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It is not only about developing what we find scientifically interesting, but also about understanding what potential partners are looking for

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Developing effective CAR-T therapies for T-cell malignancies remains one of the most technically challenging frontiers in cell therapy. Dr Lin Yang of PersonGen Biotherapeutics discusses the companyâ??s progress with its CD7-targeted CAR-T programme, its strategy to translate complex cell therapies into viable commercial products, and how PersonGen is repositioning its pipeline toward next-generation platforms such as in vivo CAR-T and NK-cell engagers. He also reflects on the lessons learned from building a science-driven biotech and the growing importance of global partnerships as the field evolves.

What progress has PersonGen made with its CD7-targeted CAR-T programme since we last met in 2023, and where does the platform stand today?

CD7 remains the central focus of our work at PersonGen. Our lead candidate, PA3-17, is an autologous CD7-targeted CAR-T therapy for patients with relapsed or refractory T-cell malignancies, including T-cell acute lymphoblastic leukaemia and lymphoblastic lymphoma (T-ALL/LBL) as well as related T-cell lymphomas. The programme reflects our long-standing commitment to a particularly challenging area of cell therapy. While most approved CAR-T products today target B-cell malignancies, applying CAR-T technology to T-cell cancers is far more complex. The key difficulty lies in the biology of the target itself: CD7 is expressed not only on malignant T cells but also on normal T cells, creating the risk of â??fratricideâ?•, where engineered CAR-T cells attack one

another during manufacturing. Our approach addresses this by blocking CD7 expression during the production process, enabling the generation of functional CAR-T cells capable of targeting CD7-positive disease.

Clinically, the programme has advanced significantly. PA3-17 has received Breakthrough Therapy Designation from Chinaâ??s NMPA and is currently being evaluated in a pivotal Phase II study in China. Our objective is to complete the key clinical work in 2026 and, if the results are supportive, move toward a regulatory filing in early 2027. Given the Breakthrough designation and the high unmet need in this setting, there may be a pathway to conditional approval without conducting a traditional Phase III trial. Early clinical reporting, including presentations at ASCO (PLEASE PUT THE YEAR), has shown encouraging signals in patients with relapsed or refractory T-ALL/LBL, with the recommended Phase II dose already established.

Although the patient population is smaller than in B-cell malignancies, the medical need remains substantial. T-cell cancers have a far less developed treatment landscape. In B-cell disease, physicians now have access to a broad range of approaches, including monoclonal antibodies, ADCs, bispecific antibodies, CAR-T therapies, and targeted small molecules. By contrast, patients with many T-cell malignancies still rely largely on chemotherapy, with few effective second-line options. Epidemiologically, T-cell subtypes account for less than 15 percent of non-Hodgkin lymphoma in Western populations, though the incidence is somewhat higher in parts of Asia, and they represent around 15 percent of paediatric and roughly 25 percent of adult cases of acute lymphoblastic leukaemia.

Operationally, the pivotal study is progressing steadily. Our statistical planning suggests that approximately 35 patients could support a potential filing under a conditional approval pathway. Six patients have already been treated and more than ten are currently entering the trial, with recruitment moving smoothly, in part because patients in this setting have very limited therapeutic alternatives. The study is being conducted across 15 hospitals in mainland China. At the same time, we are advancing a paediatric programme toward a Phase I study in China and exploring a potential IND filing with the FDA. Establishing a regulatory pathway in the United States remains important, particularly as other CD7-directed programmes, including those from Wugen Therapeutics, are already entering clinical development there.

How is PersonGen addressing the manufacturing and commercialisation challenges associated with bringing a complex CAR-T therapy such as PA3-17 to market?

As PA3-17 advances toward potential approval, a central question is how to translate a technically complex therapy into a sustainable commercial model. CAR-T therapies require far more than clinical efficacy alone. They depend on specialised manufacturing infrastructure, reliable supply chains, and strong commercial networks capable of supporting hospital-based treatment delivery. At PersonGen, we have invested early in internal manufacturing capabilities. Through our subsidiary PersonGen-Anke, we operate a CAR-T production facility in Hefei that enables us to control much of the process internally, from plasmid generation and lentiviral vector production to CAR-T cell manufacturing within a GMP environment. This level of vertical integration allows us to manage production quality, timelines, and cost more effectively as the programme progresses through clinical development.

