ELCC 2016 Industry Satellite Symposium

Navigating the advanced NSCLC patient pathway: new markers and targets

Chaired by Martin Reck

Thursday 14th April 2016 **13:00 – 14:00, Room A**

Springer Healthcare IME

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Programme

13:00 – 13:05	**Welcome and introduction**	**Martin Reck**
13:05 – 13:15	**Trail markers in squamous NSCLC: signposts for clinical efficacy**	**Keith Kerr**
13:15 – 13:40	**Navigating the advanced NSCLC patient pathway: a case study**	**Johan Vansteenkiste**
13:40 – 13:55	**Patient management in the targeted age: finding the way through increased complexity**	**All**
13:55 – 14:00	**Closing remarks**	**Martin Reck**

Learning objectives

Following attendance at this symposium delegates are expected to:

- **Understand how best to use biomarkers to guide therapy for advanced squamous NSCLC**
- **Understand and demonstrate knowledge on the latest treatment pathways for patients with advanced squamous NSCLC**
- **Understand the emerging therapies for advanced squamous NSCLC and the new treatment paradigms they raise**

Welcome message

Dear Colleagues,

Welcome to Geneva and thank you for attending this satellite symposium *'Navigating the advanced NSCLC patient pathway: new markers and targets'* at the European Lung Cancer conference, which we hope you will find engaging and informative.

Geneva again provides an excellent host city for this conference bringing together a unique community of medical professionals to facilitate a personalised approach to the management of lung and other thoracic cancers, and the implementation of new discoveries, into clinical practice.

This symposium will address the challenges of treating advanced NSCLC patients in an increasingly complex therapy landscape.

The therapy landscape and, accordingly, the patient pathway through it, has greatly increased in complexity in recent years. During this session, the expert Faculty will guide us through this complexity by placing the latest developments in advanced NSCLC into the context of treatment. They will provide their insights into how we can use our biological knowledge not only to improve treatment pathways, but also to maximise treatment outcomes by understanding approaches.

We hope that you find this symposium educational and that it will further your understanding of this evolving field, providing advice to facilitate decision making in your clinical practice. Accordingly, we aim to provide maximum interaction and discourse between Faculty and audience so that we may work together to optimise patient outcomes.

We would be grateful if you would kindly provide your feedback by completing the evaluation form provided with this booklet.

Yours faithfully,

Martin Reck

Martin Reck – Chair

Faculty biographies

Martin Reck
(Symposium Chair)
Grosshansdorf, Germany

Professor Reck undertook his medical training at The University of Hamburg, Germany, from 1986 to 1993. He completed his doctorate at the General Hospital Wandsbek, Hamburg, in 1995 and received post-graduate training at the Hospital Grosshansdorf, Germany. In 2001 he was appointed as a specialist in internal medicine and in 2002 he was also appointed as a specialist in pulmonology. In 2008 he was awarded a post-doctoral lecturing qualification by the University of Schleswig-Holstein, Germany.

Professor Reck has been a Principal Investigator (PI) or Co-PI in various clinical trials since 1993. His main interests are targeted therapies in non-small-cell lung cancer, new approaches in small-cell lung cancer and modern therapies in malignant pleural mesothelioma, as well as translational research related to predictive markers. He has been involved in several key trials investigating new treatment approaches in the treatment of advanced stage of disease such as, maintenance treatment or treatment with targeted therapies, as well as key biomarker trials.

He is Head of the Department of Thoracic Oncology as well as Head of the Clinical Trial Department in the Department of Thoracic Oncology at the Lung Clinic Grosshansdorf. Furthermore he is PI in the German centre for lung research (DZL) in the area of lung cancer.

Martin Reck is a member of: the German Working Group for Lung Cancer, the German Cancer Society, the German Society of Pulmonology, the International Association for the Study of Lung Cancer, the European Society for Medical Oncology (ESMO) and the American Society of Clinical Oncology (ASCO).

Johan Vansteenkiste
Leuven, Belgium

Professor Vansteenkiste is Professor of Internal Medicine in the Faculty of Medicine at the Catholic University of Leuven, Belgium, and Head of Clinic in the Respiratory Oncology Unit and its Clinical Trial Unit at the Leuven University Hospital.

He studied medicine at the University of Leuven before becoming a Board Certified Pulmonologist-Oncologist. He had additional training in respiratory oncology at the European School of Oncology in Milan, Italy, and in respiratory endoscopy at the Laser Centre in Marseille, France, before gaining his PhD at the University of Leuven in 1996.

Professor Vansteenkiste is an active member of different international societies such as ESMO, IASLC, ASCO, and others. He was Secretary of the Thoracic Oncology Assembly of the ERS and a member of the ERS School Board in 2009-2012. He was a member of the Board of Directors of IASLC in 2009-2013. He is a member of the ESMO Lung Educational Group and Guidelines Group, and chaired the European Lung Cancer Conference in April 2015.

