Helen Yang – Co-Founder, Chairwoman & CEO, Oricell Therapeutics

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Founded by Dr Helen Yang and Dr Peter He, Oricell Therapeutics stands at the forefront of next-generation cell and gene therapy innovation. Built on a comprehensive platform that integrates antibody discovery, CAR-T engineering, and advanced manufacturing, Oricell is advancing differentiated therapies for solid tumours such as hepatocellular carcinoma and hematologic malignancies. With clinical programmes progressing in both China and the United States, and new strategic growth initiatives on the horizon, the company is entering a pivotal stage in its global expansion.

What inspired you to establish Oricell Therapeutics, and how did its scientific foundations take shape?

Before founding Oricell, my career was in a completely different sector. I co-founded Canature Health Technology Group, a company focused on residential and commercial water purification, which we grew into an international enterprise and listed Canature on the Shanghai stock market in 2011. Our purpose then was to enhance everyday wellbeing by improving the quality of water in people’s homes. Yet over the years, I witnessed a growing number of cancer cases among friends, colleagues, and family members, which made the issue deeply personal to me. My partner’s sister later received an early form of immune-cell therapy at Tsinghua University, led by my future co-

founder and now Chief Scientific Officer of Oricell Therapeutics, Dr Peter He. Her life was extended by more than a decade as a result of receiving the therapy, an experience that left a lasting impression and motivated me to enter the field of cell therapy.

In 2015, Peter and I started Oricell with the conviction that cell therapy represented a new frontier in medicine. We began by building a solid scientific foundation that could continuously generate innovations. Our antibody discovery platform, OriAb, now one of the largest antibody libraries applied for cell therapy development, enables the identification and optimisation of high-quality antibody sequences for effective CAR-T design. This evolved into our OriCAR engineering platform, which focuses on creating next-generation CAR-T constructs capable of maintaining durable efficacy and functioning within the complex tumour microenvironment. Complementing these, our manufacturing and CMC platform integrates lentiviral vector technology, GMP-grade production, and stemness-based innovations to preserve cell vitality and reduce production timelines.

We are now extending this foundation into in-vivo CAR-T approaches, wherein the CAR is generated directly inside the patient body. Together, these platforms reflect Oricell's core philosophy: to translate scientific excellence into therapies that are not only effective and safe but also accessible to a broader patient population.

How does Oricell's antibody platform underpin your CAR-T development, and how does it connect with your broader innovation strategy?

Our antibody platform sits at the core of Oricell's scientific foundation. It integrates a human naïve phage-display library and a synthetic nanobody library, providing a vast repertoire of antibody sequences for both CAR-T and antibody-based therapies. From the outset, we built the library meticulously, screening and validating every sequence to ensure diversity and quality across most oncology targets. This internal capability allows us to identify, optimise, and test antibodies directly, without the dependency on external CROs that most developers face, substantially accelerating discovery and ensuring full control of scientific standards.

As our Chief Scientific Officer, Dr Peter He, often emphasizes, a high-quality antibody binder is fundamental to an effective CAR-T construct. Importantly, an antibody sequence that performs well in a conventional antibody drug does not automatically translate into an effective or safe CAR-T, given the fundamental differences in their mechanisms of action. To deliver best-in-class performance and sustain next-generation innovation, it is essential to own a proprietary antibody library and to establish a robust screening and engineering process tailored specifically for CAR-T

applications. Building this capability required nearly five years of dedicated effort, and it now serves as the cornerstone of our platform.

The strength of this foundation has also attracted growing interest from external partners. Several biotech companies developing antibodies or antibody-drug conjugates (ADCs) have approached us to access our sequences, and we have already out-licensed a bispecific antibody that has proven valuable to a collaborator. While we do not actively commercialize the library itself, its reputation for quality continues to generate inbound collaboration opportunities.

The quality of the antibody determines far more than just efficacy, it is closely tied to safety, particularly in reducing the risk of Cytokine Release Syndrome (CRS) when CAR-T cells are administered. Building on this, we developed the OriCAR engineering platform, which focuses on designing armoured constructs capable of functioning in the complex and immunosuppressive microenvironment of solid tumours. These CARs are engineered to enhance T-cell infiltration, maintain functional persistence, and preserve a high proportion of memory T cells, translating into greater durability and patient benefit.

Complementing these advances is our manufacturing and CMC platform, which continually refines production efficiency, consistency and increase accessibility. We developed three production modules: conventional autologous production, a three-day fast-manufacturing process, and in-vivo CAR production, where the CAR-Ts are expressed and expanded directly within the patient’s body.

Together, these platforms form an integrated innovation ecosystem – spanning antibody discovery, CAR engineering, and manufacturing – designed to continually improve the safety, efficacy, and accessibility of next-generation cell therapies.

How is Oricell advancing CAR-T therapies for solid tumours, and what distinguishes your approach?

Oricell”s progress in solid tumors is built on three integrated pillars:

The first is our clinically validated pipeline with leading efficacy data. The company’s lead program, Ori-C101 (targeting GPC3 for hepatocellular carcinoma), has generated compelling clinical data presented at ASCO. In heavily pretreated advanced HCC patients, it achieved a 60 percent overall response rate and a 90 percent disease control rate in an IIT study, with a median overall survival of 9.4 months. Crucially, in the Phase I IND study’s highest dose cohort, the ORR reached 100 percent, including one patient with a complete response and progression-free survival exceeding

24 months.

