



To News Editor
For Immediate Release

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**Groundbreaking CUHK-led Lung Cancer Study
First Recognized by European Union as Personalized Therapy**

Advances in science are making cancer treatments more personalized to individual patients, giving them longer survival periods and better quality of life. A study led by the Department of Clinical Oncology at The Chinese University of Hong Kong (CUHK) has found that gefitinib as a targeted therapy for lung cancer, if administered right after definite diagnosis, has a higher efficacy than the conventional intravenous chemotherapy for patients with adenocarcinoma harbouring epidermal growth factor receptor (EGFR) mutation, both in terms of the rate of progression-free survival (PFS) and cancer growth reduction.

Results of the CUHK-led study have been published in the latest issue of *The New England Journal of Medicine*. This is the first Hong Kong-led lung cancer study of its kind to be published in that journal. Based on the data of this study, the European Union's (EU) medical authorities have recently granted gefitinib for lung cancer patients with EGFR mutation in all lines of therapy for advanced stage disease. This highlights the leading position that CUHK holds in lung cancer therapy studies worldwide.

Lung cancer is the most common cancer in Hong Kong, and its local incidence ranks the highest among advanced metropolises across Asia. Smoking and environmental factors such as long-time exposure to passive smoking, asbestos and radon, are known risk factors. In addition, activation of the EGF-EGFR signaling pathways will affect cell proliferation, survival and motility. The cause of EGFR mutation remains unknown.

CUHK leads the first Asian large-scale study on NSCLC

Lung cancer with EGFR mutation is relatively more common among Asian countries. Incidence of EGFR mutation in Asian non-smokers with adenocarcinoma is 60%, which is much higher than those in Europe and the US. Gefitinib is a novel oral targeted therapy that can control cancer growth. Currently, it is indicated for patients with pre-treated advanced non-small cell lung cancer (NSCLC).

Led by the principal investigator Professor Tony S K Mok from the Department of Clinical Oncology at CUHK since 2006, the IRESSA Pan-Asia Study (IPASS) was an open-label, randomized, parallel-group study of 1,217 Asians with advanced NSCLC. The study aims to assess the efficacy, safety and tolerability of gefitinib as a first-line therapy for lung cancer versus carboplatin/paclitaxel in the conventional chemotherapy. The primary objective of IPASS is to compare the PFS rates, and to demonstrate that gefitinib as a first-line therapy is not inferior to the doublet chemotherapy of carboplatin/paclitaxel.

The study population of 1,217 patients with adenocarcinoma of lung are treatments naive who are either non-smokers or very light smokers. About 35% of them are from mainland China and Hong Kong, 20% from Japan, and 45% from the rest of Asia. ‘This large-scale study is the first of its kind in Asia and has major impacts on lung cancer management, especially in Asia,’ said Dr KC Lam, Clinical Assistant Professor (Honorary) of the Department of Clinical Oncology, CUHK.

Gefitinib highly efficacious on patients with EGFR mutation positive

In the pre-planned subgroups’ analyses defined by the biomarker status of the patient’s tumour, it has been found that gefitinib is remarkably efficacious for patients with EGFR mutation, and their rate of progression-free survival is 50% longer than those who received chemotherapy. In terms of treatment side effects and control of cancer growth, gefitinib has proved to be more efficacious than chemotherapy. Results of IPASS have verified the efficacy of gefitinib as a first-line therapy for lung cancer with EGFR mutation.

New era of personalized therapy for lung cancer

Professor Tony Mok, principal investigator of IPASS, said, ‘The study is a milestone in personalised medicine for cancer patients. In the past, all patients diagnosed with lung cancer would take chemotherapy, but not all of them would benefit. Now our study has shown that gefitinib is more efficacious on lung cancer patients with EGFR mutation. The new paradigm is that doctors may check for EGFR mutation and prescribe a personalized treatment plan for the appropriate patient.’

‘The EU’s decision to grant registration for gefitinib as an all-line therapy for lung cancer patients with EGFR mutation will gradually help to generalise the EGFR testing. In Hong Kong, we have at least five institutes, including CUHK, which can offer the service. Moreover, the study has established Hong Kong’s leading position in clinical research. I believe we will be able to attract even more pharmaceutical companies to conduct clinical trials in Hong Kong, given that we have shown our data to have respectfully gained approval by the European Union,’ Professor Mok concluded.

