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With the right expertise and collaborative spirit, there is no reason why Hong Kong should not be a leader in advanced cell therapies.

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A long-standing figure in Hong Kong's haematology landscape, Professor Kenny Lei has played a pivotal role in advancing lymphoma care and cellular therapies over the past three decades. His contributions span the early adoption of autologous peripheral blood stem cell transplantation and active involvement in establishing the city's first hospital-based CAR-T research programme in university teaching hospital, an initiative shaped by scientific discipline, institutional collaboration, and clinical necessity.

How has your clinical and academic background shaped your approach to treating haematological malignancies in Hong Kong?

My professional journey has been deeply rooted in the field of haematological malignancies, with a particular emphasis on lymphomas – one of the most prevalent and clinically diverse cancers in Hong Kong, consistently ranking among the top ten. I currently serve as the consultant at Prince of Wales Hospital (PWH) and hold an honorary associate professorship at the Chinese University of Hong Kong, (CUHK) where my academic and clinical work spans translational research, clinical trials, and patient care. We see new lymphoma referrals each week, including aggressive, low-grade, and region-specific subtypes, reflecting the heterogeneity and clinical complexity of the

disease in this part of the world.

My early training began in medical oncology, but over time I expanded into haematology. In 1995, I was fortunate to receive a scholarship that enabled me to spend a year in laboratory research and haematology fellowship training at the University of Minnesota. There, I had the privilege of working with Dr Harry S Jacob MD, then the President of the American Society of Haematology (ASH) in 1998– and Dr Gregory Vercellotti MD, gaining hands-on experience in both laboratory science and bone marrow transplantation. That period proved foundational to my later work in cellular therapies.

Upon returning to Hong Kong, I joined forces with Professor Nicholas Wickham, Senior Lecturer, Department of Clinical Oncology, CUHK, to establish a comprehensive haematology oncology and transplant programme at PWH. While allogeneic transplantation was considered the gold standard at the time, our efforts focused on autologous transplantation using peripheral blood stem cell collections, a far less invasive and more resource-conscious alternative. This approach allowed us to avoid traditional marrow harvesting under general anaesthesia, offering a more accessible option for local patients. With the support of Professor Philip Johnson, Chairman, Department of Clinical Oncology, CUHK, mentor and enduring friend, we established the second adult centre in Hong Kong to provide this form of transplantation for patients with blood cancer and solid tumors.

The complexity of lymphoma has only deepened with the advent of molecular diagnostics, which have revealed the disease to be a collection of distinct subtypes rather than a single entity. This has driven a paradigm shift towards personalised treatment strategies tailored to individual molecular profiles. In my view one of the most transformative advances in this space has been immunotherapy, in particular, the development of chimeric antigen receptor T-cell (CAR-T) therapy. The story of CAR-T cell therapy goes back a little more before it was approved for clinical use. I vividly recall the Special-interest Session on Chimeric Antigen Receptor Driven Immunotherapy at the ASH Annual Meeting in December 2013, which brought together leading scientists and clinicians, to present exciting early data on CAR-T cell therapy in patients with advanced lymphoma and leukaemia, including the inspiring case of Emily Whitehead, the first paediatric patient in the world to receive CAR-T cell therapy, who remains thriving and cancer-free.

The science behind CAR-T is profoundly compelling. Using genetic engineering technology, we are able to reprogramme a patient’s own T cells to express specific receptors that recognise and eliminate tumour cells. As long as an appropriate target can be identified, the modified cells can be directed with remarkable precision, offering a powerful new approach to otherwise refractory blood cancers. Clinical trials have since validated this approach in leukaemia, lymphoma and myeloma,

opening new therapeutic frontiers that were unimaginable just a decade ago.

What were your first impression about with CAR-T therapies, and how did you help bring this treatment to Hong Kong?

My initial encounter with CAR-T therapy at the ASH Annual Meeting in 2013 was both inspiring and sobering. The clinical outcomes, particularly for patients with relapsed or refractory haematological malignancies who had exhausted all other treatment options, were extraordinary, offering real hope where little had previously existed. At the same time, the reality of implementation quickly came into focus – how could we deliver this in Hong Kong, and more pressingly, how could this expensive therapy be funded and made accessible to the public? The financial burden was significant, and without a clear funding or reimbursement mechanism, even proven efficacy risked being inaccessible.

After attending the ASH Meeting, I presented the data at our journal club and stressed the importance of local preparedness. Soon after, CUHK launched a CAR-T research initiative led by Professor Li Chi Kong, a paediatric haematologist. Given that the majority of eligible patients would be adults with lymphoma, I joined the project as co-investigator. Working closely with the Hong Kong Institute of Biotechnology (HKIB) and with strong institutional support, we developed a local study protocol, secured advanced cell processing equipment, and navigated a challenging regulatory landscape. Despite delays brought on by the COVID-19 pandemic, we obtained full approval from local regulatory bodies and launched our clinical study in the summer of 2023, establishing Hong Kong’s first hospital-based CAR-T clinical trial using CAR-T cells domestically manufactured at our own GMP laboratory facility.