Our commercial strategy reflects the different realities of global markets. In China, where PA3-17 is currently being developed, we have the technical capacity to manufacture the therapy ourselves, but commercialisation would likely benefit from a partner with an established sales force and market

access capabilities. In the United States, however, developing and commercialising a CAR-T therapy would almost certainly require collaboration with a partner that already has clinical development, regulatory, and commercial infrastructure in place. For this reason, we actively participate in international partnering forums such as the J.P. Morgan Healthcare Conference, where biotechnology companies engage with pharmaceutical partners and investors to explore licensing opportunities and strategic collaborations.

Pricing dynamics also differ significantly between markets. In China, the manufacturing cost structure for CAR-T therapies is considerably more competitive than in the United States. Currently approved CD19 CAR-T therapies in China are priced at roughly one million yuan per treatment, which is substantially lower than the several hundred thousand dollars typically associated with CAR-T therapies in the US. With our existing manufacturing platform, we believe we could remain competitive within this environment while maintaining a viable cost structure once PA3-17 reaches the market.

From a clinical and regulatory perspective, early response data play an important role in Chinaâ??s approval pathway for therapies addressing serious diseases with high unmet need. In some CAR-T studies, the overall response rate at three months has served as a key registration endpoint. In our Phase I study, we have already observed that around 20 percent of treated patients achieved complete remission lasting more than two years following a single CAR-T infusion after lymphodepletion. Although the dataset remains limited and longer follow-up is ongoing, these results are encouraging in a disease setting where therapeutic options remain scarce. At the same time, the global partnering landscape has shifted, with large pharmaceutical companies increasingly focusing on newer modalities such as in vivo cell therapies, T-cell engagers, and antibodyâ??drug conjugates. In this context, our immediate priority is to advance PA3-17 toward approval in China, generate sustainable cash flow, and then explore opportunities to expand into other regions, including parts of the Middle East and Asia-Pacific, where regulatory authorities may recognise approvals granted by Chinaâ??s NMPA.

How has PersonGenâ??s pipeline evolved beyond CD7, and what strategic priorities are shaping its next phase of development?

Our pipeline has evolved through a process of learning, not simply expansion. Several years ago, we recognised that autologous CAR-T, while powerful, also has structural limitations, which led us in 2018 to begin work on an allogeneic programme based on gamma-delta T cells, with a particular focus on the VÎ´1 subset. We believed this approach could offer important biological advantages in an off-the-shelf setting, and we advanced our lead candidate, UTAA09, an allogeneic anti-CD19 CAR-VÎ´1 T-cell therapy, into clinical development for relapsed or refractory B-cell malignancies. However, the early human data did not show the level of efficacy we felt was necessary. That was an important lesson for us. In the end, the market does not reward a programme simply because it is allogeneic or technically interesting. It still has to deliver clinical performance that is competitive, and that experience made us more disciplined in how we allocate resources.

That discipline is one reason in vivo CAR-T has become a more important direction for us over the past three years. We chose to pursue a lentiviral approach because we believe persistence and efficacy will ultimately determine whether in vivo CAR-T can become a meaningful alternative to conventional ex vivo cell therapy. Other delivery systems, such as messenger ribonucleic acid lipid nanoparticles, may offer certain safety advantages, but their expression is transient, which may limit durability. Lentiviral delivery may offer stronger and more sustained activity, although it also raises important questions around targeting and safety. Our approach is designed to transduce resting T

cells efficiently without the need for strong activation, which we believe could help reduce some of the safety risks seen elsewhere in the field. We have already begun an investigator-initiated trial, the first patient has been treated, and while the initial safety observations are encouraging, we remain cautious. Our earlier experience with allogeneic CAR-T reinforced how differently a programme can perform in patients compared with preclinical models, so we prefer to move step by step and let the clinical data guide us.