He is the principal investigator or co-investigator in several clinical trials in the area of lung cancer. He is Associate Editor at the *Annals of Oncology*, a member of the editorial board of several other journals, and author or co-author of more than 250 peer-reviewed papers and book chapters.

Keith Kerr
Aberdeen, UK

Professor Kerr completed his BSc with first class honours in Pathology in 1978, followed by MB ChB in 1981 and post-graduate training in Pathology at Edinburgh University Medical School and the Royal Infirmary of Edinburgh. He obtained a MRCPath in 1988, FRCPath in 1998 and was elected Honorary FRCP(Ed) in 2006. He has been a Consultant Pathologist in Aberdeen since 1989.

Professor Kerr has been a member of the IASLC for 16 years. He was elected to the IASLC Board of Directors for four years, 2013-2017, and is also Associate Editor for the *Journal of Thoracic Oncology*. Professor Kerr is also a member of the International Mesothelioma Panel, and served as Pathology Chair for the The European Organisation for Research and Treatment of Cancer (EORTC) lung cancer group from 2006-2014. He is Pathology Chair for the ETOP Lungscape group and was a member of the panel for the 2004 and 2015 WHO lung cancer classifications. He serves on the International Pulmonary Pathology Society council and is a British Thoracic Society member.

He is currently involved in the revision of the BTS Mesothelioma guidelines and is a panel member for the revision of the The College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP) guidelines for molecular pathology testing in lung cancer. He is a lead author of the ESMO Consensus Guidelines on pathology and molecular biomarkers for non-small-cell lung cancer.

Throughout his career, he has worked in diagnostic histopathology with a special interest in thoracic pathology. He has had a career-long interest in lung cancer and has research interests in pulmonary pre-neoplasia and carcinogenesis, lung tumour diagnosis and classification, and in the identification of predictors of therapy response.

Symposium information

Organisers

This educational activity has been planned and independently implemented by Springer Healthcare IME.
Springer Healthcare IME is the Independent Medical Education group of Springer Nature global publishing group.

Accreditation

An application has been made to the European Accreditation Council for Continuing Medical Education (EACCME) to provide the following CME activity for medical specialists. The EACCME is an institution of the European Union of Medical Specialists (UEMS).

'Navigating the advanced NSCLC patient pathway: new markers and targets' is designated for a maximum of (or 'for up to') 1 hour of European external CME credits. Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity.

Through an agreement between the European Union of Medical Specialists and the American Medical Association, physicians may convert EACCME credits to an equivalent number of AMA PRA Category 1 Credits™.

Educational sponsorship

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Filming and photography

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EMA pre-registered and approved therapies in NSCLC

Drug information can be found at the website of the European Medicines Agency

All information correct as of 17 March 2016.
http://www.ema.europa.eu/ema

Generic name and MoA	Patient segment	Route/formulation
Afatinib http://bit.ly/218d9DL • EGFR inhibitor • ERBB2 inhibitor • ERBB4 inhibitor	• EGFR TKI-naïve adult patients with locally advanced or metastatic NSCLC with activating EGFR mutation(s). • CHMP new indication for locally advanced or metastatic NSCLC of squamous histology progressing on or after platinum-based chemotherapy.	Before starting treatment, the doctor will have to establish that the patient has mutated EGFR genes. Afatinib is available as tablets (20, 30, 40 and 50 mg) and is only available with a prescription. The recommended dose is 40 mg once daily but this may be increased to up to 50 mg per day in patients who tolerate the 40 mg dose, or interrupted and reduced in patients experiencing side effects. Treatment should continue for as long as possible, until the disease worsens or the side effects become too severe. The tablets should be taken without food and no food should be eaten for at least three hours before and one hour after taking the tablets.
Erlotinib http://bit.ly/1L698hx • EGFR inhibitor	• First-line treatment of patients with locally advanced or metastatic NSCLC with EGFR-activating mutations. • Monotherapy for maintenance treatment in patients with locally advanced or metastatic NSCLC with stable disease after four cycles of standard platinum-based first-line chemotherapy. • Patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.	In patients who have not yet received chemotherapy, EGFR mutation testing should be performed before starting erlotinib therapy. For lung cancer, the recommended daily dose of erlotinib is 150 mg. Erlotinib is taken at least one hour before or two hours after food. If needed (for example because of side effects), the dose may be reduced in 50 mg steps.
Gefitinib http://bit.ly/1Ro6DUi • EGFR inhibitor	• Adult patients with locally advanced or metastatic NSCLC with activating mutations of EGFR.	The recommended dose is one tablet once a day. The tablet can be dispersed in water for patients who have difficulty swallowing.
Osimertinib http://bit.ly/1WV0bYZ • EGFR inhibitor	• Adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC.	Before starting treatment, doctors must have confirmation that their patients have the T790M mutation. This should be done by genetic testing in an appropriate laboratory. Osimertinib is available as tablets (40 and 80 mg). The recommended dose is 80 mg once a day. Treatment with osimertinib may continue for as long as the disease improves or remains stable and the side effects are tolerable. If certain side effects develop the doctor may decide to reduce the dose or stop treatment.
Ceritinib http://bit.ly/1LxAUUb • ALK inhibitor	• ALK-positive locally advanced or metastatic NSCLC.	The presence of genetic defects affecting ALK ('ALK-positive' status) has to be confirmed in advance by appropriate methods. The medicine is available as capsules (150 mg). The recommended dose is 750 mg (5 capsules) once a day taken on an empty stomach and no food should be eaten for two hours before or after the dose. The doctor may decide to reduce the dose or stop treatment temporarily if side effects occur. In certain cases treatment should be permanently stopped.

