

(Incorporated in Hong Kong with limited liability)

(Stock Code: 013)

## **OVERSEAS REGULATORY ANNOUNCEMENT**

Please refer to the attached announcement of Hutchison China MediTech Limited, which is listed on the Alternative Investment Market operated by the London Stock Exchange and a 71.6% owned subsidiary of Hutchison Whampoa Limited.

As at the date of the announcement, the Directors of Hutchison Whampoa Limited are:

### **Executive Directors:**

Mr. LI Ka-shing (*Chairman*) Mr. LI Tzar Kuoi, Victor (*Deputy Chairman*) Mr. FOK Kin-ning, Canning Mrs. CHOW WOO Mo Fong, Susan Mr. Frank John SIXT Mr. LAI Kai Ming, Dominic Mr. KAM Hing Lam

### **Non-executive Directors:**

Mr. George Colin MAGNUS Mr. William SHURNIAK

### **Independent Non-executive Directors:**

The Hon. Sir Michael David KADOORIE
Mr. Holger KLUGE
Mr. William Elkin MOCATTA (Alternate to The Hon. Sir Michael David Kadoorie)
Mr. OR Ching Fai, Raymond
Mr. WONG Chung Hin

Hong Kong, 2 July 2007



# Hutchison China MediTech Limited ("Chi-Med")

## (AIM: HCM)

## Chi-Med Announces Positive Phase II Proof-of-Concept Data for HMPL-004 in Ulcerative Colitis

London, Monday, 2 July 2007: Chi-Med, the Hutchison Whampoa backed pharmaceutical and healthcare Group, today announces positive results for its Phase II proof-of-concept study for HMPL-004 in mild-to-moderate Ulcerative Colitis, a form of inflammatory bowel disease. The trial met its objective in that HMPL-004 was well tolerated and showed an equivalent drop in clinical symptom score to the comparator drug, Mesalazine, the current first-line standard of care in mild-to-moderate Ulcerative Colitis.

The Phase II proof-of-concept study, conducted by Chi-Med's wholly-owned drug R&D subsidiary, Hutchison MediPharma Limited ("Hutchison MediPharma"), was a multicenter, randomized, double-blind, comparator study of 120 patients with mild-tomoderate Ulcerative Colitis conducted in China. The study evaluated HMPL-004 at 400mg taken three times a day, orally, compared to Mesalazine, the current first-line standard of care. The four trial endpoints were patients: clinical symptom score; overall clinical evaluation; colonoscopic score; and safety evaluation. After treatment for eight weeks, the percentage of patient's clinical symptom score reduction for HMPL-004 was 56% versus 59% for Mesalazine in the Intent-To-Treat population. The overall remission rate (combination of complete and partial remissions) for HMPL-004 was 57% by clinical score compared to 53% for Mesalazine in the Intent-To-Treat population and 47% for HMPL-004 versus 42% for Mesalazine by colonoscopy in the Intent-To-Treat population. HMPL-004 was well tolerated in the study and the adverse event rate was half that of the Mesalazine group.

Chi-Med's extensive preclinical work with HMPL-004 has shown that HMPL-004 acts on multiple cellular targets in the inflammatory signal transduction pathways resulting in suppressed inflammation cytokine expression including TNF-alpha, IL-1beta and IL-6. HMPL-004 was demonstrated to inhibit TNF-alpha and IL-1beta production in cell-based assays and is also able to inhibit NF-kB activation. The novel mechanism of action of HMPL-004, compared to current conventional therapies, including Mesalazine, allows it to access a unique patient population. Moreover, Mesalazine is well known to be effective in about 60% of the patients it is used in and patients' resistance over long-term use is common. The Directors believe that today's result is highly important because it shows that HMPL-004 has a similar margin of effect yet offers a different mechanism of action and therefore provides a direct alternative to the current best standard of care. If ultimately approved, HMPL-004 will provide significant commercial value to Chi-Med.

HMPL-004 is an orally active, proprietary botanical product that acts on multiple targets in the pathogenesis of inflammation. It is a compound extracted from a Chinese herb that has extensive history of use in China and South East Asia against respiratory infections and inflammation. This documentation enabled Chi-Med to accelerate the clinical process for HMPL-004 by by-passing Phase I trials, based on the FDA's 2004 guidance on botanical drug products. HMPL-004 is currently also in Phase II trial in the US for the treatment of Crohn's Disease.

Chi-Med has a further botanical candidate, HMPL-002, a radio-sensitizer for head and neck and non-small cell lung cancer, which is in Phase I/II in the US and in proof-of-concept study in China. Chi-Med's further pre-clinical drug development pipeline is focused on oncology and auto-immune indications. These compounds include synthetic and semi-synthetic single chemical entities in addition to botanical and natural product candidates.

At the meeting of Hutchison MediPharma's Scientific Advisory Board held in Shanghai, China in late-June 2007, the Board, which includes key opinion leaders in the inflammatory bowel disease area, such as Dr. William J. Sandborn, Professor of Medicine at the Mayo Clinic College of Medicine, Vice Chair of the Division of Gastroenterology and Hepatology, and Director of the Inflammatory Bowel Disease Interest Group of the Mayo Clinic and Dr. Stephan Targan, Director of both the Inflammatory Bowel Disease Center and Division of Gastroenterology at Cedars-Sinai Medical Center, Los Angeles expressed high enthusiasm over HMPL-004.

