Je-Jung Lee – CEO, Vaxcellbio

Vaxcellbio aims to become a genuine game changer in the global immune cell therapy market

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Dr Je-Jung Lee, CEO of Vaxcellbio, discusses how his experience as a physician and immunotherapy researcher shaped the company's patient-centred mission. He outlines Vaxcellbio's differentiated NK cell, CAR-T and CAR-MIL platforms, manufacturing strategy, Korea's evolving regulatory landscape, and the company's ambition to become a globally integrated immune cell therapy leader through innovation, partnerships and commercialisation.

How has your background as a physician directly shaped Vaxcellbio's direction?

I began my haematology training in 1997, following my residency in internal medicine, and have spent close to three decades since then split between patient care and cancer immunotherapy research. Around 2000, during a period of considerable tension between Korea's medical and pharmaceutical sectors, I spent six months at Japan's National Cancer Centre in Tokyo, where I studied dendritic cell immunotherapy specifically. That period shaped the direction of my research for years afterward.

Early in my career, I cared for many patients with advanced haematologic malignancies whose treatment options were extremely limited. Witnessing their urgent need for new therapies reinforced my determination to translate scientific discoveries into treatments that could reach patients more quickly. Those experiences became the foundation of my long-term commitment to developing innovative immune cell therapies.

This commitment led me to join Korea's national Frontier Project, one of the country's flagship government research initiatives for pioneering biomedical technologies. The programme provided an opportunity to further develop my research while pursuing the broader goal of advancing next-generation cancer immunotherapies in Korea.

That formative period led me to a research fellowship at the University of Pittsburgh from 2005, and on returning to Korea, a pharmaceutical company's interest in licensing my academic research prompted colleagues to suggest forming a private company instead, to mature the technology further before any licensing decision. That became Vaxcellbio, founded in 2010 alongside a senior colleague, a microbiologist at Chonnam National University. In the earliest years, I divided my time roughly 70 percent clinical practice and 30 percent building the company, splitting my university laboratory's research capacity in much the same way, a balance that has evolved considerably as the company has grown.

That same period also placed me on the committee helping draft Korea's original cell therapy regulatory framework in 2005, which drew on Japanese, European and US precedent in forming Korea's own rules. Those rules were, in hindsight, quite restrictive for a decade or more, though as I will touch on later, that landscape is now genuinely evolving.

Drawing on this combined clinical and research background, Vaxcellbio's priority has never been theoretical or academic research alone, but developing immune cell and gene therapies capable of demonstrating meaningful efficacy and a strong safety profile in real clinical practice. We have built a diversified portfolio spanning NK cell therapy, CAR-T, CAR-MIL, in vivo CAR, and bispecific and trispecific antibodies, and are working to advance these rapidly into clinical development.

Beyond the corporate statement, what is Vaxcellbio's mission and positioning today?

Vaxcellbio's vision is "A Better Life through Cancer Immunotherapy." Our core mission is to develop innovative cancer immunotherapies, commercialise world-class advanced medical technology, and extend both the length and quality of patients' lives, with the ultimate goal of maximising the productivity and efficiency of therapeutic manufacturing so that cancer immunotherapy becomes genuinely more accessible.

To that end, we concentrate our R&D on cancers that respond poorly to existing therapy or carry a particularly poor prognosis, including hepatocellular carcinoma, gastric cancer, pancreatic cancer and small-cell lung cancer among solid tumours, alongside multiple myeloma in haematologic

malignancy. Built on our proprietary immune cell expansion and genetic engineering technology, we have developed integrated capability spanning research, preclinical work, clinical development and commercialisation, positioning ourselves as a specialised cell therapy company with genuinely differentiated technology in the global immuno-oncology market.

Vaxcellbio does not intend to remain a single-pipeline biotechnology company. Our ambition is to grow into a genuine platform company built around immune cell therapy broadly, spanning autologous NK cell therapy, CAR-MIL, dual CAR-T, CAR-NK, in vivo CAR, next-generation antibody platforms and DDS-based drug candidates, an R&D structure in which these platforms complement one another, allowing us to respond flexibly to a rapidly evolving therapeutic landscape while building a genuinely sustainable foundation for growth.