We are initially applying the in vivo CAR-T platform in settings where the biology is already well understood. The first concept targets CD19 in B-cell leukaemias and lymphomas, where ex vivo CD19 CAR-T has already validated the target and provides a logical basis for proof of concept. We are also exploring a bispecific in vivo CAR-T approach for autoimmune disease, designed to address both pathogenic B cells and pathogenic T cells. In that setting, one component targets CD19, while the other is directed toward PD-1 positive T cells. The rationale is that autoimmune disease is often driven not only by B cells but also by activated pathogenic T cells, so a broader immunological approach may be needed. At the same time, we recognise that safety expectations in autoimmunity are far more demanding than in oncology, which means this area will require careful research and cannot be advanced too aggressively.

That same concern around safety is also behind our interest in natural killer cell engagers (NKCEs), which represent a third platform for us. Rather than recruiting T cells, these molecules recruit NK cells through CD16A, with the aim of eliminating pathogenic immune cells in a potentially more controlled manner. We are exploring constructs against targets such as CD19 and PD-1, including trispecific formats intended to address pathogenic B cells and T cells simultaneously. Taken together, our strategy is pragmatic. PA3-17 remains the programme that could generate the first commercial revenue for PersonGen, while in vivo CAR-T and NKCEs represent the next stage of the companyâ??s development. They are earlier, but if the data are strong, they could open the door to future partnerships and broader strategic opportunities.

After more than a decade building PersonGen largely around internal research, how are you approaching partnerships and business development today?

Part of the explanation reflects my own background. I was trained as a scientist, and like many scientist-founders the early years of PersonGen were driven primarily by the goal of solving a specific scientific problem. In our case that meant committing strongly to the CD7 CAR-T programme and focusing our resources on making that technology work. When a company is built around a scientific challenge, it is natural to concentrate on advancing the asset itself rather than thinking first about external partnerships or positioning the platform for collaboration. Over time, however, we realised that building a sustainable biotechnology company requires a broader perspective. It is not only about developing what we find scientifically interesting; it is also about understanding what potential partners are looking for and how our capabilities can complement theirs. PersonGen has strong early-stage research and development capabilities, and collaboration with multinational or mid-sized pharmaceutical companies can be an important way to translate that strength into broader impact.

This realisation has gradually changed how we engage with the global industry. Over the past year I have become more active in international partnering meetings such as BIO-Europe and the BIO International Convention, as well as the J.P. Morgan Healthcare Conference. These forums are important because they allow us not only to present our science but also to better understand how potential partners evaluate technologies and where collaboration opportunities may exist. For a company like PersonGen, participating in these discussions is an important step toward positioning

our platforms more effectively and building the partnerships that will support the next stage of growth.

For multinational companies evaluating potential partnerships, what does PersonGen believe it can offer as a collaborator?

The biotechnology environment in China is extremely competitive, and that reality has influenced how we think about partnerships. In such a landscape, it is not realistic for a company to try to do everything alone, so the key question becomes how to differentiate technology in a meaningful way. At PersonGen, we are focusing on areas where we believe we can contribute real technical value. For our in vivo CAR-T platform, for example, one of the main priorities is addressing safety while maintaining strong therapeutic activity. In autoimmune disease, we are exploring strategies that could provide improved safety compared with existing immune-modulating approaches. Rather than positioning ourselves purely around speed, our goal is to develop assets that solve important technical problems and therefore create a stronger basis for collaboration.

At the same time, our discussions with potential partners have made it clear that expectations across the industry have become more demanding. Companies increasingly want to see clear biological evidence before entering serious partnerships, ideally early human data or at least strong non-human primate data. For this reason, one of our main priorities for 2026 is to generate early clinical data for the in vivo CAR-T platform and robust non-human primate data for our NK-cell engager programme. If those results are sufficiently convincing, they can support more substantive business development discussions. Despite the funding challenges currently affecting the biotechnology sector, we remain confident that the efficiency of research and development in China, combined with relatively competitive costs, will allow companies like PersonGen to engage more actively with global partners and expand beyond the domestic market.

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