OriCell's GPC3 CAR-T Receives NMPA Clearance for Confirmatory Phase II Trial in Late-Line Advanced Hepatocellular Carcinoma

SHANGHAI, June 8, 2026 — OriCell Therapeutics Holdings Limited (The "Company" or "Oricell") , today announced that its proprietary GPC3-targeted autologous CAR-T therapy, Ori-C101, has received clearance from China's National Medical Products Administration (NMPA) to proceed into a confirmatory Phase II clinical trial in patients with GPC3-positive advanced hepatocellular carcinoma (HCC). The study is designed as a prospective, randomised, open-label, multi-centre registration trial evaluating the efficacy and safety of Ori-C101 in patients who have failed two or more prior lines of therapy.

This marks the first GPC3-directed immune cell therapy anywhere in the world to enter a confirmatory trial, and the first CAR-T product for a liver cancer indication to reach a Phase II randomised controlled study — a milestone that underscores China's potential to lead the next wave of innovation in cell therapy for solid tumours.

HCC, a disease with few options at the late line

Hepatocellular carcinoma is among the most prevalent malignancies globally, with China alone accounting for roughly 410,000 new cases and 317,000 deaths each year. For patients whose disease has progressed through both immune checkpoint inhibitors (ICI) and tyrosine kinase inhibitors (TKI), options are essentially exhausted: existing second-line agents were developed for patients intolerant of, or progressing on, first-line sorafenib, and nothing has been approved beyond that point. The unmet need is acute.

Phase I data of Ori-C101: robust efficacy and manageable safety

Results from the Phase I BEACON study were featured as an oral presentation at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting, which recently wrapped up in Chicago, drawing significant attention from the oncology community. All enrolled patients had failed at least two prior lines of therapy, including both TKI and ICI treatment.

Key results:

Objective response rate (ORR): 50% across the evaluable population; 66.7% in the recommended Phase II dose (RP2D) cohort; 100% in the highest dose cohort (DL4)

Speed of response: 89% of responders had already achieved objective response by their first post-infusion assessment, with marked tumour shrinkage

Overall survival (OS): Median OS of 21.4 months in the overall population; 12-month survival rate of 69.3% — more than double the roughly 10.6-month historical median seen

with available second-line agents, heralding a potential new era of long-term survival for patients with advanced HCC

Safety: Cytokine release syndrome (CRS) was manageable; no immune effector cell-associated neurotoxicity syndrome (ICANS) or off-target toxicity was observed, and tolerability was favourable across the study population

Notable case: One patient achieved partial response at first assessment, progressed to complete response by month four, and remains in remission at 24 months

Mechanism and broader potential

GPC3 (Glypican-3) is overexpressed in more than 70% of hepatocellular carcinomas, as well as in gastric cancer, lung squamous cell carcinoma, and ovarian clear cell carcinoma — making it a highly specific and compelling target for cancer therapy. Ori-C101 is engineered to identify and eliminate GPC3-positive tumour cells with precision, drawing on two proprietary platforms: Ori®Ab (AI-assisted antibody discovery and engineering) and Ori®Armoring (structure-enhanced cell platform).

Ori-C101's profile has the potential to support use in earlier lines of treatment, and GPC3's expression across multiple tumour types provides a strong scientific rationale for future indication expansion. As the confirmatory trial advances, the goal of treatment in advanced HCC has the potential to shift from controlling disease to achieving durable remission — or even cure.

Principal investigators

The confirmatory Phase II study is a nation-wide, multi-centre trial co-led by Professor Fan Jia (Academician of the Chinese Academy of Sciences and Honorary President of Zhongshan Hospital, Fudan University) and Professor Qin Shukui (Qiantang Scholar and Professor at Nanjing Tianyinshan Hospital, China Pharmaceutical University).

In a joint statement, the two investigators said: "In our earlier work on late-line advanced HCC, the BEACON study delivered important progress. GPC3 is specifically overexpressed in HCC and represents an ideal therapeutic target, yet GPC3-directed CAR-T approaches have historically been constrained by the immunosuppressive tumour microenvironment. BEACON was designed precisely to break through that barrier and find a new, accessible path for patients who have exhausted their options. The preliminary results from this novel 'armoured' GPC3 CAR-T construct — showing strong objective response rates with a manageable safety profile — not only address an evidence gap in late-line refractory HCC but offer broader lessons for innovative immune cell therapies in solid tumours. We look

forward to the Phase II randomised controlled study, and to obtaining the expected results under rigorous scientific design, comprehensive management, and strict quality control."