In cell and gene therapy specifically, reliable manufacturing and robust quality management matter just as much as scientific innovation. We have therefore built our Advanced Manufacturing Platform, AMP, connecting R&D for next-generation modalities directly through to clinical and, eventually, commercial-scale manufacturing, strengthening both the practical applicability of our technology and its commercial competitiveness. We regard AMP as essential to our evolution from an R&D-focused company into a fully integrated cell and gene therapy business with genuinely global manufacturing competitiveness.

Recent reform of Korea’s advanced regenerative medicine framework should mark an important turning point for the immune cell therapy sector more broadly, and Vaxcellbio, drawing on our clinical experience, GMP manufacturing capability and integrated platform, is positioning itself to respond proactively, while expanding hospital and research partnerships so more patients gain faster access to immune cell therapy. Globally, our ambition is to be recognised both as an innovative immune cell therapy platform company and as a fully integrated business connecting R&D, manufacturing, clinical development and commercialisation within a single value chain, expanding global partnerships and technology licensing while developing new business models, including CDMO services, to help lead innovation in the global immune cell therapy industry.

How do Vaxcellbio’s core platforms, from your third-generation NK cell technology to CAR-MIL and dual-target CAR-T, address the industry’s persistent bottlenecks?

Cell and gene therapy has advanced rapidly in recent years, yet several major challenges remain genuinely unresolved: limited durability of response, insufficient efficacy in solid tumours, complex manufacturing, and high production cost. Despite promising research, many cell therapies continue

to struggle with large-scale manufacturing, process standardisation and commercialisation specifically. Rather than relying on a single technology, we have deliberately built multiple complementary immune cell therapy platforms alongside integrated competitiveness spanning the full journey from R&D to manufacturing. Our NK cell platform originated, in fact, from an earlier dendritic cell vaccine programme, VAX-DC, which completed Phase I/II trials in refractory multiple myeloma around 2014 to 2015. Attending ASH shortly afterward, where CAR-T, bispecific antibodies and ADCs were being introduced as the field's next wave, prompted me to pause our planned Phase IIb dendritic cell trial and instead pursue two complementary directions: a broadly accessible cell therapy platform in NK cells, and genuinely innovative CAR-based platforms alongside it.

Our proprietary third-generation feeder cell-based NK cell platform uses internally developed feeder cell technology to substantially enhance both large-scale expansion and functional activity of NK cells, improving therapeutic efficiency and manufacturing productivity simultaneously. Research we published this year demonstrated NK cell expansion of up to 100,000-fold, providing a genuine foundation for reliably securing sufficient cell quantities for treatment. We have also established a manufacturing protocol producing patient-specific autologous NK cells within roughly 10 to 14 days, alongside cryopreservation technology, improving both treatment accessibility and commercial potential. These same third-generation NK cells are now being applied to next-generation CAR-NK development, through an actively progressing collaboration with a Canadian research group.

Beyond the cell platform itself, I consider what may matter even more is how these cells are deployed clinically, particularly in combination with existing standard-of-care treatment. That combination strategy draws directly on my dual background as both clinician and immunologist. In hepatocellular carcinoma, our protocol combines NK cell therapy with hepatic arterial infusion chemotherapy, and has produced genuinely strong results: roughly double the response rate and double the progression-free survival we had originally anticipated going into the trial. We are applying the same combination logic elsewhere, pairing NK cell therapy with a PD-L1 inhibitor in small-cell lung cancer, and with modified FOLFIRINOX-based chemotherapy in pancreatic cancer, where certain chemotherapeutic agents show genuine synergy with NK cell activity.

On the CAR side, CAR-MIL, VCB-1201, is, to our knowledge, the world's first CAR platform built on marrow-infiltrating lymphocytes rather than peripheral blood T cells. Conventional CAR-T has shown strong efficacy in haematologic malignancy but continues to struggle with long-term durability; in multiple myeloma specifically, existing marketed CAR-T therapies have shown

response rates approaching 90 percent initially, yet many patients relapse within twelve to 14 months, with somewhat longer durability, closer to 25 to 35 months, for newer-generation constructs. CAR-MIL is built on bone marrow-derived central memory T cells, which we believe offers superior in vivo persistence, stronger bone marrow homing, and more durable long-term anti-tumour immunity, while combining CAR-mediated targeting of a specific antigen with the broader, polyclonal endogenous T-cell response MILs bring against a wider range of tumour antigens, addressing antigen heterogeneity and antigen loss directly. We are currently preparing our IND filing for this programme.

