Phase IV lung cancer study confirms the safety and outstanding efficacy benefit of Avastin-based therapy in a ‘real world’ setting

This update outlines the key data from four presentations on Avastin in advanced non-small cell lung cancer (NSCLC) at the joint ECCO 15\(^1\) and ESMO 34\(^2\) congress:

Data from two large studies:

- **Final efficacy and safety results from SAiL**: Phase IV international trial in a broad population of over 2,000 patients with advanced non-small cell lung cancer (NSCLC), representative of physician clinical practice, including elderly, hypertensive patients and those with brain metastases. The data show outstanding median overall survival (OS) of 14.6 months across the real-life population of patients receiving Avastin (bevacizumab) in combination with chemotherapy and confirm Avastin’s well established and manageable safety profile.

- **Preliminary safety results from ARIES**: U.S. prospective, observational cohort study enrolling approximately 2,000 patients with advanced NSCLC, including the elderly, those with brain metastases and patients on anticoagulants. Interim data confirm Avastin’s well established and manageable safety profile in real-world clinical population.

**SAiL**

SAiL is an international, multicentre, open-label, single-arm study designed to assess the safety and efficacy of first-line Avastin plus chemotherapy in a daily oncology practice population. Patients with untreated locally advanced, metastatic or recurrent non-squamous NSCLC received Avastin (7.5 or 15mg/kg every three weeks) plus standard chemotherapy for up to six cycles, followed by Avastin until disease progression.

**Data presented**

- Efficacy: Avastin-based therapy resulted in outstanding median OS of 14.6 months in the

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\(^1\) European CanCer Organisation  
\(^2\) European Society for Medical Oncology
overall trial population, with disease control rate of over 88% and median time to disease progression (TTP) of 7.8 months.

- Elderly: Avastin-based therapy offered a similar level of clinical benefit irrespective of age with elderly patients receiving the same OS benefit of 14.6 months. Patients >65 years were not at increased risk of experiencing adverse events (AEs) of special interest when treated with first-line Avastin-based therapy compared with patients ≤65 years.
- Bleeding events: Rates of grade ≥3 bleeding were low (3.6%) in patients who received Avastin-based therapy. Grade ≥3 pulmonary haemorrhage was a rare event, occurring in 0.7% of patients.

**Clinical relevance**

- The results of SAiL further document, in a real-world population, the safety and efficacy outcomes seen in pivotal phase III randomised clinical trials of Avastin in NSCLC.
- The median OS seen in SAiL is outstanding across this broad non-squamous NSCLC population and confirms Avastin-based therapy as a proven treatment option in NSCLC.

“The encouraging efficacy results seen in the large, real-life population in SAiL are consistent with results from randomised controlled trials of Avastin in first-line NSCLC. SAiL provides further confidence in Avastin’s safety profile especially in sub-populations that were not fully explored previously, with no new safety signals reported” said SAiL investigator Prof. Lucio Crino, Director Medical Oncology from the Azienda Ospedaliera Santa Maria della Misericordia in Perugia, Italy.

**ARIES**

ARIES is a U.S. community-based prospective, observational cohort study to assess clinical outcomes of first-line Avastin with different chemotherapy regimens not included in pivotal trials, and among under-represented subgroups. Choice of chemotherapy, Avastin dose and schedule are by investigator decision. ARIES is an ongoing study, enrolling approximately 2,000 patients with locally advanced or metastatic NSCLC.

**Data presented**

- The ARIES interim analysis (based on 1,758 patients) confirms the safety of Avastin-based therapy for the treatment of patients with NSCLC, with adverse event rates consistent with previous reports.
- Safety: Rates of grade ≥3 bleeding were low (3.2%) in patients who received Avastin-based therapy. Incidence of severe pulmonary haemorrhage was also low (0.7%).
- Efficacy: Preliminary efficacy results will be presented in 2010.

**Clinical relevance**
- ARIES is an ongoing study; the results will provide further information on the safety of Avastin-based therapy for a broad patient population, as shown by SAiL, and will further support Avastin-based therapy as a safe and efficacious option for first-line NSCLC treatment.

*ARIES is an observational study including patients with advanced non-small cell lung cancer (NSCLC) as well as patients with advanced colorectal cancer. Only the NSCLC data from ARIES are represented in this report.

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**ECCO/ESMO abstracts/posters**

Safety and efficacy of first-line bevacizumab (Bv) plus chemotherapy in elderly patients (pts) with advanced or recurrent non-squamous non-small cell lung cancer (NSCLC), SAiL (MO19390); Pilar Garrido, Nick Thatcher, Lucio Crinò, Eric Dansin, Janessa Laskin, Nick Pavlakis, Chun-Ming Tsai, Martin Beck, Claus-Peter Schneider, Frank Griesinger on behalf of the SAiL study group. Poster discussion 221 on 23 September 2009, ECCO 15 and ESMO 34.

Safety and efficacy of first-line bevacizumab-based therapy in advanced non-small cell lung cancer (NSCLC): results of the SAiL study (MO19390), Eric Dansin, Chun-Ming Tsai, Nick Pavlakis, Janessa Laskin, Frank Griesinger, Pilar Garrido, Lucio Crinò, Yi-Long Wu, Guo-Liang Jiang, Nick Thatcher on behalf of the MO19390 (SAiL) study group. Poster discussion 219 on 23 September 2009, ECCO 15 and ESMO 34.

Low incidence of grade ≥3 bleeding events and low discontinuation rates associated with first-line bevacizumab (Bev) in patients with advanced NSCLC: data from the SAiL (MO19390) study. Chun-Ming Tsai, Frank Griesinger, Janessa Laskin, Lucio Crinò, Nick Pavlakis, Eric Dansin, Nick Thatcher, Yon-Dechun Ko, Jörg Merger, Pilar Garrido, on behalf of the SAiL study group. Poster discussion 222 on 23 September 2009, ECCO 15 and ESMO 34.


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**About Avastin**

Avastin is an antibody that specifically binds and blocks VEGF (vascular endothelial growth factor). VEGF is the key driver of tumour angiogenesis – an essential process of development and maintenance of blood vessels which is required for a tumour to grow and to spread (metastasize) to other parts of the body. Avastin’s precise mode of action helps control tumour growth and metastases with only a limited impact on side effects of chemotherapy.

Avastin has proven survival benefits across multiple tumour types. Avastin is approved in Europe for the treatment of the advanced stages of four common types of cancer: colorectal cancer, breast cancer, non-small cell lung cancer (NSCLC) and kidney cancer. These types of cancer collectively cause nearly 3 million deaths each year. In the US, Avastin was the first anti-angiogenesis therapy approved by the FDA and is now approved for the treatment of five tumour types: colorectal cancer, non-small cell lung cancer, breast cancer, glioblastoma, and renal cell carcinoma.

More than 500,000 patients have been treated with Avastin so far. A comprehensive clinical programme with over 450 clinical trials is investigating the use of Avastin in various tumour types.
(including colorectal, breast, non-small cell lung, brain, gastric, ovarian, prostate and others) and different settings (advanced or early stage disease).

About Roche
Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.
In 2008, Roche had over 80,000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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To download images and videos relating to Avastin in non-small cell cancer please visit: http://www.thenewsmarket.com/