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致新聞編輯
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中大領導肺癌基因研究 首獲歐盟採納為個人化治療方案

科學的進步，令癌症的治療越趨個人化，病人的存活期和生活質素亦得以提高。由香港中文大學（中大）醫學院腫瘤學系領導的一項亞洲區研究發現，基因出現突變的腺性肺癌病人在確診後隨即服用肺癌標靶治療藥物吉非替尼（Gefitinib），相對於注射傳統化療藥，無論在無疾病存活率和腫瘤縮小的比率方面，效果均更為顯著。

這項亞洲區研究由中大領導，在最新一期醫學權威雜誌《新英倫醫學雜誌》（*The New England Journal of Medicine*）中發表，亦是首項由本港領導的非小細胞肺癌研究獲該醫學期刊刊載。歐洲聯盟（歐盟）更根據研究結果，最近批准吉非替尼註冊為「表皮生長因子受體」（EGFR）基因出現突變的晚期肺癌患者的全線療法，足證中大在治療肺癌領域上的國際領導地位。

肺癌是本港最常見的癌症，本地病發率亦為亞洲區先進城市之首。吸煙及一些環境因素如長期接觸二手煙、石棉及氬氣等皆是已知的致癌因素。另外，表皮生長因子（EGF）是人體內控制細胞生長的重要機制，當表皮生長因子與受體結合，並啟動細胞內一連串的訊號，便會影響細胞的增生、生存及移動。醫學界目前仍未知道導致 EGFR 基因突變的原因。

中大領導亞洲展開大型非小細胞肺癌研究

EGFR 基因出現突變的肺癌個案在亞洲區較常見。亞洲非吸煙人士患上腺性肺癌，同時出現 EGFR 基因突變的個案病發率佔整體肺癌個案多達六成，遠比歐美為高。目前，吉非替尼是控制癌細胞生長的新穎口服標靶療法，並可作為曾接受治療的晚期非小細胞肺癌藥物。

中大醫學院腫瘤學系教授莫樹錦教授自 2006 年開始領導 IPASS 研究（IRESSA Pan-Asia Study），對 1,217 名患有晚期非小細胞肺癌的亞洲病人進行開放性的隨機試驗平行對照研究，就吉非替尼與傳統化療藥卡鉑／紫杉醇（carboplatin / paclitaxel）作為第一線治療的效力、安全性及可忍受度進行評估。研究的首要目標是比較兩者的無疾病存活率，以證明吉非替尼亦可作為第一線療法，並不遜於卡鉑／紫杉醇雙合化療。

參與研究的 1,217 人均從未接受過任何治療，並為非吸煙或甚少吸煙的腺性肺癌患者，其中約 35% 來自內地和香港、20% 來自日本，其餘 45% 則來自亞洲其他地區。中大腫瘤學系名譽臨床助理教授林國智醫生說：「這是亞洲首項同類型的大型研究，對亞洲肺癌病人有特別重大的意義。」

吉非替尼對 EGFR 基因突變的患者療效顯著

在預先計劃用病人腫瘤生物標記物狀態的群組分析中，結果發現吉非替尼的療效對 EGFR 基因出現突變的患者尤為顯著，其無疾病存活期較接受化療的病人增加 50%。在副作用和腫瘤受控的情況方面，吉非替尼的表現亦比化療為佳，證實吉非替尼可以作為 EGFR 基因突變病人的第一線治療。

肺癌治療將邁向個人化

IPASS 首席研究計劃主任莫樹錦教授形容，這次研究成果是肺癌治療邁向個人化的一個重要里程碑，為醫學上的一大突破。他說：「以往所有肺癌病人都須接受化療，但並非所有病人的病情都得到改善。是次研究證明吉非替尼對 EGFR 基因突變病人的療效較為顯著，建議醫生日後可先替患者進行基因突變測試，再為合適的病人處方個人化的治療方案。」

莫樹錦教授總結：「歐盟今次將吉非尼替註冊為 EGFR 基因出現突變的肺癌患者的全線療法，將促進基因突變測試普及化。目前，本港共有五所機構提供有關服務，中大亦為其一。這項研究亦同時確立本港在臨床研究上的領導地位，相信未來可吸引更多製藥機構在本港進行臨床研究。」

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