YOUR ACTIVE INVOLVEMENT IN DRUG DEVELOPMENT

Dear Doctor/ Oncologist,



Welcome to our 4th 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 earlyphase oncology research activities and facilitate the referral process. Please feel free to contact us using the links below if you are interested in referring patients to any of our studies.

Oncology focus

Oncology early-phase studies

Active Recruitment:

For details about inclusion criteria of each study, please refer to http://www.clo.cuhk.edu.hk/cctu/trials_phase1.html You are encouraged to contact the PI (see email below) or Phase 1 Clinical Trial Centre (p1ctc@cuhk.edu.hk) before making a medical referral. Thanks!

Status	Title	Type of Study	PI/ contract	Disease sites
Active	A phase I/II, multicenter, open-label study of oral FGF401 in adult patients with hepatocellular carcinoma or solid malignancies characterized by positive FGFR4 and KLB expression	1,2	Chan Lam (I_chan@clo.cuhk. edu.hk)	НСС
Active	A phase I/II, multicenter, open-label study of MAK683 in adult patients with advanced malignancies	1,2	Brigette Ma (brigette@clo.cuhk .edu.hk)	NPC, ovary, lymphoma, RCC
Active	A phase Ib/II, open-label, multi-center study of INC280 in combination with PDR001 or PDR001 single agent in advanced hepatocellular carcinoma	1	Chan Lam (I_chan@clo.cuhk. edu.hk)	НСС
Active	A Phase 1 Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of BLU-554 in Patients with Hepatocellular Carcinoma	1	Chan Lam (I_chan@clo.cuhk .edu.hk)	НСС
Active	A multi-center, open -label study to assess the safety and efficacy of combination ceritinib (LDK378) and nivolumab in adult patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC)	1	Herbert Loong (h_loong@clo.cu hk.edu.hk)	Lung
Active	Phase 1/2 Study of PF-06463922 (An ALK/ROS1 Tyrosine Kinase Inhibitor) in Patients with Advanced Non-Small Cell Lung Cancer Harboring Specific Molecular Alterations	1b, 2	Herbert Loong (h_loong@clo.cu hk.edu.hk)	Lung
Active	A Phase I/II, open label, multicenter study of the safety and efficacy of LAG525 single agent and in combination with PDR001 administered to patients with advanced malignancies	1,2	Brigette Ma (brigette@clo.cuhk .edu.hk)	RCC, mesothelioma, melanoma, lung
Active	A phase Ib/II, open-label, multi-center study of INC280 in combination with PDR001 or PDR001 single agent in advanced hepatocellular carcinoma	1b, 2	Chan Lam (I_chan@clo.cuhk. edu.hk)	нсс

Further strengthening our phase 1 efforts through strategic partnership and collaborations

Dear Colleagues,

Thank you for your support to our oncology phase 1 clinical trials efforts throughout the last three years. We have continued to gain momentum in developing our phase 1 capabilities by increasing our active clinical trials portfolio, and with your assistance with referrals, have also seen an increase in patient numbers. We are continuing to look to expand our efforts in the early clinical trials arena by capitalizing our status as a referral centre for oncology clinicals trials in the territory, as well as being a China Food & Drug Administration (CFDA) accredited phase 1 centre.

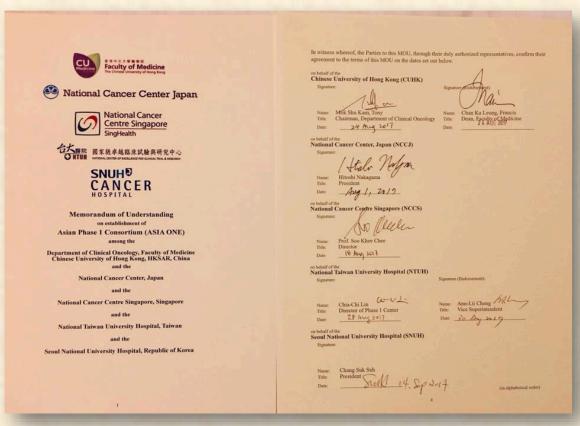


Dr. Herbert Loong, Deputy Medical Director of P1CTC, CUHK

Looking forward, I am pleased to inform you that we have recently signed a Memorandum of Understanding between four other eminent phase 1 clinical trials units in the region, namely National Cancer Center Japan (NCC Japan), National Taiwan University Hospital (NTUH), National Cancer Centre Singapore (NCCS), and Seoul National University Hospital (SNUH), to form the Asian Oncology Early Phase 1 Consortium. Our mission is to increase the awareness and interests of developmental therapeutics in oncology in the Asia-Pacific region, and to collectively take on suitable early phase trials with a specific Asian focus.



Asian Oncology Early Phase 1 Consortium Business Meeting held at ESMO Asia 2017, November 2017, Singapore



Memorandum of Understanding signed by all founding members of the Asian Phase 1 Consortium

I have had the opportunity to present Hong Kong's and specifically CUHK's phase 1 capabilities at the recent 2nd National Cancer Center Hospital Workshop on Methods in Oncology & Phase 1 Trials and Translational Research held at NCC Japan earlier in July 2017, and I believe that has helped us consolidate our presence in the phase 1 arena both as a region, and as an institution. Education and professional development are also key components to this strategic partnership, and we look forward to organizing workshops and preceptorships for our colleagues in other academic centres or in the community.

Dr. Herbert Loong
Deputy Medical Director of P1CTC, CUHK



Herbert Loong (CUHK), Toshio Shimizu (NCC Japan) and Daniel Tan (NCCS) as invited faculty at the 2nd NCCH Workshop on Methods in Oncology & Phase 1 Trials, July 2017