HUTCHISON CHINA MEDITECH LTD

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# Hutchison China Meditech Limited ("Chi-Med") (AIM: HCM)

## Chi-Med plans to broaden clinical trials of its leading oncology drug candidate

- **US FDA gives Chi-Med permission to amend its HMPL-002 Investigational New Drug (IND) clinical protocol from patients receiving radiation therapy alone to now include the much larger patient population undergoing concurrent platinum-based chemoradiotherapy.**

Chi-Med today announces that, following the FDA's recent permission to amend its HMPL-002 IND, work will begin to prepare for a broadening of its US phase I/II clinical trials on its leading oncology drug candidate (HMPL-002). Chi-Med plans to expand HMPL-002 trials to a patient population undergoing concurrent radiation therapy and platinum-based chemoradiotherapy, rather than as up to now only among the much smaller patient population receiving radiation therapy alone.

**Christian Hogg, CEO of Chi-Med, said:**

*"This is good news. Widening the universe among which we can conduct clinical trials will make it easier and speedier to recruit trial patients. More fundamentally, it broadens the future market potential for this important drug candidate."*

HMPL-002 is a botanical extract intended for use as an orally administered radiosensitiser and is under development for the treatment of head and neck cancer and non-small cell lung cancer in patients undergoing radiotherapy. Current US Phase I/II clinical trials of HMPL-002 are as a radiosensitiser administered in locally advanced HNC cancer patients receiving radiation therapy alone.

Chi-Med has been actively looking to broaden the potential market for HMPL-002 by pursuing the development for concomitant use with platinum-based chemoradiotherapy that is now considered the standard treatment for most locally advanced HNC patients.

**Dr. A. Trotti, a leading HNC radiation oncologist from the H. Lee Moffitt Cancer Center in Tampa said:**

*"Radiation therapy, used as a single modality, is no longer the sole treatment choice for locally advanced HNC patients who are not s uitable for surgical resection; platinum-based*

*regimens concurrently administered with conventional radiation have become a preferred standard for many patients in recent years. There is, however, still a need to improve outcomes in patients with locally advanced HNC (the 3-year survival estimate for Cisplatin concurrent with radiation is only about 40%). Integrating new radiation sensitisers into concurrent combined-modality programs is an active area of investigation for this patient group."*

HMPL-002 achieves its radiosensitising effect by reducing hypoxic conditions within the tumour cells, thus increasing the tumour's response to radiation. This biological effect is mediated by inhibition of multiple cellular metabolic pathways in tumour cells such as the regulation of oxygen homeostasis.

HMPL-002 is already a marketed radiosensitiser in China and indicated for concurrent use with radiotherapy to treat lung, esophageal and head and neck cancer. Multiple trials from phase I-III were conducted in China from 1993-1998 on over 3,000 human subjects, which demonstrated the treatment's efficacy and safety in the Chinese population and were the basis for its final market approval in China by the State Food and Drug Administration in 1998.

**Dr. Samantha Du, Chi-Med's Chief Scientific Officer said:**

*"We are excited about the FDA's permission to amend our HMPL-002 IND protocol. This amendment allows us to further investigate this promising drug candidate in a much larger patient population where there is a clear unmet need."*

Squamous cell carcinoma of the head and neck is a major public health problem with approximately 40,000 new cases of head and neck cancer occurring in the US in 2005. Improving the outcome for patients with locally advanced head and neck carcinomas by rational modification of radiation fractionation regimens or combinations of radiation with chemotherapy has been the subject of intensive clinical investigation for more than three decades. There is still a major unmet medical need for further improvements in the current treatment. Although the conventional or hyperfractionated radiation therapy is applied to almost all locally advanced HNC patients, the local-regional control rate and long-term survival benefit still remain unsatisfactory to the medical community.

**Ends**

**Enquiries**

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## About Chi-Med

Chi-Med is the holding company of a pharmaceutical and healthcare group based primarily in China and is listed on the Alternative Investment Market of the London Stock Exchange.

Chi-Med conducts pharmaceutical research and development of botanical drugs, semi-synthetic natural product drugs, and synthetic single chemical entity drugs through its wholly owned Hutchison MediPharma subsidiary. Hutchison MediPharma aims to bring novel drugs to the global market for the treatment of cancer and auto-immune diseases by using modern drug discovery and development technologies and clinical standards that meet the requirements of ICH guidelines.

Chi-Med is majority owned by Hutchison Whampoa Limited, an international corporation listed on the Main Board of the Hong Kong Stock Exchange.