ISSUE 02, MAY 2015

YOUR ACTIVE INVOLVEMENT IN DRUG DEVELOPMENT

Dear Doctor/ Oncologist,
Welcome to our second 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 using the links below if you are interested in referring patients to any of our studies.

Oncology focus

Oncology early-phase studies under recruitment

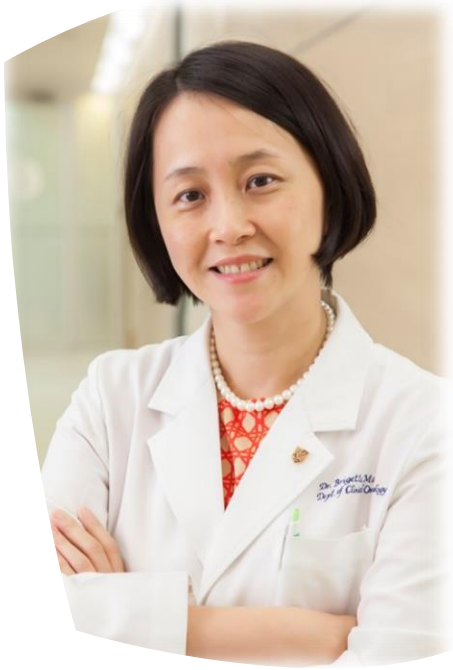
For details about inclusion criteria of each study, please refer to http://www.clo.cuhk.edu.hk/cctu/trials_phase1.html.
You are encouraged to contact the PI (see email below) or Phase 1 Clinical Trial Centre (p1ctc@cuhk.edu.hk) before making a medical referral. Thanks!

1. **Advanced NSCLC with EGFR mutation (LUN070):**
   - Inclusion: Age ≥ 18, ECOG 0-1, locally advanced or metastatic (Stage IIIB not eligible for definitive chemo-radiotherapy, Stage IV, or recurrent) NSCLC
   - Contact of PI (for doctors only): Prof. Brigette Ma (brigette@clo.cuhk.edu.hk)

2. **HCC or solid malignancies characterized by positive FGFR4 and KLB expression (ACT006):**
   - Inclusion: Age ≥ 18, ECOG ≤ 1.
   - Contact of PI (for doctors only): Dr. Chan Lam Stephen (l_chan@clo.cuhk.edu.hk)

3. **Recurrent or metastatic EGFR wild-type with high c-MET expression NSCLC (ACT004):**
   - Inclusion criteria: Age ≥ 18, ECOG 0-1, patients should not receive more than three prior lines of antineoplastic therapy for NSCLC.
   - Contact of PI (for doctors only): Prof. Brigette Ma (brigette@clo.cuhk.edu.hk)

4. **Recurrent or metastatic HER2 negative hormone positive breast cancer in post-menopausal women (BRE028)**
   - Inclusion criteria: Age ≥ 18, ECOG 0-1, patient not received more than one chemotherapy line for advanced breast cancer. Radiological or objective evidence of recurrence or progression on or after the last systemic therapy prior to randomization.
   - Contact of PI (for doctors only): Prof. Brigette Ma (brigette@clo.cuhk.edu.hk)



Prof. Brigette MA, Medical Director of P1CTC, CUHK

ASCO Policy Statement Update: The Critical Role of Phase 1 Trials in Cancer Research and Treatment

"NEWER META-ANALYSES OF PATIENTS' RESPONSE RATES IN PHASE 1 TRIALS IN CANCER HAVE FOUND HIGHER RATES OF EFFECTIVENESS..... RESPONSE RATES BETWEEN 5% AND 18% IN PHASE 1 TRIALS IN CANCER ARE EQUIVALENT TO THE RESPONSE RATES FOR MANY FDA-APPROVED DRUGS."

Phase 1 clinical trials now offer a greater potential for clinical benefit than in the past because molecular screening of study subjects for suitable treatment.

"It is critical that patients have the opportunity to make informed decisions about participating in phase 1 trials as part of their cancer treatment, given the potential for these trials to provide clinical benefit….", quoted from the updated policy statement on Phase 1 cancer trials *(Weber J, et al. JCO 2015; 33(3): 278-284)*.

The updated policy has 5 recommendations targeting the 5 main stakeholders, namely payers, professional societies and patient advocacy organizations, clinicians, researchers, and biopharmaceutical industry and other trial sponsors, in clinical trials:

- Improve payers' coverage of routine patient costs in phase 1 trials
- Improve patients' and clinicians' understanding of goals of phase 1 trials
- Increase number of patients who enroll onto phase 1 trials
- Increase researcher and trial sponsor compliance with best practices for phase 1 trials
- Increase biopharmaceutical industry support of pediatric phase 1 trials

Full policy can be viewed from below:
http://jco.ascopubs.org/content/33/3/278.full.pdf+html

Your feedback on how we improve our service is important to us.
We respect your privacy, if you do not wish us to send you this newsletter again, please let us know.

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