ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 01/27/2015

A Study of Tarceva (Erlotinib) Following Platinum-Based Chemotherapy in Patients With Advanced, Recurrent, or Metastatic Non-Small Cell Lung Cancer (NSCLC)

This study has been completed.

Sponsor:	Hoffmann-La Roche
Collaborators:	
Information provided by (Responsible Party):	Hoffmann-La Roche
ClinicalTrials.gov Identifier:	NCT00556712

Purpose

This 2 arm study will evaluate the efficacy, safety, and pharmacokinetics of Tarceva, compared with placebo, following platinum-based chemotherapy in patients with advanced, recurrent, or metastatic NSCLC who have not had disease progression or unacceptable toxicity during chemotherapy. Following 4 cycles of platinum-based chemotherapy, eligible patients will be randomized to receive either Tarceva 150mg po daily, or placebo daily. The anticipated time on study treatment is until disease progression; the target sample size is 500+ individuals.

Condition	Intervention	Phase
Non-Small Cell Lung Cancer	Drug: erlotinib [Tarceva] Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety/Efficacy Study
Official Title: A Randomized, Double-blind Study to Evaluate the Effect of Tarceva or Placebo Following Platinum-based CT on Overall Survival and Disease Progression in Patients With Advanced, Recurrent or Metastatic NSCLS Who Have Not Experienced Disease Progression or Unacceptable Toxicity During Chemotherapy

Further study details as provided by Hoffmann-La Roche:

Primary Outcome Measure:

- Percentage of Participants With PD According to Response Evaluation Criteria in Solid Tumors (RECIST) or Death (Data Cutoff 17 May 2008) [Time Frame: Screening, BL [≤21 days after randomization], every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  Progression-free survival (PFS) was defined as the time from randomization to PD or death, whichever occurred first. For target lesions (TLs), PD was defined at least a 20 percent (%) increase in the sum of the largest diameter (SLD), taking as reference the smallest SLD recorded from baseline (BL) more the appearance of one or more new lesions. For non-target lesions (NTLs), PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented.
- PFS in All Participants (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  The median time, in weeks, from randomization to PFS event. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% confidence interval (CI) was estimated using Kaplan-Meier methodology.
- Probable Percentage of Participants Remaining Alive and Free of Disease Progression at 6 Months (Data Cutoff 17 May 2008) [Time Frame: 6 months] [Designated as safety issue: No]

  PFS was defined as the time from randomization to PD or death, whichever occurred first. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded from BL more the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% CI was estimated using Kaplan-Meier methodology.
- Percentage of Epidermal Growth Factor Receptor (EGFR) Immunohistochemistry (IHC) Positive Participants With PD or Death (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  PFS was defined as the time from randomization to PD or death, whichever occurred first. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded since treatment started or the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented.
- PFS in EGFR IHC Positive Population (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤ 21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  The median time, in weeks, from randomization to PFS event. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% CI was estimated using Kaplan-Meier methodology.
- Probable Percentage of Participants in the EGFR IHC Positive Population Remaining Alive and Progression Free at 6 Months (Data Cutoff 17 May 2008) [Time Frame: 6 months] [Designated as safety issue: No]

  PFS was defined as the time from randomization to PD or death, whichever occurred first. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded since treatment started or the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% CI was estimated using Kaplan-Meier methodology.

Secondary Outcome Measures:

- Percentage of All Participants Who Died (Data Cutoff 12 January 2012) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 12 January 2012 (up to 71 months).] [Designated as safety issue: No]
- Overall Survival (OS) in All Participants (Data Cutoff 12 January 2012) [Time Frame: Screening, BL (≤ 21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 12 January 2012 (up to 71 months)] [Designated as safety issue: No]

OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.

- Probable Percentage of Participants Remaining Alive at 1 Year (Data Cutoff 12 January 2012) [Time Frame: 1 year] [Designated as safety issue: No]
  OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.
- Percentage of EGFR IHC Positive Participants Who Died (Data Cutoff 12 January 2012) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 12 January 2012 (up to 71 months)] [Designated as safety issue: No]
- OS in EGFR IHC Positive Population (Data Cutoff 12 January 2012) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 12 January 2012 (up to 71 months)] [Designated as safety issue: No]
  OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.
- Probable Percentage of Participants in the EGFR IHC Positive Population Remaining Alive at 1 Year (Data Cutoff 12 January 2012) [Time Frame: 1 year] [Designated as safety issue: No]
  OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.
- Percentage of EGFR IHC Negative Participants With PD or Death (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 71 months)] [Designated as safety issue: No]
  PFS was defined as the time from randomization to PD or death, whichever occurred first. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded since treatment started or the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented.
- PFS in EGFR IHC Negative Participants (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]
  The median time, in weeks, from randomization to PFS event. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% CI was estimated using Kaplan-Meier methodology.
- Probable Percentage of Participants in the EGFR IHC Negative Population Remaining Alive and Free of Disease Progression at 6 Months (Data Cutoff 17 May 2008) [Time Frame: 6 months] [Designated as safety issue: No]
  PFS was defined as the time from randomization to PD or death, whichever occurred first. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded since treatment started or the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% CI was estimated using Kaplan-Meier methodology.
- Percentage of EGFR IHC Negative Participants Who Died (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]
- OS in EGFR IHC Negative Participants (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.

- Probable Percentage of Participants in the EGFR IHC Negative Population Remaining Alive at 1 Year (Data Cutoff 17 May 2008) [Time Frame: 1 year] [Designated as safety issue: No]

  OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.
- Time to Progression (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  The median time, in weeks, between randomization and TTP event. Participants without PD were censored at the date of last tumor assessment where non-progression was documented. If a participant received a second anti-cancer therapy without prior documentation of PD, the participant was censored at the date of last tumor assessment before starting new chemotherapy.
- Probable Percentage of Participants Remaining Progression-Free in the TTP Analysis at 6 Months (Data Cutoff 17 May 2008) [Time Frame: 6 months] [Designated as safety issue: No]

  TTP was defined as the time from the date of randomization to the first date PD was recorded. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded since treatment started or the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD were censored at the date of last tumor assessment where non-progression was documented. If a participant received a second anti-cancer therapy without prior documentation of PD, the participant was censored at the date of last tumor assessment before starting new chemotherapy. The 95% CI was estimated using Kaplan-Meier methodology.
- Percentage of Participants With a Best Overall Response (BOR) of Confirmed Complete Response (CR) or Partial Response (PR) According to RECIST (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  BOR was defined as CR or PR confirmed by repeat assessments performed no less than 4 weeks after the criteria for response was first met. For TLs, CR was defined as the disappearance of all TLs, and PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the baseline (BL) SLD. For NTLs, CR was defined as the disappearance of all NTLs and normalization of tumor marker levels. The 95% CI for one sample binomial was determined using the Pearson-Clopper method.
- Percentage of Participants With a CR, PR, Stable Disease (SD), or PD According to RECIST (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  For TLs, CR was defined as the disappearance of all TLs; PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the BL SLD; SD was defined as neither sufficient decrease in SLD to qualify for PR nor sufficient increase in SLD to qualify for PD; and PD was defined as at least a 20% increase in the SLD of TLs, taking as reference the smallest SLD recorded since the treatment started. For NTLs, CR was defined as the disappearance of all NTLs and normalization of tumor marker levels; SD/incomplete response was defined as the persistence of 1 or more NTLs and/or maintenance of tumor marker levels above normal limits; and PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. The 95% CI for one sample binomial was determined using the Pearson-Clopper method.
- Percentage of Participants With a Response Upgrade From BL According to RECIST (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  Response upgrade was defined by a change of PR to CR or of SD to PR or CR from BL to the end of treatment. For TLs, CR was defined as the disappearance of all TLs; PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the BL SLD; SD was defined as neither sufficient decrease in SLD to qualify for PR nor sufficient increase in SLD to qualify for PD; and PD was defined as at least a 20% increase in

the SLD of TLs, taking as reference the smallest SLD recorded since the treatment started. For NTLs, CR was defined as the disappearance of all NTLs and normalization of tumor marker levels; SD/incomplete response was defined as the persistence of 1 or more NTLs and/or maintenance of tumor marker levels above normal limits; and PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. The 95% CI for one sample binomial was determined using the Pearson-Clopper method.

- Percentage of Participants With a Change of PR to CR or SD to PR or CR From BL to End of Treatment According to RECIST (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  For TLs, CR was defined as the disappearance of all TLs; PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the BL SLD; SD was defined as neither sufficient decrease in SLD to qualify for PR nor sufficient increase in SLD to qualify for PD; and PD was defined as at least a 20% increase in the SLD of TLs, taking as reference the smallest SLD recorded since the treatment started. For NTLs, CR was defined as the disappearance of all NTLs and normalization of tumor marker levels; SD/incomplete response was defined as the persistence of 1 or more NTLs and/or maintenance of tumor marker levels above normal limits; and PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. The 95% CI for one sample binomial was determined using the Pearson-Clopper method.

