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新聞稿 PRESS RELEASE

To News Editor
For Immediate Release 19 September 2008

A New Paradigm in First Line Treatment of Lung Cancer

Lung cancer, accounting for 21% of all newly diagnosed cancer and 30% of all cancer deaths, is the most common cancer in Hong Kong. About 4,000 new cases of lung cancer were diagnosed in 2007 and close to 3,500 died from the illness. The incidence of lung cancer in Hong Kong is ranked as the highest among the developed cities in Asia. Cigarette smoking, the major cause of lung cancer, is still on the rise in Hong Kong and Asia. The incidence of lung cancer is anticipated to remain high.

About 60% of all lung cancer cases are presented at advanced stage. Current standard first line therapy, meaning the treatment at initial diagnosis, is a two-drug combination chemotherapy that includes cisplatin or carboplatin. Common side effects may include hair loss, nausea, vomiting, weakness, infection and bone marrow suppression. Although the new generation of chemotherapy has a much improved toxicity profile, many patients would want to avoid the adverse effect.

Epidermal growth factor receptor tyrosine kinase inhibitors (EGFR TKI), including gefitinib (Iressa) and erlnotinib (Tarceva), are a novel oral targeting therapy that can control cancer growth, with a much improved toxicity profile. The drugs have been established to be a second line therapy, meaning to be used after chemotherapy-failure, but their role as first line therapy remains to be defined.

Since 2006, Professor Tony Mok from the Department of Clinical Oncology at The Chinese University of Hong Kong (CUHK) has been leading the largest comparative lung cancer study in Asia that determines the role of gefitinib as first line therapy. IPASS (IRESSA Pan-ASia Study) was an open label, randomised, parallel-group study that assessed the efficacy, safety and tolerability of gefitinib versus carboplatin/paclitaxel as first line treatment in a clinically selected population of patients from Asia. The primary endpoint of IPASS was progression-free survival (PFS), with the objective of demonstrating that gefitinib was non-inferior to carboplatin/paclitaxel doublet chemotherapy. The study enrolled 1,217 patients in Asia with advanced NSCLC who had not received prior chemotherapy, whose tumours were adenocarcinoma histology and who had either never smoked, or were former light smokers (ceased smoking at least 15 years ago or low exposure with less than 10 packs per year). About 50% of the study population is from China, 20% from Japan and 30% from the rest of Asia.

On 15 September, Professor Tony Mok presented the data at the Presidential Symposium at European Society of Medical Oncology (ESMO) meeting in Stockholm. He showed that IPASS exceeded its primary objective, demonstrating superior PFS and higher tumour response for the oral anti-cancer drug gefitinib, compared with intravenous carboplatin/paclitaxel chemotherapy in the overall population of clinically selected patients with advanced NSCLC in Asia.

In pre-planned analyses of subgroups defined by the biomarker status of the patient's tumour, PFS was significantly longer for gefitinib than chemotherapy in patients with EGFR mutation positive tumours, and significantly longer for chemotherapy than gefitinib in patients with EGFR mutation negative tumours.

Gefitinib also demonstrated a more favourable tolerability profile and superior quality of life improvement rates for patients versus chemotherapy. Lead Investigator of IPASS, Professor Tony Mok said, "Results from the IPASS study offer a new paradigm in first line treatment of advanced NSCLC. Patients with adenocarcinoma who are either non or light smokers can now choose gefitinib (a single oral tablet once daily) over chemotherapy, and expect the benefit of longer progression free survival, higher tumor response, less toxicity and better quality of life."

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致新聞編輯
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肺癌一線治療新里程

肺癌是香港最普遍的癌症。在所有新症及癌症死亡的百分率中，肺癌分別佔 21%和 30%。在 2007 年，有大約 4,000 個新的肺癌病例，當中有近 3,500 人死亡。香港是亞洲所有先進國家的城市之中，肺癌發生率最高的地方。吸煙是肺癌的主要成因，由於吸煙的人數在香港和亞洲持續上升，令肺癌的發生率持續高企。

在所有肺癌的個案中，大約有 60%在發現病症時已屬於晚期。目前標準的第一線治療，即最初診斷時所使用的療法，是由兩種藥物組合而成的化療，而其中一種含有順鉑（cisplatin）或卡鉑（carboplatin）成份，可引致的副作用包括脫髮、噁心、嘔吐、虛弱、感染和骨髓抑制。雖然新一代的化療藥物在毒性方面改良了不少，但許多患者仍希望盡量避免這些副作用。

表皮生長因子受體酪氨酸激酶抑制劑（EGFR TKI），包括吉非替尼 Gefitinib（Iressa）和厄洛替尼 Erlotinib（Tarceva）兩種藥物，是能控制癌細胞生長的新穎口服標靶療法，其毒性比化療低。這兩種藥物屬於第二線療法，即在化療失敗後才使用，但其作為第一線療法的角色仍然有待確定。

從 2006 年開始，香港中文大學（中大）醫學院腫瘤學系莫樹錦教授領導 IPASS（IRESSA Pan-ASia Study）研究，進一步驗證吉非替尼作為第一線療法的角色。這是一項開放性的隨機試驗平行對照研究，就吉非替尼與卡鉑/紫杉醇（carboplatin/paclitaxel）作為第一線治療的效力、安全性和可忍受度進行評估。IPASS 的首要目標是比較無疾病進展存活率，其目的在於證明吉非替尼並不遜於卡鉑/紫杉醇雙合化療。此項研究共有 1,217 名患有後期非小細胞肺癌的亞洲病人參與。他們事前未有接受化療，屬於腺性肺癌，為非吸煙或者是甚少吸煙人士（停止吸煙至少 15 年或每年吸煙量不多於 10 包）。大約 50%的研究病者來自中國、20%來自日本，而亞洲其他地區則佔 30%。

中大腫瘤學系莫樹錦教授於本月 15 日在瑞典斯德哥爾摩舉行的歐洲內科腫瘤學會的會長討論會上發表了這項研究數據，顯示 IPASS 超出了初期目標，證明那些經臨床挑選使用口服抗癌藥物吉非替尼的亞洲非小細胞肺癌患者比那些接受靜脈注射卡鉑/紫杉醇化療藥物的患者，有更長的無疾病進展存活率及更高的有效率。

在預先計劃用病人腫瘤生物標記物狀態的小群分析中，結果指出吉非替尼對那些腫瘤屬於患有 EGFR 基因突變的肺癌病人比用化療的同類病人有更長的無疾病進展存活率。相反，用化療的那些腫瘤非屬 EGFR 基因突變的病人比用吉非替尼的同類病人有較長的無疾病進展存活率。

相對於化療，吉非替尼亦帶來更少副作用，令病人獲得更佳的生活質素。IPASS 首席研究計劃主任莫樹錦教授表示：「IPASS 的研究結果提供了治療後期非小細胞肺癌第一線的新範例。非吸煙或甚少吸煙的腺性肺癌病人現時可避用化療，改而選用吉非替尼（每日口服一粒藥丸）， 以得到更長的無疾病進展存活率、更有效的療效評價及更優良的生活質素，而所吸收的毒素亦較低。」

2008 年 9 月 19 日