For solid tumours, our Dual CAR-T, VCB-1204, targets PD-L1 and EphA2 simultaneously. EphA2 is broadly overexpressed across many tumour types, and our monobody-based targeting format is expected to support strong tumour penetration, while the PD-L1 arm both eliminates PD-L1-expressing tumour cells and helps counter immunosuppressive elements within the tumour microenvironment, such as regulatory T cells and myeloid-derived suppressor cells. Importantly, the PD-L1-binding component is engineered to dissociate after a defined period of engagement, reducing the risk of on-target, off-tumour toxicity against healthy PD-L1-expressing tissue. Together, these mechanisms are designed to minimise antigen escape while controlling toxicity, and we are preparing to file our IND for this programme as well, targeting initiation around the middle of next year.

We are also extending our CAR-NK platform beyond oncology into autoimmune disease, leveraging NK cells’ favourable safety profile and broad applicability, an area we expect to become an important future growth driver for the company.

Given how early-stage much of this pipeline is, how are you approaching clinical trial design, geographic sequencing and eventual commercialisation?

Our approach differs meaningfully across our NK cell and CAR platforms, reflecting where each stands developmentally. Disease geography plays a direct role in our thinking: hepatocellular carcinoma is heavily concentrated in East Asia, and Japan already reimburses certain NK cell-based treatment, making our regional focus a natural fit. NK cell therapy is also considerably less costly to manufacture than CAR-based therapy, which makes it particularly well suited to markets with real cost sensitivity; we have previously explored collaboration with partners in Vietnam, and see considerable long-term potential in extending access to lower-cost, high-quality immune cell therapy across the region more broadly.

Our Phase IIa hepatocellular carcinoma programme has so far been conducted entirely within Korea, comparing outcomes against historical controls given the combination design with hepatic arterial infusion chemotherapy. We recognise a fully randomised controlled design would strengthen this further, and we are now preparing exactly that within Korea. Should international regulators or partners require a more rigorous comparative dataset, we are fully prepared to pursue that path as our clinical strategy matures.

CAR-MIL and Dual CAR-T represent a different, earlier stage entirely, and we intend to begin their first-in-human trials in Korea specifically, which offers genuinely world-class clinical trial infrastructure; our own clinical team already participates in a wide range of internationally significant trials here. Once we have Phase I data in hand for these programmes, we would expect to pursue global licensing, following the same path many early-stage biotechs take, though we recognise that larger multinational partners generally prefer to engage at the earliest possible stage of clinical validation, which shapes how we think about timing those conversations.

Which international markets and partnership models are you prioritising to realise that global potential?

We are pursuing genuinely flexible, diversified partnership models to support our international expansion, exploring technology licensing, joint R&D and regional or global commercialisation agreements with biotechnology companies and research institutions worldwide.

This year, we entered a companion animal healthcare partnership with Lever Genetics in Taiwan, establishing a foundation for collaboration across Taiwan and other markets around Vaxleukin-15, our veterinary prescription immunotherapeutic, alongside veterinary immune diagnostics and immune-support products for companion animals. We are also conducting joint research with a Canadian group, both on CAR-NK development using our third-generation feeder cell technology and on bispecific antibody development.

In parallel, we are strengthening our position across Asian and global markets through a comprehensive global IP strategy, reflected in the registration of our anti-PD-L1 CAR-T patent in Japan, and we continue participating in major international partnering events, including BIO Korea, the BIO International Convention in the US, BIO Japan and CPhI China. Going forward, we intend to accelerate global commercialisation and technology transfer of our immune cell therapy platforms and antibody-based candidates considerably further.

What specific strengths of the Korean biotech ecosystem allow companies like Vaxcellbio to compete globally?