- Percentage of Participants With CR, PR, or SD or With SD [Maintained For Greater Than (>) 12 Weeks] or CR or PR (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  Disease control was defined as a best response of CR or PR or SD or a best response of SD for more than 12 weeks, or CR or PR. For TLs, CR was defined as the disappearance of all TLs; PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the BL SLD; SD was defined as neither sufficient decrease in SLD to qualify for PR nor sufficient increase in SLD to qualify for PD. For NTLs, CR was defined as the disappearance of all NTLs and normalization of tumor marker levels; SD/incomplete response was defined as the persistence of 1 or more NTLs and/or maintenance of tumor marker levels above normal limits. The 95% CI for one sample binomial was determined using the Pearson-Clopper method.

- Percentage of Participants With Symptom Progression Assessed Using the Lung Cancer Subscale (LCS) (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  LCS scores were obtained from a 7-item questionnaire from the Functional Assessment of Cancer Therapy - Lung (FACT-L) version (V) 4. Participants responded to questions assessing symptoms commonly reported by lung cancer patients; such as shortness of breath, loss of weight, and tightness in chest; on a scale from 0-4, where 0 equaled (=) "not at all" and 4 = "very much." The participants' responses were summed to result in an overall score, where a higher score indicated more severe symptoms. A change of 2 to 3 points in score was determined to be a clinically meaningful decline.

- Time to Symptom Progression (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  The median time, in weeks, from the date of randomization to the date of documented clinically meaningful decline in LCS from BL or death, whichever occurred first. LCS scores were obtained from a 7-item questionnaire from the FACT-L V 4. Participants responded to questions assessing symptoms commonly reported by lung cancer patients; such as shortness of breath, loss of weight, and tightness in chest; on a scale from 0-4, where 0 = "not at all" and 4 = "very much." The participants' responses were summed to result in an overall score, where a higher score indicated more severe symptoms. A change of 2 to 3 points in score was determined to be a clinically meaningful decline. The 95% CI was determined using Kaplan-Meier methodology.

- Probable Percentage of Participants Remaining Without Symptom Progression at 6 Months (Data Cutoff 17 May 2008) [Time Frame: 6 months] [Designated as safety issue: No]

  LCS scores were obtained from a 7-item questionnaire from the FACT-L V 4. Participants responded to questions assessing symptoms commonly reported by lung cancer patients; such as shortness of breath, loss of weight, and tightness in chest; on a scale from 0-4, where 0 = "not at all" and 4 = "very much." The participants' responses were summed to result in an overall score, where a higher score indicated more severe symptoms. A change of 2 to 3 points in score was determined to be a clinically meaningful decline. The 95% CI was estimated using Kaplan-Meier methodology.

- Percentage of Participants With Deterioration Assessed Using the Trial Outcome Index (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

The Trial Outcome Index (TOI) was defined as the sum of the scores of the Physical Well-Being (PWB), Functional Well-Being (FWB), and LCS. PWB, FWB, and LCS scores were obtained from 7-item questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in TOI score was defined as at least a 6 point decline from BL. Participants without a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L assessment.

- Time to Deterioration in TOI (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  The median time, in weeks, from the date of randomization until a clinically meaningful decline from BL in TOI or death, whichever occurred first. TOI was defined as the sum of PWB, FWB, and LCS scores, which were obtained from 7-item questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in TOI score was defined as at least a 6 point decline from BL Participants without a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L assessment. The 95% CI was determined using Kaplan-Meier methodology.
- Probable Percentage of Participants Remaining Without Deterioration in TOI at 6 Months (Data Cutoff 17 May 2008) [Time Frame: 6 months] [Designated as safety issue: No]

  TOI was defined as the sum of the scores of the PWB, FWB, and LCS. PWB, FWB, and LCS scores were obtained from 7-item questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in TOI score was defined as at least a 6 point decline from BL. Participants without a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L assessment. The 95% CI was estimated using Kaplan-Meier methodology.
- Percentage of Participants With Deterioration in Quality of Life Assessed Using TOI, SWB, and EWB (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  Deterioration in quality of life (QoL) was defined as a clinically meaningful decline in the total FACT-L score, the sum of the TOI, Social/Family Well-Being (SWB) and Emotional Well-Being (EWB) of the FACT-L questionnaires. TOI (PWB + FWB + LCS), SWB and EWB scores were obtained from 7-item (6-item in the case of EWB) questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in FACT-L score was defined as at least a 6 point decline from BL. Participants without a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L.
- Time to Deterioration in QoL (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]

  The median time, in weeks, from the date of randomization until a clinically meaningful decline from BL in total FACT-L or death, whichever occurred first. Total FACT-L score was defined as the sum of the TOI, SWB and EWB of the FACT-L questionnaires. TOI (PWB + FWB + LCS), SWB and EWB scores were obtained from 7-item (6-item in the case of EWB) questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in FACT-L score was defined as at least a 6 point decline from BL. Participants without a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L assessment. The 95% CI was determined using Kaplan-Meier methodology.
- Probable Percentage of Participants Remaining Without Deterioration in QoL at 6 Months (Data Cutoff 17 May 2008) [Time Frame: 6 months] [Designated as safety issue: No]

  Deterioration in QoL was defined as a clinically meaningful decline in the total FACT-L score, the sum of the TOI, SWB and EWB of the FACT-L questionnaires. TOI (PWB + FWB + LCS), SWB and EWB scores were obtained from 7-item (6-item in the case of EWB) questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in FACT-L score was defined as at least a 6 point decline from BL. Participants without

a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L. The 95% CI was estimated using Kaplan-Meier methodology.

- Functional Assessment of Chronic Illness Therapy - Lung (FACT-L) Scores (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]
  Total FACT-L score=sum of TOI, SWB, and EWB of FACT-L questionnaires. TOI (PWB+FWB+LCS), SWB, and EWB scores obtained from 7-item (6-item for EWB) questionnaires from FACT-L V4. Participants responded to questions assessing symptoms (scale 0-4; 0="not at all" and 4="very much"). Higher score=more severe symptoms. The 7-item LCS assessed symptoms such as shortness of breath, loss of weight, tightness in chest. Participants responded to questions assessing symptoms (scale: 0-4; 0="not at all" and 4="very much"). Scores from 0-35; higher score=more severe symptoms. The 27 items of FACT-G were scored in the following domains: PWB (7 items, total score 0-28), SWB (7 items; total score 0-28), EWB (6 items, total score 0-24), and FWB (7 items; total score 0-28), higher scores=better QoL. Participants responded to items on 5-point Likert scale (0="Not at all" to 4="Very much"; total score: 0-108). Higher score=better QOL. TOI score=PWB+FWB+LCS; Total TOI score: 0-92; higher scores=better QOL.
- Change From BL in FACT-L Scores (Data Cutoff 17 May 2008) [Time Frame: Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)] [Designated as safety issue: No]
  Total FACT-L score=sum of TOI, SWB, and EWB of FACT-L questionnaires. TOI (PWB+FWB+LCS), SWB, and EWB scores obtained from 7-item (6-item for EWB) questionnaires from FACT-L V4. Participants responded to questions assessing symptoms (scale 0-4; 0="not at all" and 4="very much"). Higher score=more severe symptoms. The 7-item LCS assessed symptoms such as shortness of breath, loss of weight, tightness in chest. Participants responded to questions assessing symptoms (scale: 0-4; 0="not at all" and 4="very much"). Scores from 0-35; higher score=more severe symptoms. The 27 items of FACT-G were scored in the following domains: PWB (7 items, total score 0-28), SWB (7 items; total score 0-28), EWB (6 items, total score 0-24), and FWB (7 items; total score 0-28), higher scores=better QoL. Participants responded to items on 5-point Likert scale (0="Not at all" to 4="Very much"; total score: 0-108). Higher score=better QOL. TOI score=PWB+FWB+LCS; Total TOI score: 0-92; higher scores=better QOL.

Enrollment: 889
Study Start Date: January 2006
Primary Completion Date: November 2010
Study Completion Date: November 2010

Arms	Assigned Interventions
Experimental: Erlotinib Participants received erlotinib, 150 milligrams (mg), orally (PO), daily from randomization until progressive disease (PD), death, or unacceptable toxicity.	Drug: erlotinib [Tarceva] 150mg po daily
Placebo Comparator: Placebo Participants received a placebo, PO, daily, from randomization until PD, death, or unacceptable toxicity.	Drug: Placebo po daily

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- adult patients >=18 years of age;
- histologically documented, locally advanced , recurrent or metastatic NSCLC;
- measurable disease;
- no disease progression after 4 cycles of platinum-based chemotherapy.

Exclusion Criteria:

- unstable systemic disease;
- any other malignancies in the last 5 years.