How did your exposure to commercial CAR-T therapies influence the design and implementation of your local programme in Hong Kong?

Before initiating our own CAR-T platform, I had clinical exposure to commercially available products such as tisagenlecleucel and axicabtagene ciloleucel. While the therapeutic results were promising, particularly for patients with limited treatment options, these therapies came with distinct and often severe toxicities, primarily cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). Unlike conventional chemotherapy, these side effects frequently required intensive monitoring and, in some cases, critical care support. Initially, the

toxicity profiles were daunting, but over time, international collaboration and published guidelines, particularly from the European Society for Blood and Marrow Transplantation (EBMT), significantly improved our ability to manage these complications effectively.

Anticipating similar challenges in Hong Kong, I led a comprehensive institutional effort to prepare for the safe integration and launching of CAR-T therapies. This involved the development of clinical guidelines, standardised protocols, detailed training materials, and cross-departmental engagement with emergency physicians, ICU teams, transplant colleagues, and nurses. It was essential to ensure that everyone involved in patient care, which ranged from cell collection, CAR-T cells infusion, and to the management of potential complications, understood their roles and were confident in managing the risks. We also established a quality management framework to formalise safety measures and procedural consistency. Our quality management system for CAR-T cell therapy received high praise from experts during a recent successful hospital accreditation process under China's International Hospital Accreditation Standards.

To deepen my clinical insight, I spent one month at The University of Texas MD Anderson Cancer Centre, observing the operational nuances of their CAR-T programme. This hands-on experience proved instrumental in shaping our own approach, which was ultimately endorsed by hospital leadership and driven forward by a committed, well-trained multidisciplinary team.

What clinical or logistical challenges led you to pursue a hospital-based CAR-T solution tailored to Hong Kong?

Fundamentally, this initiative was driven by a deep passion for science and a desire to go beyond routine clinical care in search of more effective treatments. While I have always found meaning in patient interactions, it is the pursuit of better solutions through research, innovation, and translational science that sustains my professional motivation. Although commercial CAR-T therapies are available internationally, their adoption in Hong Kong faces significant logistical and financial constraints. Most CAR-T products require fresh cells as starting material for manufacturing. This is a big hurdle for long distant shipping of cells across the continent. Thus, commercial product that allows cryopreservation of cells before processing is currently the only option available in Hong Kong. Most importantly, patients may have rapid disease progression and are unable to receive their CAR-T cells in time due to the long waiting period in manufacturing overseas.

These constraints highlighted the need for a local, clinically viable alternative, one that could offer shorter turnaround times, reduced costs, and logistical proximity to patients. Establishing our own CAR-T platform was not only our dream and a scientific challenge, but a necessary step in ensuring that our patients would not be excluded from cutting-edge therapies due to geographic or economic limitations. As part of the initial proof-of-concept, I volunteered as the first blood donor, followed by Professor Li Chi Kong and Dr Raymond Wong. The results demonstrated that our laboratory at HKIB could successfully re-engineer our blood cells to CAR-T cells.

Ultimately, this project reflects our commitment to building sustainable, high-quality, and regionally relevant therapeutic solutions. With the right expertise, infrastructure, and collaborative spirit, we are in a position to be a leader in the development and delivery of advanced cell therapies.

How has your trial progressed in terms of eligibility criteria, patient enrolment, and early clinical outcomes?

Since initiating our clinical trial in June last year, we have enrolled five patients, including three adults. While this number may appear limited when compared to larger cohorts overseas, it reflects the nuanced landscape of patient participation in Hong Kong. Each candidate is offered the choice between enrolling in the trial or receiving a commercially available therapy. As a research protocol, we are obliged to inform patients that our treatment remains investigational. This transparency, though essential, often deters participation, particularly within the more risk-averse cultural context of the local community. Unlike in the US, where clinical trials are frequently embraced and seen as opportunities, patients here may hesitate, fearing they are being used as test subjects.

Nonetheless, we succeeded in recruiting adult participants, supported by a broader eligibility framework than that of current commercial options. For instance, tisagenlecleucel is approved only for patients under 25 with relapsed acute lymphoblastic leukaemia, whereas our trial includes adult patients up to 65, provided they are clinically fit. Similarly, for B-cell lymphomas, our protocol accommodates a wider range of subtypes so long as the patient has failed at least two lines of standard therapy.

Though still in its early stages, the trial has yielded encouraging results. Our first case, a patient with relapsed, refractory leukaemia, achieved complete molecular remission with minimal residual disease negativity. All three adult patients remain in remission, and importantly, we have demonstrated that locally manufactured CAR-T cells are both feasible and clinically effective. The

treatment has been well tolerated, with only mild toxicities observed. While extended follow-up is required, these early findings offer meaningful validation of our scientific approach and confirm the potential of locally developed cell therapy solutions.

How do you evaluate the relative merits of autologous stem cell transplantation and CAR-T therapy in the current treatment landscape specially in comparison to stem cell transplantation?