Dr. Stephan Targan commented:

"HMPL-004 has a different mechanism of action. Based on the promising results from this study, HMPL-004 is warranted for further clinical studies to fully evaluate its efficacy and safety profile for the treatment of Ulcerative Colitis."

Dr. Samantha Du, Chief Scientific Officer of Chi-Med and Managing Director of Hutchison MediPharma said:

"This is a significant milestone for us. We are encouraged by the positive results from this study, which suggest HMPL-004 can be a novel class of anti-inflammatory drug for the treatment of Ulcerative Colitis. We believe that HMPL-004 has significant potential to bring patients another option for the treatment of this chronic, painful and frequently recurring disease, which may lead to abdominal surgery. We are looking forward to further clinical studies to fully evaluate the clinical benefits of HMPL-004. Today's announcement further validates our new drug discovery and development capability and will also further accelerate recruitment in the on-going Phase II Crohn's Disease trial in the US."

Mr. Christian Hogg, CEO of Chi-Med, said:

"We are extremely pleased with the trial results, which fully meet our expectations. Ulcerative Colitis and Crohn's Disease are core focus areas of our R&D programme, and we also look forward to the delivery of the Phase II results for HMPL-004 in Crohn's Disease after which we would seek to out-license this product, in line with our stated strategy. Today's results once more also highlight the potential of Traditional Chinese Medicine to provide a reservoir for innovative new drugs for the global pharmaceutical market."

### Enquiries

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### Notes to Editor

About Intestinal Bowel Disease

Ulcerative Colitis and Crohn's Disease are forms of inflammatory bowel disease, which is considered an auto-immune disorder. They are chronic diseases which, once they start, recur regularly and cannot currently be cured. Ulcerative Colitis generally affects the large intestine and Crohn's Disease generally affects the small intestine. Ulcerative Colitis is the inflammation of the gut, which results in extensive ulceration of its inner surface with consequential pain, loss of function and blood loss. The disease can require surgical removal of sections of the gut and, in extreme cases, it may cause death. Crohn's Disease displays similar but more severe laceration of the lining of the small intestine.

Current first line treatments have effect on around 60% of patients. They can cause adverse events such as nausea, heartburn, diarrhea and headaches. Second line treatments can cause more severe adverse events and can be significantly more expensive.

In 2005 in the US, Ulcerative Colitis affected approximately 347,000 patients, an increase from around 300,000 patients in 2001. Potentially a further two to three times as many individuals may suffer from Ulcerative Colitis but are currently undiagnosed. Crohn's Disease is more prevalent with an estimated 558,000 cases in the US in 2005. The US market for Ulcerative Colitis drugs was estimated to be US\$420 million in 2002 and is expected to reach US\$500 million by 2012, a CAGR of four percent. The US market for Crohn's Disease drugs was estimated to be US\$590 million, growing to around US\$980 million by 2012. In both cases, the global market is estimated to be twice the size of the US. Global sales of Ulcerative Colitis drugs are estimated to reach US\$1 billion by 2012 and, for Crohn's Disease, the estimate is around US\$2 billion. Current treatments include Aminosalicylates (5-ASAs) to reduce and control inflammation. In addition, Corticosteroids and Immunomodulators are prescribed for patients who do not respond to first line treatments.

### About HMPL-004

HMPL-004 acts on multiple cellular targets in the inflammatory signal transduction pathways resulting in suppressed inflammation cytokine expression including TNF-alpha, IL-1beta and IL-6. HMPL-004 was demonstrated to inhibit TNF-alpha and IL-1beta production in cell-based assays. HMPL-004 is also able to inhibit NF-kB activation. NF-kB is a family of transcriptional factors that regulate a wide spectrum of genes critically involved in host defence and inflammation. The mechanism of action of HMPL-004 was further supported in inflammatory bowel disease pre-clinical models. Treatment of inflammatory bowel disease rats with HMPL-004 caused a significant drop in plasma cytokine concentrations, including TNF-alpha and IL-1beta. Pre-clinical trails for HMPL-004 have shown the almost total restoration of the inner lining of the gut.

### About Chi-Med

Chi-Med is the holding company of a pharmaceutical and healthcare group based primarily in China and was admitted to trading on the Alternative Investment Market of the London Stock Exchange in May 2006. Chi-Med is focused on researching, developing, manufacturing, and selling pharmaceuticals, health supplements and other consumer health and personal care products derived from Traditional Chinese Medicine and botanical ingredients.

Hutchison MediPharma is Chi-Med's wholly-owned drug R&D subsidiary and has a team of around 120 scientists and staff focusing on botanical drugs, semi-synthetic natural product drugs, and synthetic single chemical entity drugs. It currently has two candidates in clinical development in both the US and China. HMPL-002, a radiosensitiser for head and neck and non-small cell lung cancer, is in Phase I/II in the US and in proof-of-concept in China. HMPL-004, an inhibitor to a group of inflammatory cytokines, has completed a Phase II proof-of-concept study in Ulcerative Colitis and is in Phase II studies in Crohn's Disease in the US. Hutchison MediPharma also has a pipeline of single molecular entity discovery projects in auto-immune/inflammatory diseases and oncology therapeutic areas, which have shown activity against clinically validated targets.

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

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