Contacts and Locations

Locations

Australia, New South Wales
St. Leonards, New South Wales, Australia, 2065
Waratah, New South Wales, Australia, 2298
Australia, Queensland
Brisbane, Queensland, Australia, 4101
Australia, South Australia
Adelaide, South Australia, Australia, 5041
Australia, Victoria
East Bentleigh, Victoria, Australia, VIC 3165
Fitzroy, Victoria, Australia, 3065
Geelong, Victoria, Australia, 3220
Melbourne, Victoria, Australia, 3084
Austria
Innsbruck, Austria, 6020
Klagenfurt, Austria, 9010
Wien, Austria, 1145
Wien, Austria, 1140
Belgium
Antwerpen, Belgium, 2020
Edegem, Belgium, 2650
Canada, Manitoba
Winnipeg, Manitoba, Canada, R3E 0V9
Canada, Ontario
Oshawa, Ontario, Canada, L1G 2B9
Sault Ste Marie, Ontario, Canada, P6A 2C4
Toronto, Ontario, Canada, M4C 3E7
Canada, Quebec

Laval, Quebec, Canada, H7M 3L9
Montreal, Quebec, Canada, H4J 1C5

Chile
Santiago, Chile, 0000

China
Beijing, China, 100730
Guangzhou, China, 510060
Guangzhou, China, 510080
Shanghai, China, 200032

Czech Republic
Ceské Budejovice, Czech Republic, 370 87
Olomouc, Czech Republic, 775 20
Plzen, Czech Republic, 305 99

Denmark
Herlev, Denmark, 2730
Odense, Denmark, 5000

France
Bayonne, France, 64100
Brest, France, 29200
Clermont-ferrand, France, 63003
Dijon, France, 21079
Dijon, France, 21079
Le Mans, France, 72037
Lille, France, 59020
Limoges, France, 87042
PAU, France, 64046
Paris, France, 75908
Paris, France, 75674
Toulouse, France, 31400
Vandoeuvre-les-nancy, France, 54511

Germany
Bad Berka, Germany, 99437
Bochum, Germany, 44791
Halle (Saale), Germany, 06120
Herne, Germany, 44625
Neuruppin, Germany, 16816
Villingen-Schwenningen, Germany, 78052

Greece
Athens, Greece, 11527
Athens, Greece, 14564
Heraklion, Greece, 71110

Hungary
Budapest, Hungary, 1125
Budapest, Hungary, 1122
Budapest, Hungary, 1529

Budapest, Hungary, 1529
Budapest, Hungary, 1529
Deszk, Hungary, 6772
Nyíregyháza, Hungary, 4400
Pecs, Hungary, 7635
Szombathely, Hungary, 9700
Torokbalint, Hungary, 2045

Italy
Bologna, Emilia-Romagna, Italy, 40139
Roma, Lazio, Italy, 00168
Ancona, Marche, Italy

Korea, Republic of
Daegu, Korea, Republic of, 700-712
Seoul, Korea, Republic of, 120-752
Seoul, Korea, Republic of, 138-736
Seoul, Korea, Republic of, 110-744
Seoul, Korea, Republic of, 135-710
Seoul, Korea, Republic of, 139-709
Suwon, Korea, Republic of

Lithuania
Kaunas, Lithuania
Klaipeda, Lithuania, 92288
Vilnius, Lithuania, 08660

Malaysia
Kuala Lumpur, Malaysia, 59100
Penang, Malaysia, 11200

Netherlands
Amsterdam, Netherlands, 1081 HV
Heerlen, Netherlands, 6419 PC
Nieuwegein, Netherlands, 3435 CM
Vlissingen, Netherlands, 4382 EE

New Zealand
Auckland, New Zealand, 1009
Christchurch, New Zealand

Poland
Lodz, Poland, 91-520
Lodz, Poland, 94-306
Otwock, Poland, 05-400

Romania
Bucuresti, Romania, 022328
Cluj Napoca, Romania, 400015
Iasi, Romania, 6600
Timisoara, Romania, 1900

Russian Federation
Arkhangelsk, Russian Federation, 163045

Arkhangelsk, Russian Federation, 163045
Balashikha, Russian Federation, 143900
Chelyabinsk, Russian Federation, 454 087
Kazan, Russian Federation, 420111
Kazan, Russian Federation, 420029
Kazan, Russian Federation, 420111
Kirov, Russian Federation
Kirov, Russian Federation
Krasnodar, Russian Federation, 350040
Krasnodar, Russian Federation
Kuzmolovo, Russian Federation, 188663
Moscow, Russian Federation, 125284
Moscow, Russian Federation, 117837
Moscow, Russian Federation, 105203
Moscow, Russian Federation, 105229
Moscow, Russian Federation, 115478
Nizhny Novgorod, Russian Federation, 603000
Perm, Russian Federation, 614 066
Perm, Russian Federation, 614 066
Smolensk, Russian Federation
Soshi, Russian Federation, 354057
St Petersburg, Russian Federation, 191015
St Petersburg, Russian Federation
St Petersburg, Russian Federation
St Petersburg, Russian Federation, 197022
St Petersburg, Russian Federation, 195067
Yaroslavl, Russian Federation, 150054

Slovakia

Banska Bystrica, Slovakia, 975 17
Bratislava, Slovakia, 825 56
Nitra, Slovakia, 949 88
Poprad, Slovakia, 058 87

Slovenia

Golnik, Slovenia
Ljubljana, Slovenia, 1000
Maribor, Slovenia

South Africa

Durban, South Africa, 4091
Johannesburg, South Africa, 2196
Pretoria, South Africa, 0001

Spain

Oviedo, Asturias, Spain, 33006
Santander, Cantabria, Spain, 39008
La Coruña, La Coruña, Spain, 15006
Valencia, Valencia, Spain, 46026

Zaragoza, Zaragoza, Spain, 50009
Ukraine
Kharkov, Ukraine, 61024
Uzhgorod, Ukraine, 88000
Zaporozhye, Ukraine, 69104
United Kingdom
Chelmsford, United Kingdom, CM1 7ET
Dundee, United Kingdom, DD1 9SY
Leicester, United Kingdom, LE1 5WW
Plymouth, United Kingdom, PL6 8DH
Venezuela
Caracas, Venezuela, 1062

Investigators

Study Director:	Clinical Trials	Hoffmann-La Roche

More Information

Responsible Party:	Hoffmann-La Roche
Study ID Numbers:	BO18192
Health Authority:	Russia: Ministry of Health

Study Results

Participant Flow

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without progressive disease (PD) according to Response Evaluation Criteria in Solid Tumors (RECIST) were randomized to receive a placebo, orally (PO) as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 Milligrams Per Day (mg/Day)	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Overall Study

	Placebo	Erlotinib, 150 Milligrams Per Day (mg/Day)
Started	451	438
Completed	0 [1]	0 [1]
Not Completed	451	438
Adverse Event	7	19
Death	5	10
Progressive Disease	383	320
Protocol Violation	3	2
Refused Treatment	17	16
Failure to Return	2	3
Not Specified	2	2
Ongoing at Data Cutoff	32	66

[1] Data cutoff date: 17 May 2008

Baseline Characteristics

Analysis Population Description

Full analysis set (FAS): all randomized participants presented according to the therapy that they were randomized to receive

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Baseline Measures

	Placebo	Erlotinib, 150 mg/Day	Total
Number of Participants	451	438	889
Age, Continuous [units: years] Mean (Standard Deviation)	59.7 (9.39)	59.8 (9.52)	59.8 (9.44)
Gender, Male/Female [units: participants]			
Female	113	117	230
Male	338	321	659

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With PD According to Response Evaluation Criteria in Solid Tumors (RECIST) or Death (Data Cutoff 17 May 2008)
Measure Description	Progression-free survival (PFS) was defined as the time from randomization to PD or death, whichever occurred first. For target lesions (TLs), PD was defined at least a 20 percent (%) increase in the sum of the largest diameter (SLD), taking as reference the smallest SLD recorded from baseline (BL) more the appearance of one or more new lesions. For non-target lesions (NTLs), PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented.
Time Frame	Screening, BL [≤21 days after randomization], every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; participants with PD prior to randomization were excluded from analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

	Description
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	447	437
Percentage of Participants With PD According to Response Evaluation Criteria in Solid Tumors (RECIST) or Death (Data Cutoff 17 May 2008) [units: percentage of participants]	89.5	79.9

2. Primary Outcome Measure:

Measure Title	PFS in All Participants (Data Cutoff 17 May 2008)
Measure Description	The median time, in weeks, from randomization to PFS event. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% confidence interval (CI) was estimated using Kaplan-Meier methodology.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; participants with PD prior to randomization were excluded from analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

	Description
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	447	437
PFS in All Participants (Data Cutoff 17 May 2008) [units: weeks] Median (95% Confidence Interval)	11.1 (8.1 to 11.7)	12.3 (12.0 to 13.3)

Statistical Analysis 1 for PFS in All Participants (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.71
	Confidence Interval	(2-Sided) 95% 0.62 to 0.82
	Estimation Comments	[Not specified]

3. Primary Outcome Measure:

Measure Title	Probable Percentage of Participants Remaining Alive and Free of Disease Progression at 6 Months (Data Cutoff 17 May 2008)
Measure Description	PFS was defined as the time from randomization to PD or death, whichever occurred first. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded from BL more the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	6 months
Safety Issue?	No

Analysis Population Description

FAS; participants with PD prior to randomization were excluded from analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	447	437
Probable Percentage of Participants Remaining Alive and Free of Disease Progression at 6 Months (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)	15.0 (12.0 to 19.0)	25.0 (21.0 to 29.0)

