

Non-small cell lung cancer: Game changing immunotherapies to revolutionise treatment - KOL Insight

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Abstracts

Change is coming to the NSCLC treatment algorithm—and it's coming soon. Revolutionary new immunotherapies, more personalised treatment choices and further drug developments are all set to roll out in the near future. What are the potential blockbusters, who will gain approvals first and what are the future challenges?

Drivers of change

Revolutionary immunotherapies. From cancer vaccines to checkpoint inhibitors, several therapies in late-stage development are due to launch very soon. According to KOLs interviewed, the most promising are programmed cell death protein 1 (PD-1) pathway inhibitors. The race is on between Bristol-Myers Squibb's nivolumab, Merck & Co.'s MK-3475 and Roche's RG7446 to become the first to be approved.

Mutation analysis. Personalised targeted therapy has been a paradigm shift towards assessing patients' treatment based on mutation status. Leading the way is Xalkori (crizotinib; Pfizer) with its associated Anaplastic Lymphoma Kinase (ALK)-testing diagnostic—yet it faces pending competition from several other therapies in early- to late-stage development.

Key opportunities in EGFR resistance. Since patients all develop resistance to currently marketed EGFR inhibitors, significant opportunities exist in developing a therapy to tackle the T790 mutation responsible for approximately half of acquired resistance cases. While pipeline therapies have not yet proven they have the answer, KOLs believe early phase 1 results from Clovis's CO-1686

position it well.

Unique insider clinical opinion

Comprehensive, concise and offering rare access to the most forward-thinking KOL analysis of NSCLC treatments, development and competition, KOL Insight: Non-small cell lung cancer is an essential tool for keeping abreast of events that will shape the future.

Based on in-depth interviews with 12 experienced and highly-regarded KOLs across North America and Europe, the report provides the latest insights into the current and future treatment landscapes. Chosen for their unique abilities, clinical experience, publications and treatment guideline development as well as presence on the international stage, the KOLs bring incisive, real-world analysis of NSCLC treatment.

Pressing issues and questions:

Which drug attributes create a first- and subsequent-line treatment preference for patients who are EGFR mutation positive, EML4-ALK translocation positive and EGFR mutation/ EML4-ALK translocation negative?

How are current targeted NSCLC therapies perceived by clinicians in terms of efficacy, tolerability, ease of administration, and other product attributes?

Which recently completed or ongoing clinical trials have the greatest potential to impact the future treatment of NSCLC, e.g. the REVEL, SELECT-1, MAGRIT, LUME LUNG 1, ARCHER 1050 and CheckMate 057 trials?

What do pipeline NSCLC targeted therapies need to show in order to become the treatment of choice in a specific patient segment and line of therapy?

How will the use of each current and pipeline NSCLC product change in the future in terms of patient segment, line of therapy and preference?

Key benefits

Developments in the treatment of NSCLC are progressing rapidly. In KOL Insight: Non-

small cell lung cancer, you will:

Gain an invaluable overview into the most dynamic areas of the NSCLC market

Understand the role of Pfizer's Xalkori in mutation analysis and personalised treatment therapy

Obtain insight into why KOLs view EGFR resistance as the largest opportunity for developers—and why Clovis's CO-1686 may be well-positioned Understand why competition will grow in first- and second-line settings for Avastin and Alimta

This report will allow you to:

View the spectrum of NSCLC treatments and KOL opinion of emerging clinical data

Analyse current and future treatment algorithms

Identify promising late-stage drug developments

Track KOL opinion continuously over the next 12 months

Understand which drugs are most vulnerable to competition and which upcoming therapies will address unmet needs

KOL Panel

KOLs from North America:

Dr Paul Bunn, Distinguished Professor, Division of Medical Oncology/University of Colorado, USA.

Dr Giuseppe Giaccone, Associate Director for Clinical Research, Lombardi Comprehensive Cancer Center (LCCC) at Georgetown University, Washington, DC, USA.

Dr Leora Horn, Assistant Professor of Medicine (Haematology/Oncology) and

Clinical Director of the Thoracic Oncology Program at Vanderbilt-Ingram Cancer Center, Tennessee. USA.

