

### 收案中試驗

計畫編碼	計畫中/英文名稱	計畫英文名稱	計畫主持人
42756493BLC3001	有關 Erdafitinib 相較於 Vinflunine 或 Docetaxel 或 Pembrolizumab 使用於帶有選定 FGFR 基因變異之晚期泌尿上皮癌受試者的一項第 3 期試驗	A Phase 3 Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Subjects with Advanced Urothelial Cancer and Selected FGFR Gene Aberrations	黃國埕
CACZ885V2201C	一項以 canakinumab 或 pembrolizumab 單一療法或合併療法用於可手術切除之非小細胞肺癌受試者，做為術前輔助治療的隨機分配、開放標記、第 II 期試驗 (CANOPY-N)	A randomized, open-label, phase II study of canakinumab or pembrolizumab as monotherapy or in combination as neoadjuvant therapy in subjects with resectable non-small cell lung cancer (CANOPY-N)	邱倫瑋
CT4005	開放標示、隨機對照第三期臨床試驗評估 EndoTAGR-1 併用 paclitaxel 及 gemcitabine 相較於 paclitaxel 併用 gemcitabine 作為內臟轉移性三陰性乳癌之第一線治療的療效與安全性	An open-label, randomized, controlled phase III trial evaluating the efficacy and safety of EndoTAGR -1 in combination with paclitaxel and gemcitabine compared to paclitaxel and gemcitabine as first-line therapy in patients with visceral metastatic tripl	鍾奇峰
D3615C00001	一項第 III 期雙盲隨機分配試驗，對於在芳香酶抑制劑治療期間或之後復發或惡化之局部晚期（無法手術）或轉移性的荷爾蒙受體陽性，人類表皮生長因子受體 2 陰性 (HR +/HER2-) 乳癌，評估 Capiasertib + Fulvestrant 相較於安慰劑 + Fulvestrant 治療的療效和安全性 (CAPItello-291)	A Phase III Double-blind Randomised Study Assessing the Efficacy and Safety of Capiasertib + Fulvestrant Versus Placebo + Fulvestrant as Treatment for Locally Advanced(Inoperable) or Metastatic Hormone Receptor Positive, Human Epidermal Growth Factor Receptor 2 Negative(HR+/HER2?) Breast Cancer Following Recurrence or Progression On or After Treatment with an Aromatase Inhibitor (CAPItello-291)	鍾奇峰
MK3475-756	一項以 Pembrolizumab 或安慰劑併用前導性化學療法和輔助性內分泌療法，治療高風險早期雌激素受體陽性、第 2 型人類表皮生長因子受體陰性 (ER+/HER2-) 乳癌的隨機分配、雙盲、第三期臨床試驗 (KEYNOTE-756)	A Randomized, Double-Blind, phase III study of pembrolizumab versus placebo in combination with neoadjuvant chemotherapy and adjuvant endocrine therapy for the treatment of high-risk early-stage estrogen receptor-positive, human epidermal growth factor re	鍾奇峰