4. Primary Outcome Measure:

Measure Title	Percentage of Epidermal Growth Factor Receptor (EGFR) Immunohistochemistry (IHC) Positive Participants With PD or Death (Data Cutoff 17 May 2008)
Measure Description	PFS was defined as the time from randomization to PD or death, whichever occurred first. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded since treatment started or the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; only participants with EGFR IHC positive tumors were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	311	307
Percentage of Epidermal Growth Factor Receptor (EGFR) Immunohistochemistry (IHC) Positive Participants With PD or Death (Data Cutoff 17 May 2008) [units: percentage of participants]	89.4	79.5

5. Primary Outcome Measure:

Measure Title	PFS in EGFR IHC Positive Population (Data Cutoff 17 May 2008)
Measure Description	The median time, in weeks, from randomization to PFS event. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	Screening, BL (≤ 21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS;only participants with EGFR IHC positive tumors were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	311	307
PFS in EGFR IHC Positive Population (Data Cutoff 17 May 2008) [units: weeks] Median (95% Confidence Interval)	11.1 (7.1 to 11.7)	12.3 (12.0 to 17.7)

Statistical Analysis 1 for PFS in EGFR IHC Positive Population (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	< 0.0001
	Comments	[Not specified]
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.69
	Confidence Interval	(2-Sided) 95% 0.58 to 0.82
	Estimation Comments	[Not specified]

6. Primary Outcome Measure:

Measure Title	Probable Percentage of Participants in the EGFR IHC Positive Population Remaining Alive and Progression Free at 6 Months (Data Cutoff 17 May 2008)
Measure Description	PFS was defined as the time from randomization to PD or death, whichever occurred first. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded since treatment started or the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/ or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	6 months
Safety Issue?	No

Analysis Population Description

FAS; only participants with EGFR IHC positive tumors were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

	Description
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	311	307
Probable Percentage of Participants in the EGFR IHC Positive Population Remaining Alive and Progression Free at 6 Months (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)	16.0 (12.0 to 21.0)	27.0 (22.0 to 32.0)

7. Secondary Outcome Measure:

Measure Title	Percentage of All Participants Who Died (Data Cutoff 12 January 2012)
Measure Description	
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 12 January 2012 (up to 71 months).
Safety Issue?	No

Analysis Population Description

FAS

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

	Description
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	451	438
Percentage of All Participants Who Died (Data Cutoff 12 January 2012) [units: percentage of participants]	87.1	82.0

8. Secondary Outcome Measure:

Measure Title	Overall Survival (OS) in All Participants (Data Cutoff 12 January 2012)
Measure Description	OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	Screening, BL (≤ 21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 12 January 2012 (up to 71 months)
Safety Issue?	No

Analysis Population Description

FAS

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

	Description
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	451	438
Overall Survival (OS) in All Participants (Data Cutoff 12 January 2012) [units: months] Median (95% Confidence Interval)	11.0 (9.9 to 12.0)	12.4 (10.6 to 13.9)

Statistical Analysis 1 for Overall Survival (OS) in All Participants (Data Cutoff 12 January 2012)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0097
	Comments	[Not specified]
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.83
	Confidence Interval	(2-Sided) 95% 0.72 to 0.96
	Estimation Comments	[Not specified]

9. Secondary Outcome Measure:

Measure Title	Probable Percentage of Participants Remaining Alive at 1 Year (Data Cutoff 12 January 2012)
Measure Description	OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	1 year
Safety Issue?	No

Analysis Population Description
FAS

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	451	438
Probable Percentage of Participants Remaining Alive at 1 Year (Data Cutoff 12 January 2012) [units: percentage of participants] Number (95% Confidence Interval)	45.0 (41.0 to 50.0)	50.0 (45.0 to 55.0)

10. Secondary Outcome Measure:

Measure Title	Percentage of EGFR IHC Positive Participants Who Died (Data Cutoff 12 January 2012)
Measure Description	

Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 12 January 2012 (up to 71 months)
Safety Issue?	No

Analysis Population Description

FAS; only participants with EGFR IHC positive tumors were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	313	308
Percentage of EGFR IHC Positive Participants Who Died (Data Cutoff 12 January 2012) [units: percentage of participants]	87.5	80.5

11. Secondary Outcome Measure:

Measure Title	OS in EGFR IHC Positive Population (Data Cutoff 12 January 2012)
Measure Description	OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 12 January 2012 (up to 71 months)

Safety Issue?	No

Analysis Population Description

FAS; only participants with EGFR IHC positive tumors were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	313	308
OS in EGFR IHC Positive Population (Data Cutoff 12 January 2012) [units: months] Median (95% Confidence Interval)	11.0 (9.7 to 12.8)	12.8 (11.1 to 14.7)

Statistical Analysis 1 for OS in EGFR IHC Positive Population (Data Cutoff 12 January 2012)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0050
	Comments	[Not specified]
	Method	Log Rank

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.78
	Confidence Interval	(2-Sided) 95% 0.66 to 0.93
	Estimation Comments	[Not specified]

12. Secondary Outcome Measure:

Measure Title	Probable Percentage of Participants in the EGFR IHC Positive Population Remaining Alive at 1 Year (Data Cutoff 12 January 2012)
Measure Description	OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	1 year
Safety Issue?	No

Analysis Population Description
FAS

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	313	308

	Placebo	Erlotinib, 150 mg/Day
Probable Percentage of Participants in the EGFR IHC Positive Population Remaining Alive at 1 Year (Data Cutoff 12 January 2012) [units: percentage of participants] Number (95% Confidence Interval)	47.0 (41.0 to 52.0)	52.0 (47.0 to 58.0)

13. Secondary Outcome Measure:

Measure Title	Percentage of EGFR IHC Negative Participants With PD or Death (Data Cutoff 17 May 2008)
Measure Description	PFS was defined as the time from randomization to PD or death, whichever occurred first. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded since treatment started or the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 71 months)
Safety Issue?	No

Analysis Population Description

FAS; only participants with EGFR IHC negative tumors were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	59	62
Percentage of EGFR IHC Negative Participants With PD or Death (Data Cutoff 17 May 2008) [units: percentage of participants]	89.8	77.4

14. Secondary Outcome Measure:

Measure Title	PFS in EGFR IHC Negative Participants (Data Cutoff 17 May 2008)
Measure Description	The median time, in weeks, from randomization to PFS event. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; only participants with EGFR IHC negative tumors were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	59	62

	Placebo	Erlotinib, 150 mg/Day
PFS in EGFR IHC Negative Participants (Data Cutoff 17 May 2008) [units: weeks] Median (95% Confidence Interval)	9.0 (6.4 to 12.0)	11.0 (6.6 to 13.1)

Statistical Analysis 1 for PFS in EGFR IHC Negative Participants (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1768
	Comments	[Not specified]
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.77
	Confidence Interval	(2-Sided) 95% 0.51 to 1.14
	Estimation Comments	[Not specified]

15. Secondary Outcome Measure:

Measure Title	Probable Percentage of Participants in the EGFR IHC Negative Population Remaining Alive and Free of Disease Progression at 6 Months (Data Cutoff 17 May 2008)
Measure Description	PFS was defined as the time from randomization to PD or death, whichever occurred first. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded since treatment started or the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD or death were censored at the date of last tumor assessment where non-progression was documented. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	6 months

Safety Issue?	No

Analysis Population Description

FAS; only participants with EGFR IHC negative tumors were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	59	62
Probable Percentage of Participants in the EGFR IHC Negative Population Remaining Alive and Free of Disease Progression at 6 Months (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)	11.0 (2.0 to 20.0)	22.0 (11.0 to 34.0)

16. Secondary Outcome Measure:

Measure Title	Percentage of EGFR IHC Negative Participants Who Died (Data Cutoff 17 May 2008)
Measure Description	
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; only participants with EGFR IHC negative tumors were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	59	62
Percentage of EGFR IHC Negative Participants Who Died (Data Cutoff 17 May 2008) [units: percentage of participants]	50.8	41.9

17. Secondary Outcome Measure:

Measure Title	OS in EGFR IHC Negative Participants (Data Cutoff 17 May 2008)
Measure Description	OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; only participants with EGFR IHC negative tumors were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	59	62
OS in EGFR IHC Negative Participants (Data Cutoff 17 May 2008) [units: months] Median (95% Confidence Interval)	10.2 (7.4 to 11.2)	8.6 (7.4 to NA) [1]

[1] The upper limit of the 95% CI could not be calculated due to the large number of censored events.