Dr Patrick Ma, Translational Hematology and Oncology Research and Director of the Aerodigestive Oncology Translational Research THOR Cleveland Clinic Taussig Cancer Center, Ohio, USA.

Dr Joan Shiller, deputy director of the Simmons Comprehensive Cancer Center and division director of Hematology/Oncology at the University of Texas-Southwestern Medical Center, Texas, USA.

Prof Mark Socinski, professor of medicine and thoracic surgery at the University of Pittsburgh School of Medicine, Pennsylvania, USA.

KOLs from Europe:

Dr Ahmed Awada, Professor and Head of the Medical Oncology Clinic, Jules Bordet Institute, Brussels & Free Universities, Brussels, Belgium.

Dr Cesare Gridelli, Chief of Division of Medical Oncology and Director of Department of Oncology/Hematology at the "S.G. Moscati" Hospital, Avellino, Italy.

Dr Silvia Novello, Assistant Professor of Respiratory Medicine at the Department of Clinical and Biological Sciences of the University of Turin, Orbassano, Italy.

Dr Solange Peters, head of thoracic malignancies program in the Department of Oncology of the University of Lausanne, Switzerland.

Dr Egbert Smit, VU University Medical Center, Amsterdam, The Netherlands.

Dr Nick Thatcher, previously held the post of Professor of Medical Oncology at the Christie Hospital NHS Trust in Manchester, England.

Key Quotes from the Report

"Crizotinib [Xalkori] was actually originally developed with the intent to be a c-

Met inhibitor and now the rest is history. It's an excellent ALK inhibitor." US Key Opinion Leader

"The Novartis drug [LDK378] looks quite good; it's got some different toxicities but has demonstrated it does work in crizotinib resistant patients. We don't yet know if it is better than crizotinib on the brain metastases, which seems to be a relapse problem for crizotinib-treated patients – but there could be some benefits there." EU Key Opinion Leader

"I think based on the selumetinib phase II data, I think there will be a benefit in terms of outcome. I don't know about survival but I'm sure that the response to the chemo, the docetaxel will be better when you combine it with a MEK inhibitor in KRAS mutated patients. So I consider SELECT-1 will be a positive trial in terms of outcome." EU Key Opinion Leader

"Bristol-Myers Squibb has the most advanced immunotherapy. It will probably be placed in most lines of treatment if it works. A first-line treatment in combination with chemo, combined with targeted agents for patients with mutations and they will also be used as single agents when everything else has failed. Nivolumab will be the first to really change the panorama of non-small cell lung cancer treatment." US Key Opinion Leader

"I think that the best companies with the best knowledge in oncology can make huge mistakes. So I really don't think Merck's lesser grounding in the oncology area will put it at a disadvantage. They just have to equip themselves with a good advisory board and to be intelligent in the way they formulate their clinical trials." EU Key Opinion Leader

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About

KOLS from North America

Dr Paul Bunn, Distinguished Professor, Division of Medical Oncology/University of Colorado, USA. Dr. Bunn's research interests focus on novel therapies for lung cancer and he also serves as the James Dudley Chair in Lung Cancer Research. Dr. Bunn has served as the principal investigator on numerous national and local clinical trials and is also the principal investigator for the SPORE grant in lung cancer, which seeks to conduct translational research in lung cancer. He has published more than 300 articles in peer-reviewed journals, over 122 reviews and editorials and 90 book chapters on lung cancer. In addition, Dr. Bunn has served as President of the American Society of Clinical Oncology (ASCO), International Association for the Study of Lung Cancer (IASLC), and Association of American Cancer Institutes (AACI), and also the position of chairman of the FDA Oncology Drug Advisory Committee and Executive Director of the IASLC.

Dr Giuseppe Giaccone, Associate Director for Clinical Research, Lombardi Comprehensive Cancer Center (LCCC) at Georgetown University, Washington, DC, USA. In addition to his work at the LCCC, Dr Giaccone also serves as the Director of Clinical Research for the MedStar Health Cancer Network's Washington Region. In addition, he has previously acted as the Chief of the Medical Oncology Branch of the Center for Cancer Research of the National Cancer Institute (NCI), where he participated in the restructuring of the organisation, and played a major role in the European Organization for Research and Treatment of Cancer (EORTC), serving as a member of the EORTC's Lung Cancer Cooperative Group and its chair. Dr. Giaccone has published more than 500 peer-reviewed papers and contributed to more than 30 book chapters and has led several major clinical studies focusing on lung cancer and mesothelioma.