OriCell co-founder, Chairman and Chief Executive Officer Dr. Yang Huanfeng commented: "We are deeply grateful to the NMPA Centre for Drug Evaluation and relevant government authorities for their strong support of innovative drug development, and to Academician Fan, Professor Qin and their teams for their trust and active participation. This approval validates the scientific soundness and feasibility of our technology platform and marks a new stage of growth for OriCell. With a clear regulatory pathway now in place, we will push forward with Ori-C101's confirmatory clinical development, with the aim of bringing a genuinely new treatment option to patients as quickly as we can. We believe this progress will also underpin China's strategy for taking innovative medicines global and competing actively in international markets."

About OriCell Therapeutics

OriCell Therapeutics is a clinical-stage, globally oriented biotechnology company committed to pioneering cancer immunotherapy. Focused on addressing unmet medical needs in oncology and immunology, the company has built a robust pipeline spanning both solid and haematological tumours, powered by three proprietary technology engines: Ori®AB (AI-assisted antibody discovery and engineering), Ori®Armoring (structure-enhanced cell platform), and Ori®OnGo (classic, rapid, and in vivo manufacturing platform). The company's clinical translation capabilities have earned broad international recognition, with multiple data readouts selected for oral presentations at leading conferences including ASCO and EHA, and published in top-tier journals such as *The Lancet Haematology*. OriCell is accelerating its global expansion, driven by a commitment to continuous innovation and the ambition to bring new hope to cancer patients worldwide. For more information, please visit www.oricell.com.

Forward-Looking Statements

This press release contains forward-looking statements. These statements are not historical facts, but rather predictions about future events based on the beliefs, assumptions, and information currently available to the management of OriCell Therapeutics Holdings Limited (the "Company"). Words and phrases such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "plan," "potential," "predict," "project," "should," "target," "will," "would," and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. Such statements involve known and unknown risks, uncertainties, and

other important factors that could cause the Company's actual results, performance, or achievements to differ materially from those expressed or implied. Any forward-looking statements contained in this press release speak only as of the date of this release. The Company wishes to clarify that this announcement is intended solely to communicate research and clinical development progress, is for reference by healthcare professionals only, is not promotional in nature, and does not constitute a recommendation for the use of any unapproved drug or indication.

全球首个｜原启生物 GPC3 CAR-T 产品获 NMPA 批准开展 II 期确证性临床试验

【中国，上海– 2026 年 6 月 8 日】全球创新肿瘤免疫疗法领军企业 Oricell Therapeutics Holdings Limited (下称“原启生物”或“Oricell”或“公司”) 今日宣布，其自主研发的靶向 GPC3 嵌合抗原受体自体 T 细胞注射液（代号：Ori-C101）已获得中国国家药品监督管理局 (NMPA）批准同意，可进入针对 GPC3 阳性晚期末线肝细胞癌（HCC）的 II 期确证性临床试验。该研究是一项前瞻性、随机对照、开放标签、全国多中心的注册临床试验，旨在评估 Ori-C101 用于既往接受过二线及以上治疗失败的晚期肝细胞癌患者的有效性和安全性。

据公开信息，这是全球首个进入确证性临床试验的靶向 GPC3 免疫细胞疗法，也是首个针对肝癌适应症进入 II 期确证性随机对照临床研究的 CAR-T 疗法，标志着中国在实体瘤细胞治疗领域实现了从"跟跑"到"领跑"的重要跨越，这也意味着 Ori-C101 有望成为全球首款治疗肝癌的 CAR-T 疗法。

未被满足的临床需求：晚期肝癌二线治疗后无药可用、困境严峻

肝细胞癌是全球高发的恶性肿瘤，在中国尤为严峻，年新发病例约 41 万，死亡病例约 31.7 万。对于已接受免疫检查点抑制剂（ICI）以及酪氨酸激酶抑制剂（TKI）治疗后失败进展的晚期肝癌患者，目前临床上缺乏行之有效的治疗手段。现有的二线治疗药物都是仅仅用于一线采用索拉非尼不耐受或者治疗发生进展的，而三线及以上治疗在全球范围内仍缺乏标准方案，临床亟需突破性疗法。Ori-C101 的 I 期数据优异：兼具高缓解率与长生存获益优势近日刚刚闭幕的 2026 年美国临床肿瘤学会（ASCO）年会上，Ori-C101 的 I 期临床研究（BEACON）结果以口头报告形式公布了令人振奋的数据，引起业界高度关注。该研究入组患者均为至少二线治疗失败（全部接受过 TKI+ICI 治疗）的晚期肝癌患者。

关键数据如下：

客观缓解率（ORR）：受试者总人群中达到 50%；其中，推荐 II 期剂量（RP2D）组 ORR 为 66.7%，而最高剂量组（DL4）ORR 高达 100%；

缓解速度：89%的应答者在输注后首次评估即获得客观缓解，肿瘤显著缩小；

总生存期（OS）：总人群中 mOS 达到 21.4 个月，12 个月生存率为 69.3%；较现有二线治疗药物的历史数据（mOS 约 10.6 个月）直接翻倍，标志着晚期肝癌患者有望迈入"长生存"时代；