Statistical Analysis 1 for OS in EGFR IHC Negative Participants (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4797
	Comments	[Not specified]
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)

	Estimated Value	0.83
	Confidence Interval	(2-Sided) 95% 0.49 to 1.40
	Estimation Comments	[Not specified]

18. Secondary Outcome Measure:

Measure Title	Probable Percentage of Participants in the EGFR IHC Negative Population Remaining Alive at 1 Year (Data Cutoff 17 May 2008)
Measure Description	OS was defined as the median time, in months, from the date of randomization to the date of death, due to any cause. Patients who have not died at the time of the final analysis will be censored at the date the patient was last known to be alive. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	1 year
Safety Issue?	No

Analysis Population Description

FAS; only participants with EGFR IHC negative tumors were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	59	62
Probable Percentage of Participants in the EGFR IHC Negative Population Remaining Alive at 1 Year (Data Cutoff 17 May 2008) [units: percentage of participants]	20.0 (3.0 to 37.0)	42.0 (25.0 to 59.0)

	Placebo	Erlotinib, 150 mg/Day
Number (95% Confidence Interval)		

19. Secondary Outcome Measure:

Measure Title	Time to Progression (Data Cutoff 17 May 2008)
Measure Description	The median time, in weeks, between randomization and TTP event. Participants without PD were censored at the date of last tumor assessment where non-progression was documented. If a participant received a second anti-cancer therapy without prior documentation of PD, the participant was censored at the date of last tumor assessment before starting new chemotherapy.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; participants with PD prior to randomization were excluded from analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	447	437
Time to Progression (Data Cutoff 17 May 2008) [units: weeks] Median (95% Confidence Interval)	11.3 (8.1 to 11.9)	12.3 (12.0 to 14.1)

Statistical Analysis 1 for Time to Progression (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.70
	Confidence Interval	(2-Sided) 95% 0.61 to 0.82
	Estimation Comments	[Not specified]

20. Secondary Outcome Measure:

Measure Title	Probable Percentage of Participants Remaining Progression-Free in the TTP Analysis at 6 Months (Data Cutoff 17 May 2008)
Measure Description	TTP was defined as the time from the date of randomization to the first date PD was recorded. For TLs, PD was defined at least a 20% increase in the SLD, taking as reference the smallest SLD recorded since treatment started or the appearance of one or more new lesions. For NTLs, PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. Participants without PD were censored at the date of last tumor assessment where non-progression was documented. If a participant received a second anti-cancer therapy without prior documentation of PD, the participant was censored at the date of last tumor assessment before starting new chemotherapy. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	6 months
Safety Issue?	No

Analysis Population Description

FAS; participants with PD prior to randomization were excluded from analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	447	437
Probable Percentage of Participants Remaining Progression-Free in the TTP Analysis at 6 Months (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)	15.0 (11.0 to 19.0)	26.0 (21.0 to 30.0)

21. Secondary Outcome Measure:

Measure Title	Percentage of Participants With a Best Overall Response (BOR) of Confirmed Complete Response (CR) or Partial Response (PR) According to RECIST (Data Cutoff 17 May 2008)
Measure Description	BOR was defined as CR or PR confirmed by repeat assessments performed no less than 4 weeks after the criteria for response was first met. For TLs, CR was defined as the disappearance of all TLs, and PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the baseline (BL) SLD. For NTLs, CR was defined as the disappearance of all NTLs and normalization of tumor marker levels. The 95% CI for one sample binomial was determined using the Pearson-Clopper method.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; only participants with CR, PR or SD at BL as determined by the Investigator were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	445	436
Percentage of Participants With a Best Overall Response (BOR) of Confirmed Complete Response (CR) or Partial Response (PR) According to RECIST (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)	5.4 (3.5 to 7.9)	11.9 (9.0 to 15.3)

Statistical Analysis 1 for Percentage of Participants With a Best Overall Response (BOR) of Confirmed Complete Response (CR) or Partial Response (PR) According to RECIST (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0006
	Comments	[Not specified]
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in Response Rates]
	Estimated Value	6.53
	Confidence Interval	(2-Sided) 95% 2.7 to 10.3
	Estimation Comments	The approximate 95% CI for the difference of two rates was determined using the Hauck-Anderson method.

22. Secondary Outcome Measure:

Measure Title	Percentage of Participants With a CR, PR, Stable Disease (SD), or PD According to RECIST (Data Cutoff 17 May 2008)
Measure Description	For TLs, CR was defined as the disappearance of all TLs; PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the BL SLD; SD was defined as neither sufficient decrease in SLD to qualify for PR nor sufficient increase in SLD to qualify for PD; and PD was defined as at least a 20% increase in the SLD of TLs, taking as reference the smallest SLD recorded since the treatment started. For NTLs, CR was defined as the disappearance of all NTLs and normalization of tumor marker levels; SD/incomplete response was defined as the persistence of 1 or more NTLs and/or maintenance of tumor marker levels above normal limits; and PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. The 95% CI for one sample binomial was determined using the Pearson-Clopper method.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; only participants with CR, PR or SD at BL as determined by the Investigator were included in the analysis; and 7 and 17 participants were not assessed from the Placebo and Erlotinib, 150 mg/day groups, respectively.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	445	436
Percentage of Participants With a CR, PR, Stable Disease (SD), or PD According to RECIST (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)		
CR	0.7 (0.1 to 2.0)	0.9 (0.3 to 2.3)
PR	4.7 (2.9 to 7.1)	11.0 (8.2 to 14.3)
SD	45.4 (40.7 to 50.1)	48.6 (43.8 to 53.4)
PD	47.6 (42.9 to 52.4)	35.6 (31.1 to 40.2)

23. Secondary Outcome Measure:

Measure Title	Percentage of Participants With a Response Upgrade From BL According to RECIST (Data Cutoff 17 May 2008)
Measure Description	Response upgrade was defined by a change of PR to CR or of SD to PR or CR from BL to the end of treatment. For TLs, CR was defined as the disappearance of all TLs; PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the BL SLD; SD was defined as neither sufficient decrease in SLD to qualify for PR nor sufficient increase in SLD to qualify for PD; and PD was defined as at least a 20% increase in the SLD of TLs, taking as reference the smallest SLD recorded since the treatment started. For NTLs, CR was defined as the disappearance of all NTLs and normalization of tumor marker levels; SD/incomplete response was defined as the persistence of 1 or more NTLs and/or maintenance of tumor marker levels above normal limits; and PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. The 95% CI for one sample binomial was determined using the Pearson-Clopper method.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; only participants with CR, PR or SD at BL as determined by the Investigator were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	445	436
Percentage of Participants With a Response Upgrade From BL According to RECIST (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)	1.3 (0.5 to 2.9)	5.5 (3.6 to 8.1)

Statistical Analysis 1 for Percentage of Participants With a Response Upgrade From BL According to RECIST (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0007
	Comments	[Not specified]
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in Response Upgrade Rates]

	Estimated Value	4.2
	Confidence Interval	(2-Sided) 95% 1.6 to 6.7
	Estimation Comments	The approximate 95% CI for the difference of two rates was determined using the Hauck-Anderson method.

24. Secondary Outcome Measure:

Measure Title	Percentage of Participants With a Change of PR to CR or SD to PR or CR From BL to End of Treatment According to RECIST (Data Cutoff 17 May 2008)
Measure Description	For TLs, CR was defined as the disappearance of all TLs; PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the BL SLD; SD was defined as neither sufficient decrease in SLD to qualify for PR nor sufficient increase in SLD to qualify for PD; and PD was defined as at least a 20% increase in the SLD of TLs, taking as reference the smallest SLD recorded since the treatment started. For NTLs, CR was defined as the disappearance of all NTLs and normalization of tumor marker levels; SD/incomplete response was defined as the persistence of 1 or more NTLs and/or maintenance of tumor marker levels above normal limits; and PD was defined as the appearance of 1 or more new lesions and/or unequivocal progression of existing NTLs. The 95% CI for one sample binomial was determined using the Pearson-Clopper method.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; only participants with CR, PR or SD at BL as determined by the Investigator were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	445	436
Percentage of Participants With a Change of PR to CR or SD to PR or CR From BL to End of Treatment According to RECIST (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)		
PR to CR	0.4 (0.1 to 1.6)	0.5 (0.1 to 1.6)
SD to PR	0.9 (0.2 to 2.3)	4.8 (3.0 to 7.3)
SD to CR	0.0 (0.0 to 0.8)	0.2 (0.0 to 1.3)

25. Secondary Outcome Measure:

Measure Title	Percentage of Participants With CR, PR, or SD or With SD [Maintained For Greater Than (>) 12 Weeks] or CR or PR (Data Cutoff 17 May 2008)
Measure Description	Disease control was defined as a best response of CR or PR or SD or a best response of SD for more than 12 weeks, or CR or PR. For TLs, CR was defined as the disappearance of all TLs; PR was defined as at least a 30% decrease in the SLD of the TLs, taking as a reference the BL SLD; SD was defined as neither sufficient decrease in SLD to qualify for PR nor sufficient increase in SLD to qualify for PD. For NTLs, CR was defined as the disappearance of all NTLs and normalization of tumor marker levels; SD/incomplete response was defined as the persistence of 1 or more NTLs and/or maintenance of tumor marker levels above normal limits. The 95% CI for one sample binomial was determined using the Pearson-Clopper method.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; only participants with CR, PR or SD at BL as determined by the Investigator were included in the analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

	Description
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	445	436
Percentage of Participants With CR, PR, or SD or With SD [Maintained For Greater Than (>) 12 Weeks] or CR or PR (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)		
CR Plus (+) PR + SD	50.8 (46.0 to 55.5)	60.6 (55.8 to 65.2)
CR + PR + SD >12 Weeks	27.4 (23.3 to 31.8)	40.8 (36.2 to 45.6)

Statistical Analysis 1 for Percentage of Participants With CR, PR, or SD or With SD [Maintained For Greater Than (>) 12 Weeks] or CR or PR (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	Analysis included CR + PR + SD rate.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0035
	Comments	[Not specified]
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in Disease Control Rates]
	Estimated Value	9.8
	Confidence Interval	(2-Sided) 95%

		3.1 to 16.4
	Estimation Comments	Approximate 95% CI for the difference of two rates was determined using the Hauck-Anderson method.

