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Oncology focus

YOUR ACTIVE INVOLVEMENT IN DRUG DEVELOPMENT

Dear Doctor/ Oncologist,

Welcome to our 5th issue of oncology newsletter of the Phase 1 Clinical Trial Centre! Your support is important to us and we hope to keep you in touch with our early-phase oncology research activities and facilitate the referral process. Please feel free to contact us if you are interested in referring patients to any of our studies.

Active early-phase studies

Title	Type of Study	PI/ contract	Disease sites
A Phase 1 Study of BLU-554 in Patients With Hepatocellular Carcinoma	1	Chan Lam (l_chan@clo.cuhk.edu.hk)	HCC
Phase 1/2 Study of LOXO-292 in Patients With Advanced Solid Tumors, RET Fusion-Positive Solid Tumors, and Medullary Thyroid Cancer	1	Herbert Loong (h_loong@clo.cuhk.edu.hk)	NSCLC, Medullary Thyroid Cancer, Colon Cancer, Solid Tumor
Study of Safety and Efficacy of Ceritinib in Combination With Nivolumab in Patients With ALK-positive Non Small Cell Lung Cancer	1	Herbert Loong (h_loong@clo.cuhk.edu.hk)	Lung
Study of EGF816 in Combination With Selected Targeted Agents in EGFR-mutant NSCLC	1	Herbert Loong (h_loong@clo.cuhk.edu.hk)	Lung
Safety And Efficacy Of LAG525 Single Agent And In Combination With PDR001 In Patients With Advanced Malignancies	1,2	Brigette Ma (brigette@clo.cuhk.edu.hk)	RCC, Melanoma, Mesothelioma, Lung
Safety and Efficacy of MAK683 in Adult Patients With Advanced Malignancies	1,2	Brigette Ma (brigette@clo.cuhk.edu.hk)	NPC, ovary, lymphoma, Prostate.C
Phase Ib/II Study of INC280 + PDR001 or PDR001 Single Agent in Advanced HCC	1b,2	Chan Lam (l_chan@clo.cuhk.edu.hk)	HCC
A Study of PF-06463922 An ALK/ROS1 Inhibitor In Patients With Advanced Non Small Cell Lung Cancer With Specific Molecular Alterations	1b,2	Herbert Loong (h_loong@clo.cuhk.edu.hk)	Lung
Phase Ib/II Study of MCS110 in Combination With PDR001 in Patients With Advanced Malignancies	2	Brigette Ma (brigette@clo.cuhk.edu.hk)	TNBC, Pancreas, Melanoma, Endometrium
Phase 1/2 Study Of TAS-120 In Patients With Advanced Solid Tumors Harbouring (FGF/FGFR)-Aberrations	2	Chan Lam (l_chan@clo.cuhk.edu.hk)	Cholangiocarcinoma
A Phase 1/2, Open-label, Multicenter Study of the Combination of NKTR-214, Nivolumab, and Other Anti-Cancer Therapies in Patients with Select Locally Advanced or Metastatic Solid Tumor Malignancies	2	Herbert Loong (h_loong@clo.cuhk.edu.hk)	Various Cancer Types

Forthcoming early-phase studies

Expected date of study recruitment	Title	Type of Study	PI/ contract	Disease sites
End of Jun 2019	Study of Safety and Efficacy of Novel Immunotherapy Combinations in Patients With Triple Negative Breast Cancer (TNBC)	1	Brigette Ma (brigette@clo.cuhk.edu.hk)	TNBC
Late Jul/ Early Aug 2019	Study of Safety and Efficacy of DKY709 Alone or in Combination With PDR001 in Patients With Advanced Solid Tumors.	1	Brigette Ma (brigette@clo.cuhk.edu.hk)	NSCLC, Melanoma, NPC, MSS-CRC, TNBC
End of 2019	G1T38, a CDK 4/6 Inhibitor, in Combination With Osimertinib in EGFR-Mutant Non-Small Cell Lung Cancer	2	Tony Mok (tony@clo.cuhk.edu.hk)	Lung

For details about inclusion criteria of each study, please refer to http://www.clo.cuhk.edu.hk/eng/comprehensive-cancer-trials-unit/current-trials/ .You are encouraged to contact the PI (see email above) or Phase 1 Clinical Trial Centre (p1ctc@cuhk.edu.hk) before making a medical referral. Thanks!

Seamless design in phase 1 oncology trials with multiple expansion cohorts

In the latest issue of Journal of the National Cancer Institute (J Natl Cancer Inst, 2019:111: djy196), the Clinical Trials Design Task Force of the National Cancer Institute's Investigational Drug Steering Committee formed a working group, which reviewed the challenges for seamless phase 1 trials. Of the 1786 early-phase trials enrolling 57 559 adult patients that were presented at ASCO meetings form 2006-2015, 51 of the *trials (2.9%)* investigated 50 investigational new drugs, were seamless, and accounted for 14.6% of the total patients. The seamless trials included a median of 3 (range: 1–13) expansion cohorts. The overall risk of clinically significant treatment-related adverse events (grade 3–4) was 49.1%. Although rapid expansion of seamless phase 1 trials may lead to earlier drug approval, the taskforce cautioned that such designs must adhere to established ethical, scientific, and statistical standards. Protocols should include prospectively planned analyses of efficacy in disease- or biomarker-defined cohorts of sufficient rigor to support accelerated approval.

> "Seamless design in phase 1 trials must adhere to established ethical, scientific and statistical standards."

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