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MK3475-966	一項隨機分配、雙盲、第三期試驗比較Pembrolizumab加上Gemcitabine/Cisplatin相較於安慰劑加上Gemcitabine/Cisplatin作為第一線療法用於晚期且/或無法切除膽管癌的受試者	A phase 3 randomized, double blind study of pembrolizumab plus Gemcitabine/Cisplatin versus placebo plus Gemcitabine/Cisplatin as first-line therapy in participants with advanced and/or unresectable biliary tract carcinoma	陳新炫
MK-3475-975	一項針對接受合併主程性放化療的食道癌患者，比較Pembrolizumab (MK-3475) 相較於安慰劑的隨機分配、雙盲、安慰劑對照之第三期臨床試驗 (KEYNOTE975)	A randomized, double-blind, placebo-controlled phase 3 trial of pembrolizumab (MK-3475) versus placebo in participants with esophageal carcinoma receiving concurrent definitive chemoradiotherapy (KEYNOTE975)	邱倫璋
MK7339-009	在患有局部復發無法手術或轉移性三陰性乳癌 (TNBC) 的受試者接受一線化療併用Pembrolizumab，誘導臨床效益後，比較Olaparib併用Pembrolizumab與化療併用Pembrolizumab的一項開放性、隨機分配、第2/3期試驗 (KEYLYNK-009)	An Open-label, Randomized, Phase 2/3 Study of Olaparib Plus Pembrolizumab Versus Chemotherapy Plus Pembrolizumab After Induction of Clinical Benefit With First-line Chemotherapy Plus Pembrolizumab in Participants With Locally Recurrent Inoperable or Metas	鍾奇峰
OBI-822-011	一項以adagloxad simolenin (OBI822) /OBI821治療高風險早期三陰性乳癌患者 (定義為接受前導性化療後有殘餘侵襲性疾病，或有 $\geq 4$ 處腋下淋巴結呈陽性) 的第三期、隨機分配、雙盲、安慰劑對照試驗	A phase III, randomized, double-blind, placebo controlled study of adagloxad simolenin (OBI822) /OBI821 treatment for high risk early stage triple negative breast cancer patients, defined as residual invasive disease following neoadjuvant chemotherapy or $\geq 4$ positive axillary nodes	鍾奇峰
ODO-TE-B202	一項Teseaxel 加上三種不同PD- (L) 1 抑制劑用於三陰性、局部晚期或轉移性乳癌病患與Teseaxel單一療法用於HER2陰性、局部晚期或轉移性乳癌老年病患的多中心、第2期試驗	A multicenter, phase 2 study of teseaxel plus three different PD- (L) 1 inhibitors in patients with triple-negative, locally advanced or metastatic breast cancer and teseaxel monotherapy in elderly patients with her2 negative, locally advanced or metastatic breast cancer	鍾奇峰

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OOTR-N016/KBCRN-B-003/HT-PAB	在患有可手術治療、荷爾蒙受體陽性且為人類表皮生長因子受體2 (HER2) 陰性之原發性乳癌女性中，比較荷爾蒙療法加上Palbociclib以及荷爾蒙療法加上安慰劑的一項第三期、隨機分配、雙盲、新輔助性試驗	A phase III randomized, double-blind, neoadjuvant study of hormonal therapy plus palbociclib versus hormonal therapy plus placebo in women with operable, hormone sensitive and Her2-Negative primary breast cancer	鍾奇峰
PCYC1141	一項針對從未接受過治療的濾泡型淋巴瘤受試者，給予布魯頓酪氨酸激酶 (BTK) 抑制劑Ibrutinib 併用 Rituximab，相較於安慰劑併用 Rituximab 之多中心、隨機分配、雙盲、安慰劑對照的第3期試驗	A Multicenter, Randomized, Double-blind, Placebo-controlled Phase 3 Study of the Bruton's Tyrosine Kinase (BTK) Inhibitor, Ibrutinib, in Combination with Rituximab versus Placebo in Combination with Rituximab in Treatment Naive Subjects with Follicular Ly	邱倫瑋
WO41554	一項第二期、隨機分配、雙盲、安慰劑對照試驗，針對罹患PIK3CA-突變、荷爾蒙受體-陽性、HER2-陰性之局部晚期或轉移性乳癌病患評估GDC-0077併用PALBOCICLIB和FULVESTRANT相較於安慰劑併用PALBOCICLIB和FULVESTRANT的療效與安全性	A phase III, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of GDC-0077 plus palbociclib and fulvestrant versus placebo plus palbociclib and fluvestrant in patients with PIK3CA-MUTANT, hormone receptor-positive, her2	鍾奇峰
WO42133	一項針對雌激素受體陽性且HER2陰性、未經治療早期乳癌的停經後女性患者，評估GDC-9545併用PALBOCICLIB相較於ANASTROZOLE併用PALBOCICLIB的療效、安全性及藥物動力學之隨機分配、多中心、開放性、雙組、第二期、前導輔助性試驗	A randomized, multicenter, open-label, two-arm, phase II, neoadjuvant study, evaluating the efficacy, safety and pharmacokinetics of GDC-9545 plus palbociclib compared with anastrozole plus palbociclib for postmenopausal women with estrogen receptor-positive and HER2-negative untreated early breast cancer	鍾奇峰