Statistical Analysis 2 for Percentage of Participants With CR, PR, or SD or With SD [Maintained For Greater Than (>) 12 Weeks] or CR or PR (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	Analysis included CR + PR + SD > 12 weeks rate.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	[Not specified]
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Other [Difference in Disease Control Rates]
	Estimated Value	13.4
	Confidence Interval	(2-Sided) 95% 7.1 to 19.7
	Estimation Comments	Approximate 95% CI for the difference of two rates was determined using the Hauck-Anderson method.

26. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Symptom Progression Assessed Using the Lung Cancer Subscale (LCS) (Data Cutoff 17 May 2008)
Measure Description	LCS scores were obtained from a 7-item questionnaire from the Functional Assessment of Cancer Therapy - Lung (FACT-L) version (V) 4. Participants responded to questions assessing symptoms commonly reported by lung cancer patients; such as shortness of breath, loss of weight, and tightness in chest; on a scale from 0-4, where 0 equaled (=) "not at all" and 4 = "very much." The participants' responses were summed to result in an overall score, where a higher score indicated more severe symptoms. A change of 2 to 3 points in score was determined to be a clinically meaningful decline.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)

Safety Issue?	No

Analysis Population Description

FAS; 56 and 48 participants were not evaluated for this outcome measure from the Placebo and Erlotinib groups, respectively.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	395	390
Percentage of Participants With Symptom Progression Assessed Using the Lung Cancer Subscale (LCS) (Data Cutoff 17 May 2008) [units: percentage of participants]	44.1	47.7

27. Secondary Outcome Measure:

Measure Title	Time to Symptom Progression (Data Cutoff 17 May 2008)
Measure Description	The median time, in weeks, from the date of randomization to the date of documented clinically meaningful decline in LCS from BL or death, whichever occurred first. LCS scores were obtained from a 7-item questionnaire from the FACT-L V 4. Participants responded to questions assessing symptoms commonly reported by lung cancer patients; such as shortness of breath, loss of weight, and tightness in chest; on a scale from 0-4, where 0 = "not at all" and 4 = "very much." The participants' responses were summed to result in an overall score, where a higher score indicated more severe symptoms. A change of 2 to 3 points in score was determined to be a clinically meaningful decline. The 95% CI was determined using Kaplan-Meier methodology.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)

Safety Issue?	No

Analysis Population Description
FAS

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	395	390
Time to Symptom Progression (Data Cutoff 17 May 2008) [units: weeks] Median (95% Confidence Interval)	17.6 (12.4 to 19.1)	18.3 (13.1 to 24.1)

Statistical Analysis 1 for Time to Symptom Progression (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3787
	Comments	[Not specified]
	Method	Log Rank

	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.91
	Confidence Interval	(2-Sided) 95% 0.74 to 1.12
	Estimation Comments	[Not specified]

28. Secondary Outcome Measure:

Measure Title	Probable Percentage of Participants Remaining Without Symptom Progression at 6 Months (Data Cutoff 17 May 2008)
Measure Description	LCS scores were obtained from a 7-item questionnaire from the FACT-L V 4. Participants responded to questions assessing symptoms commonly reported by lung cancer patients; such as shortness of breath, loss of weight, and tightness in chest; on a scale from 0-4, where 0 = "not at all" and 4 = "very much." The participants' responses were summed to result in an overall score, where a higher score indicated more severe symptoms. A change of 2 to 3 points in score was determined to be a clinically meaningful decline. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	6 months
Safety Issue?	No

Analysis Population Description
FAS

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	395	390
Probable Percentage of Participants Remaining Without Symptom Progression at 6 Months (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)	35.0 (27.0 to 42.0)	41.0 (34.0 to 47.0)

29. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Deterioration Assessed Using the Trial Outcome Index (Data Cutoff 17 May 2008)
Measure Description	The Trial Outcome Index (TOI) was defined as the sum of the scores of the Physical Well-Being (PWB), Functional Well-Being (FWB), and LCS. PWB, FWB, and LCS scores were obtained from 7-item questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in TOI score was defined as at least a 6 point decline from BL. Participants without a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L assessment.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; 59 and 49 participants were not evaluated for this outcome measure from the Placebo and Erlotinib groups, respectively.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	392	389
Percentage of Participants With Deterioration Assessed Using the Trial Outcome Index (Data Cutoff 17 May 2008) [units: percentage of participants]	43.1	50.9

30. Secondary Outcome Measure:

Measure Title	Time to Deterioration in TOI (Data Cutoff 17 May 2008)
Measure Description	The median time, in weeks, from the date of randomization until a clinically meaningful decline from BL in TOI or death, whichever occurred first. TOI was defined as the sum of PWB, FWB, and LCS scores, which were obtained from 7-item questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in TOI score was defined as at least a 6 point decline from BL Participants without a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L assessment. The 95% CI was determined using Kaplan-Meier methodology.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description
FAS

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	392	389
Time to Deterioration in TOI (Data Cutoff 17 May 2008) [units: weeks] Median (95% Confidence Interval)	18.9 (13.6 to 24.1)	18.1 (12.3 to 19.0)

Statistical Analysis 1 for Time to Deterioration in TOI (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5385
	Comments	[Not specified]
	Method	Log Rank
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	1.06
	Confidence Interval	(2-Sided) 95% 0.87 to 1.31
	Estimation Comments	[Not specified]

31. Secondary Outcome Measure:

Measure Title	Probable Percentage of Participants Remaining Without Deterioration in TOI at 6 Months (Data Cutoff 17 May 2008)
Measure Description	TOI was defined as the sum of the scores of the PWB, FWB, and LCS. PWB, FWB, and LCS scores were obtained from 7-item questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in TOI score was defined as at least a 6 point decline from BL. Participants without a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L assessment. The 95% CI was estimated using Kaplan-Meier methodology.

Time Frame	6 months
Safety Issue?	No

Analysis Population Description
FAS

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	392	389
Probable Percentage of Participants Remaining Without Deterioration in TOI at 6 Months (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)	41.0 (34.0 to 48.0)	39.0 (33.0 to 45.0)

32. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Deterioration in Quality of Life Assessed Using TOI, SWB, and EWB (Data Cutoff 17 May 2008)

Measure Description	Deterioration in quality of life (QoL) was defined as a clinically meaningful decline in the total FACT-L score, the sum of the TOI, Social/Family Well-Being (SWB) and Emotional Well-Being (EWB) of the FACT-L questionnaires. TOI (PWB + FWB + LCS), SWB and EWB scores were obtained from 7-item (6-item in the case of EWB) questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in FACT-L score was defined as at least a 6 point decline from BL. Participants without a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; 62 and 51 participants were not evaluated for this outcome measure from the Placebo and Erlotinib groups, respectively,

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	389	387
Percentage of Participants With Deterioration in Quality of Life Assessed Using TOI, SWB, and EWB (Data Cutoff 17 May 2008) [units: percentage of participants]	51.7	55.3

33. Secondary Outcome Measure:

Measure Title	Time to Deterioration in QoL (Data Cutoff 17 May 2008)

Measure Description	The median time, in weeks, from the date of randomization until a clinically meaningful decline from BL in total FACT-L or death, whichever occurred first. Total FACT-L score was defined as the sum of the TOI, SWB and EWB of the FACT-L questionnaires. TOI (PWB + FWB + LCS), SWB and EWB scores were obtained from 7-item (6-item in the case of EWB) questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in FACT-L score was defined as at least a 6 point decline from BL. Participants without a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L assessment. The 95% CI was determined using Kaplan-Meier methodology.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	389	387
Time to Deterioration in QoL (Data Cutoff 17 May 2008) [units: weeks] Median (95% Confidence Interval)	12.3 (11.9 to 17.9)	12.6 (12.1 to 18.1)

Statistical Analysis 1 for Time to Deterioration in QoL (Data Cutoff 17 May 2008)

Statistical Analysis Overview	Comparison Groups	Placebo, Erlotinib, 150 mg/Day
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.6530
	Comments	[Not specified]
	Method	Log Rank
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Hazard Ratio (HR)
	Estimated Value	0.96
	Confidence Interval	(2-Sided) 95% 0.79 to 1.16
	Estimation Comments	[Not specified]