Korea offers a genuinely excellent environment for drug development and rapid clinical validation, underpinned by world-class clinical trial infrastructure, highly skilled medical professionals and government programmes supporting advanced regenerative medicine. Vaxcellbio has drawn directly on these strengths, advancing our technology through Korea Drug Development Fund-supported projects and industry-academia-research collaboration with local government, universities and research institutions.

The Hwasun Bio-Medical Cluster, also known as the Hwasun Vaccine Industry Special Zone, where Vaxcellbio is based, is one of Korea's leading biotechnology clusters, supporting the full biopharmaceutical development cycle from R&D and preclinical work through to clinical trials and GMP manufacturing, all within one region. In practice, this means Chonnam National University's research laboratories, our own GMP manufacturing facility, a dedicated Korean toxicology testing partner, and Chonnam National University Hwasun Hospital, focused specifically on cancer care and capable of running early-phase trials directly, all sit within a single, connected ecosystem, a genuinely rare model even by international standards, and one we believe compares favourably to comparable clusters in the US and Europe. Within this cluster, we have established a new integrated headquarters connecting research, manufacturing and commercialisation under one roof, securing an in-house value chain that meaningfully strengthens our supply chain competitiveness. While Hwasun itself sits outside Korea's major metropolitan centres, our Phase IIa NK cell trial was in fact conducted nationwide, across Seoul, Daegu, Busan and Gwangju, demonstrating that supply and logistics are not a constraint even from a regional manufacturing base; we have also explored comparable international capacity through a European manufacturing partner to support future overseas supply.

Korea's regulatory environment is itself evolving in ways that should benefit companies like ours. Many Korean patients have historically travelled to Japan or China to access cell therapy unavailable domestically under Korea's historically stringent framework, one I helped shape in its earliest form back in 2005. The government is now actively working to ease that regulatory environment, moving toward a model closer to Japan and Taiwan, both of which combine rigorous oversight with genuinely workable pathways for innovator-led trials, a deliberate contrast to China's considerably looser investigator-initiated trial framework, which allows hospital-approved trials without full government sign-off and has fuelled rapid, if less rigorously governed, cell

therapy development there. We believe Korea's more measured approach, matched with growing regulatory flexibility, will make domestic cell therapy access considerably easier for Korean patients in the years ahead, while preserving the scientific rigour international partners expect.

As a company listed on KOSDAQ since 2020, we are conscious of balancing the genuinely heavy cost of R&D against investor expectations for a credible commercial pathway. Our companion animal division has been an important part of that balance: Vaxleukin-15 is already commercially available to Korean veterinary hospitals, and we are actively working to expand that business internationally, alongside other pharmaceutical distribution activity within the company, as we build toward the point where our core oncology pipeline reaches Phase I data and, we hope, a meaningful global licensing opportunity within the next two to three years.

What is the core message you want to leave with international stakeholders about Vaxcellbio's future?

Vaxcellbio aims to become a genuine game changer in the global immune cell therapy market, built on a strong scientific foundation, robust clinical data and continuous technological innovation. While rapidly advancing commercialisation of our flagship Vax-NK pipeline, we are equally focused on demonstrating meaningful progress across our next-generation programmes, CAR-T, CAR-NK, CAR-MIL, in vivo CAR and bispecific and trispecific antibodies alike.

Looking further ahead, we have recently brought on a partner with deep expertise in bispecific and trispecific antibody development and drug delivery systems, recognising that our future competitiveness depends on pairing cell therapy with genuinely innovative drug platforms, not cell therapy alone. We have also begun our own in vivo CAR development programme, an area where early results from an Australian group in multiple myeloma have been genuinely compelling, and where we believe meaningful opportunity remains for a company willing to invest early. Between in vivo CAR and our bispecific and trispecific antibody work, we see our next major growth pipeline taking shape, one we believe is capable of carrying Vaxcellbio from a strong domestic platform into a genuinely global one.

Through these efforts, we aim to give patients facing difficult-to-treat cancers genuinely new opportunities for life, while growing into a trusted biotechnology company that delivers sustainable value to global partners and shareholders alike.

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