安全性：研究中细胞因子释放综合征 (CRS) 可控，且未观察到免疫效应细胞相关神经毒性综合征（ICANS）及脱靶毒性，受试者耐受性良好；

典型病例：观察到 1 例深度缓解病例，于首次评估时即获得部分缓解 (PR)，第 4 个月时达到完全缓解 (CR)，缓解持续时间已达 24 个月，目前仍在持续获益

Ori-C101 的科学机制与广阔前景

GPC3（磷脂酰肌醇蛋白聚糖-3）在超过 70%的肝细胞癌中呈现高表达，同时在胃癌、肺鳞癌以及卵巢透明细胞癌等多种实体瘤中亦有明显表达，是极具潜力的抗肿瘤治疗特异性靶点。Ori-C101 通过独特的 Ori®Ab（AI 抗体发现与工程平台) 和 Ori®Armoring (结构增强型细胞平台), 能够高效识别并杀伤 GPC3 阳性的肿瘤细胞。基于上述初步的优异数据，Ori-C101 可能为末线肝癌患者提供了全新的治疗选择，且具备向早期治疗线序推进的重要潜力。随着后续关键性确证临床试验的启动，肝癌的治疗策略有望从"控制和延缓疾病进展"迈向"追求长期缓解乃至治愈"。此外，GPC3 靶点在多瘤种中的广泛表达，为 Ori-C101 未来拓展新的适应症奠定了科学基础。顶级专家领衔，共筑抗癌新防线。

樊嘉 院士　　秦叔逵 教授

Ori-C101 治疗肝癌的 II 期确证性临床研究，将由中国科学院院士、复旦大学附属中山医院樊嘉教授，与钱塘学者、中国药科大学附属南京天印山医院秦叔逵教授共同牵头，全国多中心协作开展。两位专家表示："在既往针对末线治疗晚期难治性肝癌的探索中，BEACON 研究取得了重要进展。众所周知, GPC3 在肝癌中呈特异性高表达，是肝癌治疗

的理想靶点，但针对 GPC3 的 CAR-T 疗法过去主要受困于肿瘤的免疫抑制微环境，始终难以取得理想疗效。BEACON 研究的初衷，正是为了突破这一技术瓶颈，给多种治疗失败的末线难治性肝癌患者寻找一条全新的、可及的生存之路。令人振奋的是，该款新型 '装甲化' GPC3 CAR-T 制剂初步显示出了优异的客观缓解率，且安全性可控，不仅填补了晚期末线难治性肝癌治疗的证据空白，也为实体瘤的免疫细胞创新疗法提供了重要启迪。现在，Ori-C101 的 II 期随机对照临床试验即将开展，期望在科学设计、全程管理和严格质控下，获得预期的结果。”

原启生物联合创始人、董事长兼首席执行官 杨焕凤博士表示

"衷心感谢国家药品监督管理局药审中心以及政府相关部门对于我们进行创新药物研发的大力支持，同时感谢樊嘉院士、秦叔逵教授及其团队给予的充分信任和积极参与。此次 Ori-C101 获批进入 II 期确证性临床试验，不仅有力地验证了公司技术平台的科学性与可行性，也标志着原启生物迈入了全新的成长阶段。随着监管路径的明确，我们将全力推进 Ori-C101 的确证性临床开发，力争早日为患者带来新的突破性治疗选择。我们相信，有关进展也将为中国创新药践行'出海'战略、角逐全球市场竞争提供坚实的支撑。"

关于原启生物

原启生物是一家处于临床阶段的生物技术公司，致力于成为全球肿瘤免疫疗法领域的先锋开拓者。公司专注于开发创新型细胞疗法，以解决肿瘤学与免疫学中亟待满足的临床需求。依托自主构建的三大技术引擎——Ori®AB AI 抗体发现与工程平台）、Ori®Armoring

（结构增强型细胞平台）及 Ori®OnGo（经典/快速/in vivo 工艺平台），原启生物系统性突破了实体瘤治疗的技术壁垒，并成功建立了涵盖实体瘤与血液瘤的丰富产品管线。公司的临床转化能力已获国际学术界高度认可：多项早期及注册临床试验验证了卓越的安全性与抗肿瘤活性，相关成果连续多次入选美国临床肿瘤学会（ASCO）、欧洲血液学协会（EHA）等国际顶尖学术会议口头报告，并发表于《柳叶刀·血液学》（Lancet Haematology）等权威期刊。原启生物正加速推进全球化布局，致力于通过持续的技术创新，为全球肿瘤患者带来新的希望。了解更多信息，请访问官网：www.oricell.com。

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