The second integrated pillar is our strategic focus on high-prevalence indications. The company leverages the high abundance of HCC patients in China for efficient clinical recruitment. This, combined with established clinical partnerships, has enabled it to build one of the largest global datasets for CAR-T therapy in HCC, creating a significant strategic advantage in developing a therapy for this difficult-to-treat solid tumor .

The final pillar is rapid, patient-centric manufacturing. Recognizing that solid tumor patients can deteriorate quickly, Oricell has optimized its manufacturing process for speed. Its “OnGo (Fast) CMC” platform enables a three-day manufacturing process, resulting in a vein-to-vein turnaround of just ten to fifteen days. This is significantly faster than the conventional month-long process, greatly improving patient access and ensuring timely treatment

Our core differentiation lies in the proprietary Ori^{TM}Armor platform, which fundamentally enhances CAR-T cell function through two key mechanisms:

The first of these mechanisms is Building Intrinsic T-Cell Resilience. Unlike standard CAR-T cells that often suffer from premature exhaustion in the hostile solid tumor microenvironment, Ori^{TM} Armor is designed to preserve T-cell “stemness.” By incorporating optimized signaling domains and metabolic programming, it promotes a T-cell stem cell memory phenotype.

The second is Actively Remodeling the Tumor Microenvironment. Ori^{TM}Armor goes beyond simply enduring the TME; it actively combats it. The platform equips CAR-T cells with features to modify their surroundings, such as: secreting antibodies or cytokines to neutralize immunosuppressive factors; employing TME factor trappers and switchers that convert inhibitory signals into activating cues; amd using membrane-anchored cytokines for sustained, localized stimulation.

In summary, Oricell distinguishes itself by combining clinically validated efficacy in a challenging solid tumor with a proprietary platform (Ori^{TM}Armor) that fundamentally tackles T-cell exhaustion and TME immunosuppression, all enabled by a rapid manufacturing process designed to meet the urgent needs of patients.

How did OriCAR-017 evolve from early trials in China to a globally recognised programme? What are the next steps?

We gained a lot of confidence in development a CAR-T for MM after we obtained very outstanding results from Ori-C101 for treating late-line HCC patients. We thought, if our CAR-Ts can deliver breakthrough response on solid tumor, our CAR-Ts can excel in MM. Therefore, OriCAR-017 began with an investigator-initiated trial (IIT) in China that delivered compelling early results and laid the foundation for our international strategy. We subsequently secured IND clearance from both the NMPA and the FDA, completing the completed the China–US technology transfer in six months, the fastest known in the industry. The process highlighted the strength of our technical and regulatory capabilities and resulted in two oral presentations at the 2022 and 2024 ASCO Annual Meetings.

For next steps, we will complete Phase I in China and advance to Phase II while pursuing a global development partnership (Several major pharmaceutical companies have expressed strong interest) to scale global trials and align with international standards. We are also advancing a GPRC5D/BCMA dual-target CAR-T to address antigen escape, blostering its MM CAR-T innovation leadership.

What are Oricell's priorities moving forward, and how are you addressing cost and access challenges in China?

Our pipeline currently centres on two major programmes: our solid tumour CAR-T for HCC, which has completed Phase I and is preparing to enter Phase II in China, and OriCAR-017 for multiple myeloma, which is approaching the same milestone. In parallel, we are running several IITs, including a secreting CAR-T with a new mechanism, a dual-targeted CAR-T, and others. We are in active discussions with global partners and expect international collaborations to accompany the next stages of development.

The limited uptake of CAR-T therapy in China today is mainly due to affordability. The current market price averages around 1.0 million RMB and is mostly out-of-pocket in terms of reimbursement since CAR-T is not yet included in the national reimbursement list. In contrast, full reimbursement in the United States and Europe has made these therapies more accessible.

Epidemiological patterns also shape the market. In China, the largest cancer burdens are lung, gastric, pancreatic, and hepatic tumors, particularly HCC, whereas multiple myeloma dominates in Western countries. As a domestic innovator, we aim to significantly lower manufacturing costs through process efficiency and localised production, enabling broader patient access.

Several major Chinese cities, including Shanghai and Hangzhou, have already launched city-level insurance schemes that provide partial coverage for high-cost therapies like CAR-T. These low-premium models, often offering reimbursement ceilings of several hundred thousand RMB, are expanding access and creating a foundation for wider adoption. Upon commercialisation, We expect our therapies to fit seamlessly into these frameworks once commercialised, helping more patients benefit from this new generation of cell therapies.

What are Oricell's financing priorities and long-term growth ambitions?

We have historically raised over $270mm with significant raise in recent years, allowing us a very healthy cash runway. To us, expanding our financing capabilities is not only about raising capital but also about establishing a foundation for sustained global growth. The resources we secure will support the advancement of our core clinical programmes, the development of next-generation cell therapies, and the expansion of strategic partnerships that can accelerate international reach. Our long-term ambition is to evolve into a globally recognised biopharmaceutical company, following the trajectory of leading US biotech innovators that transformed from focused pioneers into integrated global players. While our roots remain in China, our vision is global, we aim to accelerate the development and accessibility of transformative therapies for patients worldwide.

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