The increasing adoption of CAR-T therapy has prompted a meaningful re-evaluation of autologous stem cell transplantation (ASCT), particularly in the context of relapsed or refractory high-grade lymphomas. In the US, three pivotal Phase III randomised controlled trials have compared CAR-T with the standard of care approach, typically involving ASCT following chemotherapy. Of these, axicabtagene ciloleucel and lisocabtagene maraleucel demonstrated favourable outcomes and have since been approved for second-line use. In contrast, tisagenlecleucel, the only commercial CAR-T product currently available in Hong Kong, did not show superiority in its corresponding trial – a result that inevitably shapes local decision-making.

While CAR-T therapy has emerged as a transformative option, I continue to regard ASCT as an effective and more cost-conscious strategy for eligible patients. Transplant-related toxicities are well characterised and generally manageable, with mortality rates now below five percent. Moreover, engraftment typically occurs within 11 to 12 days, after which patients often stabilise rapidly and require relatively minimal follow-up. By contrast, CAR-T involves significant downstream toxicities. Patients may experience prolonged cytopenia, B-cell aplasia, or immune deficiency, necessitating extended monitoring, transfusions, treatment of infections, and intravenous immunoglobulin support. These long-term requirements – alongside the substantial cost of the therapy itself – add considerably to the overall burden, both for patients and healthcare systems.

Importantly, ASCT does not preclude subsequent CAR-T intervention. On the contrary, it allows us to reserve this high-cost, high-intensity therapy for those who genuinely need it after transplant failure. In that sense, ASCT continues to represent a sound first approach for our patients in Hong Kong, being clinically effective, operationally familiar, and economically sustainable. Given its proven track record and lower systemic impact, I would advocate for its use as the preferred second-line option where appropriate, while positioning the logistically challenging and expensive CAR-T as a powerful and necessary resource when transplant is no longer viable.

What is your long-term vision for advancing locally developed CAR-T research in Hong Kong?

Our ultimate goal, shared with Professor Li Chi Kong, is to expand upon this initial proof of concept and transition our work into a broader clinical and translational research platform. While the CAR construct used in our current study reflects an earlier generation of design, the real achievement lies in proving our capability to develop, manufacture, and deliver cell therapy safely and effectively within Hong Kong. We have shown that the expertise, infrastructure, and regulatory readiness are already in place, which opens the door to more advanced collaborations with academic innovators and biotechnology companies developing next-generation constructs or novel targets.

Moving forward, we hope to position ourselves as a clinical partner of choice for testing new therapies, not only in haematological malignancies, but also in solid tumours such as lung, breast, and colorectal cancers, which continue to account for high cancer incidence and mortality rates. While many therapies exist for these indications, outcomes remain suboptimal for a significant subset of patients. The opportunity to apply “living drug” technologies in these areas could represent a major step forward, and we are ready to support such efforts with the clinical rigour and operational capacity they require.

Although our current role is grounded in research and clinical delivery, there is also a broader ambition to contribute to a locally developed, regionally relevant CAR-T platform. Should the opportunity arise to create a “Made in Hong Kong” therapeutic product by Hong Kong scientists, it would be an extraordinary achievement, which I would be proud to support. As a graduate of the CUHK, playing a part in shaping a high-impact, local innovation ecosystem is both a professional responsibility and a personal honour.

What future do you envision for your CAR-T platform, and how could it complement existing commercial therapies in clinical practice?

Although our trial is ongoing, the aim is ultimately to demonstrate that this locally developed CAR-T therapy can serve as a viable and complementary option alongside commercial alternatives. The greatest limitation at present is slow patient enrolment, largely driven by cultural hesitancy around clinical trials. Despite our efforts to raise awareness, many patients remain reluctant to participate,

often due to concerns about being treated as experimental subjects. However, if we succeed in completing the study and the data are promising, there would be a strong case for formal recognition of this approach, particularly given its cost-effectiveness and operational advantages.

Among its most distinctive strengths is the two-week turnaround time from cell collection to infusion, which significantly impacts both patient outcomes and system efficiency. In many current settings, patients wait weeks before receiving commercial CAR-T products, during which time disease progression can outpace treatment readiness. Bridging therapies are often required, expensive, time-consuming, and frequently ineffective. By contrast, our approach not only reduces this waiting period but allows patients to begin conditioning therapy almost immediately. This not only alleviates clinical risk but also offers psychological reassurance, reinforcing the sense that they are actively undergoing treatment. On a systemic level, it saves hospital beds, reduces reliance on interim therapies, and optimises use of limited healthcare resources.

If supported by strong data, this model could be adopted under a hospital exemption framework, as seen in parts of Europe, offering physicians and patients a domestically available, faster, and potentially more economical alternative. Rather than replacing commercial CAR-T therapies, our platform would offer another option, tailored to local needs and healthcare realities. We also remain open to future collaboration with industry to support trials of emerging constructs, including those targeting solid tumours such as lung, breast, or colorectal cancer.

As clinicians, we believe in understanding every available therapeutic “vehicle” and using that insight to guide personalised, evidence-based decisions. Whether developed locally or abroad, any therapy that expands access and improves outcomes is worth pursuing, and we are ready to play our part in advancing that mission.

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