Belgium, constituting a significant portion of our total workforce of 1,300. The expertise and dedication of our Belgian team are instrumental in driving our company's ongoing success within the thriving biopharma ecosystem of Belgium.

Do you have a final message on behalf of Galapagos that you would like to share with stakeholders across the healthcare value chain?

At Galapagos, our mission is centered around transforming patient outcomes through life changing science and innovation for more years of life and quality of life. We firmly believe that this patient-centric focus should extend to all stakeholders in the healthcare value chain, including regulators, society, and universities. The dedication of our scientists and researchers is fueled by their passion to utilize their knowledge and expertise to make a profound difference in the lives of individuals.

In our industry, the driving force behind our work is the impact we can achieve for patients. Whether we are developing therapies for conditions like HIV or pushing the boundaries of innovative science such as CAR-T, our ultimate goal is to translate scientific discoveries into tangible improvements in the quality of life for those in need.

At Galapagos, financial gains and company growth are not the primary motivations driving our efforts. As a physician myself, my personal drive stems from witnessing the devastating effects of diseases and the strong desire to leverage science to develop new and effective treatments. It is imperative that we all share the same mission of translating excellent scientific advancements into real-life solutions that benefit society as a whole. When you create significant benefits for patients and society, the company's growth and success will follow.

We have learned an important lesson in simplifying complex science into practical solutions. By making treatments more accessible, we can reach a larger number of patients and create a significant and long-lasting impact. As we continue to advance in the field of CAR-T cell therapy, our aim at Galapagos is to explore innovative approaches to make breakthrough cancer therapies more accessible, simpler, and more effective.

Let us all work together with a shared vision, collaborating to transform scientific discoveries into meaningful healthcare solutions that enhance the lives of patients worldwide. By working collectively, we can create a brighter future where scientific breakthroughs translate into real-world benefits for individuals in need.

* *Throughout this article, 'Dr Paul Stoffels' should be read as 'Dr Paul Stoffels, acting via Stoffels IMC BV'*

See more interviews