Dr Leora Horn, Assistant Professor of Medicine (Haematology/Oncology) and Clinical Director of the Thoracic Oncology Program at Vanderbilt-Ingram Cancer Center, Tennessee, USA. Dr Horn's clinical practice focuses on lung cancer and she has a cross appointment to the Office of Teaching and Learning in Medicine where she is the Assistant Director of the Educator Development Program (EDP) at Vanderbilt. She is the principal investigator on several lung cancer clinical trials and education projects and has published more than 30 original papers, reviews and book chapters, including a recent chapter on neoplasms of the lung in Harrison's Principles of Internal Medicine.

Dr Horn is an active member in ASCO, IASLC and the Royal College of Physicians and Surgeons of Canada.

Dr Patrick Ma, Translational Hematology and Oncology Research and Director of the Aerodigestive Oncology Translational Research THOR Cleveland Clinic Taussig Cancer Center, Ohio, USA. Dr Ma's clinical practice focuses on thoracic malignancies including lung cancer, mesothelioma, and neuroendocrine tumours and cancer genomics. He is principal investigator or co-investigator in several lung cancer clinical trials investigating novel targeted therapeutics in lung cancer and was recently awarded the Department of Defense (DOD) Lung Cancer Promising Clinician Research Award and 2013 Lerner Research Institute Chair's Innovative Research Fund Award. Dr Ma has authored and co-authored numerous peer-reviewed articles and abstracts, reviews and book chapters and serves as peer reviewer for a number of journals, including Cancer Research, Clinical Cancer Research, Molecular Cancer Therapeutics, Journal of Thoracic Oncology, Clinical Lung Cancer, Nature Genetics, PNAS and Journal of Clinical Oncology. Dr. Ma has also previously presented at national and international scientific conferences in thoracic oncology.

Dr Joan Shiller, deputy director of the Simmons Comprehensive Cancer Center and division director of Hematology/Oncology at the University of Texas-Southwestern Medical Center, Texas, USA. Dr Shiller's clinical interests include small cell lung cancer, NSCLC, adenocarcinoma of the lung and bronchioloalveolar carcinoma and she has served as the principal investigator on many national clinical trials in lung cancer. In addition, Dr Shiller has authored or co-authored more than 200 articles, abstracts, book chapters, books, reviews and is editor for the Journal of Clinical Oncology. Dr Shiller has also served on a variety of National Institutes of Health (NIH) and ASCO committees, including the National Cancer Institute (NCI) Concept Evaluation Panel, the NCI Lung Cancer Progress Review Group, and ASCO's Program Committee in 2000 and 2001. She was Chair of ASCO's Bylaws Committee, has served on the International Scientific Committee for the 10th and 11th World Conferences on Lung Cancer, and is a board member and chair of the Public Issues Committee for the International Association for the Study of Lung Cancer. In addition, Dr Schiller is the founder and president of the National Lung Cancer Partnership, a chairperson for the Thoracic Oncology Committee of the Eastern Co-operative Oncology Group, and holder of the Andrea L. Simmons Distinguished Chair in Cancer Research.

Prof Mark Socinski, professor of medicine and thoracic surgery at the University of Pittsburgh School of Medicine, Pennsylvania, USA. Dr Socinski, who specialises in all thoracic malignancies, also serves as the director of the Lung Cancer Section, Division

of Hematology Oncology at the University of Pittsburgh Medical Center (UPMC) Cancer Center, co-director of the UPMC Lung Cancer Center of Excellence, and co-leader of the Lung and Thoracic Malignancies Program. Dr Socinski acts as co-Chair of the Thoracic Malignancies Steering Committee for the NCI and serves on the Respiratory Core Committee of the Cancer and Leukemia Group ? (Alliance) and has been instrumental in the development of many cooperative group trials. He is a member of numerous professional societies, including the American College of Physicians, ASCO, IASLC and the American College of Chest Physicians.