34. Secondary Outcome Measure:

Measure Title	Probable Percentage of Participants Remaining Without Deterioration in QoL at 6 Months (Data Cutoff 17 May 2008)
Measure Description	Deterioration in QoL was defined as a clinically meaningful decline in the total FACT-L score, the sum of the TOI, SWB and EWB of the FACT-L questionnaires. TOI (PWB + FWB + LCS), SWB and EWB scores were obtained from 7-item (6-item in the case of EWB) questionnaires from the FACT-L V 4. Participants responded to questions assessing symptoms on a scale from 0-4, where 0 = "not at all" and 4 = "very much." Higher score indicated more severe symptoms. A clinically meaningful decline in FACT-L score was defined as at least a 6 point decline from BL. Participants without a clinically meaningful decline in TOI at the time of analysis were censored at the time of the last FACT-L. The 95% CI was estimated using Kaplan-Meier methodology.
Time Frame	6 months
Safety Issue?	No

Analysis Population Description
FAS

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	389	387
Probable Percentage of Participants Remaining Without Deterioration in QoL at 6 Months (Data Cutoff 17 May 2008) [units: percentage of participants] Number (95% Confidence Interval)	34.0 (27.0 to 40.0)	32.0 (26.0 to 38.0)

35. Secondary Outcome Measure:

Measure Title	Functional Assessment of Chronic Illness Therapy - Lung (FACT-L) Scores (Data Cutoff 17 May 2008)
Measure Description	Total FACT-L score=sum of TOI, SWB, and EWB of FACT-L questionnaires. TOI (PWB+FWB+LCS), SWB, and EWB scores obtained from 7-item (6-item for EWB) questionnaires from FACT-L V4. Participants responded to questions assessing symptoms (scale 0-4; 0="not at all" and 4="very much"). Higher score=more severe symptoms. The 7-item LCS assessed symptoms such as shortness of breath, loss of weight, tightness in chest. Participants responded to questions assessing symptoms (scale: 0-4; 0="not at all" and 4="very much"). Scores from 0-35; higher score=more severe symptoms. The 27 items of FACT-G were scored in the following domains: PWB (7 items, total score 0-28), SWB (7 items; total score 0-28), EWB (6 items, total score 0-24), and FWB (7 items; total score 0-28), higher scores=better QoL. Participants responded to items on 5-point Likert scale (0="Not at all" to 4="Very much"; total score: 0-108). Higher score=better QOL. TOI score=PWB+FWB+LCS; Total TOI score: 0-92; higher scores=better QOL.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description

FAS; n=number of participants assessed for the given parameter at the specified timepoint.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	397	392
Functional Assessment of Chronic Illness Therapy - Lung (FACT-L) Scores (Data Cutoff 17 May 2008) [units: score on a scale] Mean (Standard Deviation)		
BL: Physical Well-Being (n=397,392)	20.85 (4.817)	20.96 (4.781)
BL: Social Well-Being (n=397,392)	20.84 (5.496)	20.98 (5.285)
BL: Emotional Well-Being (n=397,393)	16.92 (4.534)	16.77 (4.862)
BL: Functional Well-Being (n=397,393)	16.15 (5.488)	16.84 (5.514)
BL: FACT-L Subscale Score (n=397,391)	24.17 (4.892)	24.46 (4.697)
BL: Lung Cancer Subscale Score (n=397,391)	19.82 (4.188)	20.07 (4.240)
BL: Total FACT-General (FACT-G) Score (n=396,391)	74.68 (14.787)	75.52 (14.612)
BL: Trial Outcome Index (n=396,390)	56.83 (11.830)	57.90 (11.682)
BL: Total FACT-L Score (n=395,389)	98.85 (18.007)	100.02 (17.751)
Week 6: Physical Well-Being (n=274,304)	21.44 (5.117)	20.69 (5.180)
Week 6: Social Well-Being (n=274,303	20.62 (5.437)	21.43 (5.178)

	Placebo	Erlotinib, 150 mg/Day
Week 6: Emotional Well-Being (n=275,302)	16.53 (4.587)	17.17 (4.748)
Week 6: Functional Well-Being (n=275,302)	16.41 (5.234)	16.87 (5.614)
Week 6: FACT-L Subscale Score (n=275,300)	24.45 (5.231)	24.80 (5.000)
Week 6: Lung Cancer Subscale Score (n=275,300)	19.78 (4.463)	20.13 (4.336)
Week 6: Total FACT-G Score (n=274,300)	74.82 (14.380)	76.14 (15.132)
Week 6: Trial Outcome Index (n=274,299)	57.59 (12.292)	57.64 (12.482)
Week 6: Total FACT-L Score (n=274,297)	99.27 (17.857)	100.95 (18.360)
Week 12: Physical Well-Being (n=144,194)	21.93 (4.734)	20.78 (5.368)
Week 12: Social Well-Being (n=143,194)	20.38 (5.637)	20.04 (5.691)
Week 12: Emotional Well-Being (n=144,194)	17.21 (4.376)	16.85 (4.521)
Week 12: Functional Well-Being (n=144,196)	17.04 (5.770)	16.35 (5.745)
Week 12: FACT-L Subscale Score (n=144,196)	25.15 (4.735)	24.19 (5.323)
Week 12: Lung Cancer Subscale Score (n=144,196)	20.22 (4.015)	19.50 (4.600)
Week 12: Total FACT-G Score (n=144,192)	76.42 (14.889)	74.06 (15.754)
Week 12: Trial Outcome Index (n=144,194)	59.19 (12.129)	56.57 (13.276)
Week 12: Total FACT-L Score (n=144,192)	101.56 (17.824)	98.30 (19.337)
Week 18: Physical Well-Being (n=86,143)	21.60 (4.883)	21.40 (4.945)
Week 18: Social Well-Being (n=86,143)	21.08 (5.328)	19.94 (6.130)
Week 18: Emotional Well-Being (n=86,143)	17.33 (4.717)	17.14 (4.356)
Week 18: Functional Well-Being (n=86,143)	16.89 (5.289)	16.83 (5.553)
Week 18: FACT-L Subscale Score (n=86,143)	25.44 (4.645)	24.52 (5.344)
Week 18: Lung Cancer Subscale Score (n=86,143)	20.28 (4.003)	19.64 (4.635)
Week 18: Total FACT-G Score (n=86,143)	76.89 (14.385)	75.31 (16.648)
Week 18: Trial Outcome Index (n=86,143)	58.76 (11.492)	57.87 (12.803)
Week 18: Total FACT-L Score (n=86,143)	102.33 (17.502)	99.83 (20.558)
Week 24: Physical Well-Being (n=59,101)	21.78 (4.665)	21.21 (4.898)

	Placebo	Erlotinib, 150 mg/Day
Week 24: Social Well-Being (n=59,101)	20.79 (5.641)	20.49 (5.251)
Week 24: Emotional Well-Being (n=59,100)	16.86 (4.880)	16.54 (4.615)
Week 24: Functional Well-Being (n=59,100)	17.14 (6.062)	17.23 (5.300)
Week 24: FACT-L Subscale Score (n=59,101)	25.18 (5.126)	25.13 (5.245)
Week 24: Lung Cancer Subscale Score (n=59,101)	20.07 (4.246)	19.94 (4.487)
Week 24: Total FACT-G Score (n=59,99)	76.58 (16.091)	75.50 (15.754)
Week 24: Trial Outcome Index (n=59,100)	58.99 (11.837)	58.37 (12.686)
Week 24: Total FACT-L Score (n=59,99)	101.75 (19.347)	100.69 (19.831)
Week 30: Physical Well-Being (n=37,66)	21.74 (4.153)	21.77 (4.576)
Week 30: Social Well-Being (n=37,66)	20.50 (5.180)	20.74 (5.491)
Week 30: Emotional Well-Being (n=37,66)	16.37 (4.164)	17.23 (4.675)
Week 30: Functional Well-Being (n=37,66)	17.92 (5.082)	17.93 (5.510)
Week 30: FACT-L Subscale Score (n=37,66)	25.90 (3.484)	25.86 (4.817)
Week 30: Lung Cancer Subscale Score (n=37,66)	20.66 (3.073)	20.61 (4.393)
Week 30: Total FACT-G Score (n=37,66)	76.54 (11.915)	77.66 (15.078)
Week 30: Trial Outcome Index (n=37,66)	60.32 (9.753)	60.30 (11.876)
Week 30: Total FACT-L Score (n=37,66)	102.44 (14.063)	103.52 (18.367)
Week 36: Physical Well-Being (n=25,47)	21.60 (3.317)	22.26 (4.480)
Week 36: Social Well-Being (n=25,47)	20.02 (5.769)	20.15 (4.988)
Week 36: Emotional Well-Being (n=25,47)	17.31 (3.736)	17.54 (4.540)
Week 36: Fuctional Well-Being (n=25,47)	16.06 (4.287)	18.06 (5.720)
Week 36: FACT-L Subscale Score (n=25,47)	24.48 (4.089)	25.83 (5.305)
Week 36: Lung Cancer Subscale Score (n=25,47)	19.36 (3.893)	20.55 (4.463)
Week 36: Total FACT-G Score (n=25,47)	74.99 (11.066)	78.02 (15.688)
Week 36: Trial Outcome Index (n=25,47)	57.02 (9.426)	60.87 (11.963)
Week 36: Total FACT-L Score (n=25,47)	99.27 (13.672)	103.86 (19.244)
Week 42: Physical Well-Being (n=19,35)	21.76 (3.592)	22.19 (5.035)

