**Background**

- The EGFR family plays an important role in the mediating growth factor signaling and is related with cell proliferation, migration, and survival.
- A strong correlation has been found between solid tumors with high levels of EGFR and HER2 and poor prognosis.

**HM781-36B** is an orally active, irreversible pan-HER inhibitor.

**HM781-36B** showed an anti-cancer activity in several cancer cell lines, including epidermal growth factor receptor (EGFR) resistant variants in preclinical studies.

Two phase I studies were conducted to determine the maximum tolerated dose (MTD) in patients with advanced solid tumor.

**Preclinical data**

- HM781-36B is an orally active, pan-HER inhibitor showed an anti-cancer activity in several lung cancer cell lines and xenograft model.
- Anti-cancer activities to various subtypes of HER receptor suggest the therapeutic potential of HM781-36B.

**Study design**

- Two phase I studies were conducted in patients with advanced solid tumor.
- Pooled results of NSCLC patients from the two studies were used for this analysis.

**Clinical activity**

- 27 NSCLC patients were enrolled.
- 26 patients had been treated with previous EGFR TKI.
- 20 patients were heavily pretreated (24 regimens, 74.1%) and 6 patients were treated 3 regimens previously.

**Demography**

- Among all enrolled patients, 1 patient with T790M and exon 19 deletion had PR and treatment lasted 15 months.
- All patients achieved PR were treated at least 4 months.
- 26 patients had been treated with previous EGFR TKI.
- Two HM781A were orally active, pan-HER inhibitors and showed marked clinical activity in a phase I study on NSCLC harboring EGFR mutation.

**Safety**

- Most of grade 3 drug related adverse events were dermato.
- Grade 4 adverse event was not observed.

**Conclusion**

- HM781-36B was tolerable and showed evidence of efficacy in NSCLC patients in two phase I studies.
- HM781-36B showed PR in T790M and heavily treated patients, and efficacy lasted several months in some patients.

**References**

2. Chua M et al. *J Int Cancer* 2012, 130, 2454-54

**Acknowledgement**

We would like to thank all of the participating patients and their families, as well as study coordinators of the all study sites.

**Study sites participated:**

Seoul National University Hospital, Seoul National University Bundang Hospital

**This study was sponsored by Hanmi Pharmaceutical.**

Clinical Trial.gov identifier: NCT01455584