KOLs from Europe

Dr Ahmed Awada, Professor and Head of the Medical Oncology Clinic, Jules Bordet Institute, Brussels & Free Universities, Brussels, Belgium. Dr Awada has co-authored numerous studies in the field of lung cancer that have been published in journals including The Lancet Oncology, European Journal of Cancer, International Journal of Oncology, Current Opinion in Oncology and Cancer Treatment Reviews. His work has also been presented at several major medical and scientific conferences, including ASCO and ESMO.

Dr Cesare Gridelli, Chief of Division of Medical Oncology and Director of Department of Oncology/Hematology at the "S.G. Moscati" Hospital, Avellino, Italy. Dr Gridelli's research focuses on lung cancer and he is deeply invested in the clinical development of new anticancer targeted therapies. In addition. Dr Gridelli regularly speaks at international conferences and educational events for oncology societies, including ASCO and ESMO, and has authored or co-authored approximately 600 papers and several book chapters. He is also a member of the Advisory Board of scientific journals and is a member of several national and international scientific societies, including Associazione Italiana di Oncologia Medica (AIOM), Italian Association of Thoracic Oncology (AIOT), Clinical Trials Promoting Group (CTPG), IASLC and is a member of the Foundation Council of the European Thoracic Oncology Platform (ETOP).

Dr Silvia Novello, Assistant Professor of Respiratory Medicine at the Department of Clinical and Biological Sciences of the University of Turin, Orbassano, Italy. Dr Novello's research interests include thoracic malignancies, gender differences in lung cancer, development of new drugs in thoracic oncology and lung cancer screening. Dr Novello has been involved in trials and studies in different lung cancer and pleural mesothelioma clinical stages and is an author or co-author of more than 100 articles in peer-reviewed journals and of book chapters published in scientific volumes. She has been a speaker at Italian and European Congresses focused on Thoracic Oncology. In

addition. Dr Novello is a member of ASCO, the National Lung Cancer Partnership (NLCP) Scientific Committee, the IASLC Young Investigators Awards Scientific Committee, and President of the European Association - Women Against Lung Cancer in Europe (WALCE). In addition, she has served as a Board of Director Member for the IASLC since 2011.

Dr Solange Peters, head of thoracic malignancies program in the Department of Oncology of the University of Lausanne, Switzerland. Dr Peters' research focus is on developing multimodality trials for locally advanced NSCLC, among other interests. Dr Peters serves as the co-chair of the Swiss lung cancer research group (SAKK) and is also the Scientific Coordinator and Chair of the Informatics Committee of the European Thoracic Oncology Platform (ETOP). In addition, she is an IASLC publication committee member and incoming publication committee chair and a member of the ESMO E-Learning and CME Working Group (ECWG). Dr Peters is also the president of the Swiss education organization Forome, is the deputy editor of the Journal of Thoracic Oncology (JTO), an associate editor for Frontiers in Pharmacology of Anti-Cancer Drugs and Thoracic Oncology, and a reviewer for several lung cancer and oncology journals.

Dr Egbert Smit, VU University Medical Center, Amsterdam, The Netherlands. Dr Smit has authored and co-authored a number of research papers, studies and abstracts that have been published in journals including the Journal of Clinical Oncology, Future Medicine, Cancer Chemotherapy and Pharmacology, The Oncologist, Lung Cancer and the Journal of Thoracic Oncology. His research has been presented at the American Association for Cancer Research, the National Cancer Institute, and the European Organisation for Research and Treatment of Cancer Symposium on Molecular Targets in Cancer Therapeutics, ASCO and ESMO.

Dr Nick Thatcher, previously held the post of Professor of Medical Oncology at the Christie Hospital NHS Trust in Manchester, England. Dr Thatcher's research interests include combining targeted therapies with chemotherapy and novel agents for the treatment of advanced NSCLC and related translational research endeavours. Prof. Thatcher is also active in clinical trials of patients with NSCLC and small cell lung cancer and is the principal investigator for numerous clinical trials. In addition. Dr Thatcher served as Chairman of the United Kingdom Coordinating Committee Cancer Research (Trials), Chairman of the Medical Research Council Lung Cancer Working Party, Secretary of the United Kingdom Coordinating Committee (Lung Cancer) and a member of the ESMO faculty. He has co-authored more than 300 publications and is a speaker and chairman at numerous national and international meetings on lung cancer.

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