



HUTCHISON CHINA MEDITECH LTD

**Hutchison China MediTech Limited (“Chi-Med”)  
(AIM: HCM)**

**Successful Global Phase IIb Ulcerative Colitis Trial for HMPL-004:  
All Primary and Secondary Endpoints Achieved  
Hutchison MediPharma Proceeding with Development and Partnership Plans**

**London: Thursday, 5 November 2009:** Hutchison MediPharma Limited (“Hutchison MediPharma”), the wholly-owned drug R&D subsidiary of Chi-Med, today announces the completion of its 223-patient global Phase IIb clinical trial of HMPL-004 in patients with mild-to-moderate active Ulcerative Colitis (“UC”), a form of Inflammatory Bowel Disease with an estimated 250,000 to 500,000 patients in the United States. Top-line data analysis demonstrated that the trial clearly succeeded in meeting its primary efficacy endpoint of clinical response with a decrease in rectal bleeding. It also met its key secondary endpoints in relation to clinical remission and mucosal healing.

Commenting on these trial results, Dr. Stephan Targan, Director of the Inflammatory Bowel Disease Center and the Division of Gastroenterology at Cedars-Sinai Medical Center, Los Angeles expressed a high level of enthusiasm for HMPL-004: “The robust trial data clearly showed the drug’s efficacy in remission induction. The safety profiles looked clean. As a natural oral product, it offers a promising treatment option in UC and warrants continuous development into Phase III clinical tests.”

The Phase IIb UC trial was a multi-centre, double-blind, randomized and placebo-controlled study conducted in 223 UC patients in the United States, Canada and Europe. The three-armed clinical trial included 8 weeks treatment of HMPL-004 at two dose levels, 1200 mg/day or 1800 mg/day, vs. placebo. The primary efficacy endpoint of the trial was clinical response, defined as the percentage of patients with a decrease in Mayo score from baseline  $\geq 3$  AND  $\geq 30\%$  decrease in the Mayo score, along with either a decrease in rectal bleeding score  $\geq 1$  OR absolute rectal bleeding score  $\leq 1$  at Week 8. The secondary endpoints included clinical remission, defined as the percentage of patients with a Mayo score  $\leq 2$  with no individual score  $> 1$  at Week 8; and the mucosal healing rate, defined as the percentage of patients with a decrease from baseline in Mayo endoscopy sub-score  $\geq 1$  AND a Mayo sub-score of  $\leq 1$  at Week 8. The safety profile of the drug was also assessed.

Top-line data analysis demonstrated that all primary and key secondary endpoints were achieved. For the Intent-To-Treat (“ITT”) patient population, the total clinical response of the two treatment arms at Week 8 was 64% for HMPL-004 vs. 44% for placebo ( $p = 0.006$ ). The clinical remission at Week 8 was 43% vs. 28% for HMPL-004 vs. placebo ( $p = 0.03$ ). The mucosal healing rate at Week 8 was 53% vs. 36% for HMPL-004 vs. placebo ( $p=0.02$ ). For the higher dose 1800 mg/day arm, the clinical response at Week 8 was 73% for HMPL-004 vs. 44% for placebo ( $p < 0.001$ ); the clinical remission at Week 8 was 45% vs. 28% for HMPL-004 vs. placebo ( $p = 0.04$ ); and the mucosal healing rate at Week 8 was 60% vs.

36% for HMPL-004 vs. placebo ( $p=0.007$ ), respectively. In addition, HMPL-004 demonstrated an excellent safety profile at both dose levels. There were no treatment-related serious adverse events in either of the HMPL-004 arms reported by the investigators.

"We are very encouraged by these results," said Dr. Samantha Du, PhD, Chief Scientific Officer of Chi-Med and Chief Executive Officer of Hutchison MediPharma. "HMPL-004 is an innovative oral botanical drug with unique mechanism of action targeting NF- $\kappa$ B activation, which leads to inhibition of production of multiple pro-inflammatory cytokines. As such, HMPL-004 represents a new approach for the treatment of active IBD patients."

Dr. Du added, "The achievement of all UC trial endpoints, along with the trend of efficacy demonstrated in the earlier Crohn's Disease trial, gives us the confidence to proceed with our development and partnership plans for this drug candidate."

## Ends

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### Notes to Editors

#### About HMPL-004

HMPL-004 is an orally active, proprietary botanic product that acts on multiple targets in the pathogenesis of inflammation. It is a compound extracted from a Chinese herb under controlled conditions and its composition is well characterised. The anti-inflammation activity of HMPL-004 was originally identified in a cell-based anti-inflammation screening assay at Hutchison MediPharma, and further confirmed in various experimental pharmacology models.

#### About Inflammatory Bowel Diseases ("IBD")

Ulcerative Colitis ("UC") and Crohn's Disease ("CD") are the two most common forms of IBD. The patient population with UC and CD in the United States is estimated to be between 250,000-500,000 and 400,000-600,000 respectively. The estimated annual new incidences of UC and CD in the US are 2-7 cases per 100,000 and 5-7 cases per 100,000, respectively. Between 2001 and 2005 it is estimated that the number of patients with UC in the United States increased by approximately 47,000, representing a CAGR of 4% and the number of patients with CD increased by approximately 58,000, a CAGR of 3%. Information in this paragraph was provided by Cambridge Consultants Limited in 2006.

## **About Hutchison MediPharma**

Hutchison MediPharma is Chi-Med's wholly-owned drug R&D subsidiary and has a team of around 200 scientists and staff focusing on discovery and development of botanical drugs, semi-synthetic natural product drugs, and synthetic single chemical entity drugs. Hutchison MediPharma has a pipeline of single new chemical entity discovery projects in both the auto-immune/inflammatory disease and oncology therapeutic areas.

## **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. It 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.