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Generic name and MoA	Patient segment	Route/formulation
Crizotinib http://bit.ly/1IC49nk • AKL inhibitor • c-MET inhibitor	• First-line and second-line therapy or greater treatment of adults with ALK-positive advanced NSCLC.	The presence of the genetic defect affecting ALK ('ALK-positive' status) has to be confirmed in advance by appropriate methods. The recommended dose is 250 mg twice per day. If certain side effects develop the doctor may decide to interrupt or reduce the dose to 200 mg twice per day then to 250 mg once per day. Doses may need to be delayed or treatment stopped altogether if the patient develops certain severe side effects. Doses may need to be adjusted in patients with severely reduced kidney function and the medicine should not be used in patients with severely reduced liver function.
Bevacizumab http://bit.ly/24BixUx • VEGF-A antagonist	• In addition to platinum-based chemotherapy, is indicated for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent NSCLC other than predominantly squamous cell histology.	The first infusion should last 90 minutes, but subsequent infusions may be given over a shorter period if the first infusion is tolerated well. The dose is between 5 and 15 mg per kilogram body weight every two or three weeks, depending on the type of cancer being treated. The treatment is continued until the patient no longer benefits from it. The doctor may decide to interrupt or stop treatment if the patient develops certain side effects.
Nintedanib http://bit.ly/1LVdbYK • PDGFR inhibitor • FGFR inhibitor • VEGFR inhibitor	• In combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent NSCLC of adenocarcinoma tumour histology after first-line chemotherapy.	Nintedanib is available as capsules (100 and 150 mg) to be taken by mouth, preferably with food. The recommended dose is 200 mg taken twice a day (around 12 hours apart). Because nintedanib must not be given on the same day as docetaxel and because docetaxel is given on day 1 of a 21-day treatment cycle, nintedanib is given on days 2 to 21 with docetaxel being given on day 1. Treatment with nintedanib may continue after stopping docetaxel, for as long as the disease improves or remains stable and the side effects are tolerable. If severe side effects develop, the doctor may decide to interrupt treatment with nintedanib and resume it at a lower dose. If severe side effects persist, treatment should be permanently discontinued.
Ramucirumab http://bit.ly/1QrViWX • VEGFR-2 antagonist	• In combination with docetaxel, is indicated for the treatment of patients with metastatic NSCLC with disease progression on or after platinum-based chemotherapy.	Ramucirumab is available as a concentrate to be made up into a solution for infusion (drip) into a vein. It can only be obtained with a prescription and treatment should be started and supervised by a specialist who has experience in the treatment of cancer. When given in combination with paclitaxel, the recommended dose is 8 mg per kg body weight given at days 1 and 15 of a 28 day cycle, before being given the infusion of paclitaxel (which is given on days 1, 8 and 15). When given as a single medicine, the recommended dose of ramucirumab is 8 mg per kg body weight given every two weeks.
Necitumumab http://bit.ly/1XzPUSu • EGFR antagonist	• In combination with gemcitabine and cisplatin chemotherapy is indicated for the treatment of adult patients with locally advanced or metastatic EGFR-expressing squamous NSCLC who have not received prior chemotherapy for this condition.	Recommended dose is 800 mg (absolute dose) as an intravenous infusion over 60 minutes on days 1 and 8 of each 3-week cycle.
Nivolumab http://bit.ly/1VQzzZ1 • PD-1 antagonist	• Locally advanced or metastatic squamous NSCLC after prior chemotherapy in adults. • CHMP new indication for locally advanced or metastatic NSCLC after prior chemotherapy in adults.	Nivolumab is available as a concentrate that is made up into a solution for infusion (drip) into a vein. The infusion is given at a recommended dose of 3 mg per kilogram body weight over 60 minutes every two weeks for as long as the patient continues to benefit. The doctor may need to delay doses if certain side effects occur, or stop treatment altogether if side effects are severe.

Notes

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