	Placebo	Erlotinib, 150 mg/Day
Week 42: Social Well-Being (n=19,35)	18.45 (6.262)	20.40 (5.234)
Week 42: Emotional Well-Being (n=19,35)	16.95 (4.089)	17.43 (4.984)
Week 42: Functional Well-Being (n=19,35)	15.32 (3.902)	18.57 (5.500)
Week 42: FACT-L Subscale Score (n=19,35)	24.63 (4.448)	26.67 (5.357)
Week 42: Lung Cancer Subscale Score (n=19,35)	19.50 (4.092)	21.21 (4.607)
Week 42: FACT-G Score (n=19,35)	72.74 (12.406)	78.59 (16.316)
Week 42: Trial Outcome Index (n=19,35)	56.58 (9.562)	61.97 (12.622)
Week 42: FACT-L Score (n=19,35)	97.11 (14.951)	105.25 (20.385)
Week 48: Physical Well-Being (n=13,29)	21.38 (4.154)	23.23 (4.016)
Week 48: Social Well-Being (n=13,29)	17.23 (7.567)	20.24 (5.569)
Week 48: Emotional Well-Being (n=13,29)	18.69 (3.011)	17.59 (4.903)
Week 48: Functional Well-Being (n=13,29)	14.15 (2.672)	18.48 (4.501)
Week 48: FACT-L Subscale Score (n=12,29)	23.35 (3.647)	26.80 (5.591)
Week 48: Lung Cancer Subscale Score (n=12,29)	18.75 (3.646)	21.21 (4.967)
Week 48: FACT-G Score (n=12,29)	71.46 (12.069)	79.53 (14.672)
Week 48: Trial Outcome Index (n=12,29)	54.58 (9.140)	62.92 (11.105)
Week 48: FACT-L Score (n=12,29)	96.19 (14.394)	106.33 (18.701)
Week 60: Physical Well-Being (n=9,17)	22.67 (4.664)	23.65 (4.212)
Week 60: Social Well-Being (n=9,17)	17.78 (6.405)	21.31 (6.530)
Week 60: Emotional Well-Being (n=9,17)	16.78 (3.232)	19.12 (3.638)
Week 60: Functional Well-Being (n=9,17)	15.11 (3.408)	18.65 (6.828)
Week 60: FACT-L Subscale Score (n=9,17)	23.43 (5.010)	25.99 (6.844)
Week 60: Lung Cancer Subscale Score (n=9,17)	17.89 (3.919)	20.47 (5.959)
Week 60: Total FACT-G Score (n=9,17)	72.34 (11.607)	82.73 (17.803)
Week 60: Trial Outcome Index (n=9,17)	55.67 (9.695)	62.76 (14.316)
Week 60: Total FACT-L Score (n=9,17)	95.77 (15.703)	108.71 (23.069)
Week 72: Physical Well-Being (n=6,8)	22.17 (4.997)	23.25 (4.097)

	Placebo	Erlotinib, 150 mg/Day
Week 72: Social Well-Being (n=6,8)	19.00 (7.251)	21.44 (5.852)
Week 72: Emotional Well-Being (n=6,8)	17.17 (2.401)	18.25 (5.007)
Week 72: Functional Well-Being (n=6,8)	15.22 (4.457)	16.50 (5.855)
Week 72: FACT-L Subscale Score (n=6,8)	21.23 (5.154)	26.48 (6.185)
Week 72: Lung Cancer Subscale Score (n=6,8)	17.17 (4.021)	21.40 (5.724)
Week 72: Total FACT-G Score (n=6,8)	73.67 (14.820)	79.44 (16.176)
Week 72: Trial Outcome Index (n=6,8)	54.67 (11.911)	61.15 (14.343)
Week 72: Total FACT-L Score (n=6,8)	94.90 (18.833)	105.92 (21.282)
Week 84: Physical Well-Being (n=1,0)	20.00 (NA) [1]	NA (NA) [2]
Week 84: Social Well-Being (n=1,0)	14.00 (NA) [3]	NA (NA) [2]
Week 84: Emotional Well-Being (n=1,0)	13.00 (NA) [3]	NA (NA) [2]
Week 84: Functional Well-Being (n=1,0)	18.00 (NA) [3]	NA (NA) [2]
Week 84: FACT-L Subscale Score (n=1,0)	17.00 (NA) [3]	NA (NA) [2]
Week 84: Lung Cancer Subscale Score (n=1,0)	13.00 (NA) [3]	NA (NA) [2]
Week 84: Total FACT-G Score (n=1,0)	65.00 (NA) [3]	NA (NA) [2]
Week 84: Trial Outcome Index (n=1,0)	51.00 (NA) [3]	NA (NA) [2]
Week 84: Total FACT-L Score (n=1,0)	82.00 (NA) [3]	NA (NA) [2]
Off Trtmt: Physical Well-Being (n=265,215)	19.57 (5.668)	18.50 (5.534)
Off Trtmt: Social Well-Being (n=263,216)	20.01 (5.380)	20.68 (5.265)
Off Trtmt: Emotional Well-Being (n=265,216)	14.76 (5.157)	15.11 (5.183)
Off Trtmt: Functional Well-Being (n=265,216)	14.90 (5.893)	14.58 (5.934)
Off Trtmt: FACT-L Subscale Score (n=264,214)	22.80 (5.268)	22.88 (4.911)
Off Trtmt: Lung Cancer Subscale Score (n=264,214)	18.06 (4.629)	18.16 (4.383)
Off Trtmt:Total FACT-G Score (n=261,214)	69.29 (15.730)	68.94 (15.669)
Off Trtmt:Trial Outcome Index (n=263,213)	52.61 (13.475)	51.34 (12.974)

	Placebo	Erlotinib, 150 mg/Day
Off Trtmt:Total FACT-L Score (n=260,212)	92.14 (19.324)	91.89 (18.738)

[1] Standard deviation (SD) not calculated as only 1 participant was analyzed.
[2] Zero participants analyzed
[3] SD not calculated as only 1 participant was analyzed.

36. Secondary Outcome Measure:

Measure Title	Change From BL in FACT-L Scores (Data Cutoff 17 May 2008)
Measure Description	Total FACT-L score=sum of TOI, SWB, and EWB of FACT-L questionnaires. TOI (PWB+FWB+LCS), SWB, and EWB scores obtained from 7-item (6-item for EWB) questionnaires from FACT-L V4. Participants responded to questions assessing symptoms (scale 0-4; 0="not at all" and 4="very much"). Higher score=more severe symptoms. The 7-item LCS assessed symptoms such as shortness of breath, loss of weight, tightness in chest. Participants responded to questions assessing symptoms (scale: 0-4; 0="not at all" and 4="very much"). Scores from 0-35; higher score=more severe symptoms. The 27 items of FACT-G were scored in the following domains: PWB (7 items, total score 0-28), SWB (7 items; total score 0-28), EWB (6 items, total score 0-24), and FWB (7 items; total score 0-28), higher scores=better QoL. Participants responded to items on 5-point Likert scale (0="Not at all" to 4="Very much"; total score: 0-108). Higher score=better QOL. TOI score=PWB+FWB+LCS; Total TOI score: 0-92; higher scores=better QOL.
Time Frame	Screening, BL (≤21 days after randomization), every 6 weeks thereafter until Week 48, every 12 weeks thereafter until PD, discontinuation of study treatment, or end of survival follow-up, up to data cutoff of 17 May 2008 (up to 27 months)
Safety Issue?	No

Analysis Population Description
FAS; n=number of participants assessed for the given parameter at the specified timepoint.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Measured Values

	Placebo	Erlotinib, 150 mg/Day
Number of Participants Analyzed	274	303
Change From BL in FACT-L Scores (Data Cutoff 17 May 2008) [units: score on a scale] Mean (Standard Deviation)		
Week 6: Physical Well-Being (n=274,303)	0.22 (4.235)	-0.47 (4.729)
Week 6: Social Well-Being (n=274,303)	-0.24 (4.901)	0.23 (4.202)
Week 6: Emotional Well-Being (n=274,302)	-0.41 (3.801)	0.29 (3.916)
Week 6: Functional Well-Being (n=275,302)	0.24 (4.819)	-0.09 (4.711)
Week 6: FACT-L Subscale Score (n=275,298)	-0.06 (4.899)	0.24 (4.623)
Week 6: Lung Cancer Subscale Score (n=275,298)	-0.32 (4.148)	-0.03 (4.160)
Week 6: Total FACT-G Score (n=273,299)	-0.20 (12.256)	0.01 (11.453)
Week 6: Trial Outcome Index (n=274,296)	0.16 (10.276)	-0.73 (10.201)
Week 6: Total FACT-L Score (n=273,294)	-0.20 (15.133)	0.14 (14.155)
Week 12: Physical Well-Being (n=144,193)	1.00 (4.036)	-0.14 (4.908)
Week 12: Social Well-Being (n=143,194)	-0.43 (4.918)	-0.43 (5.566)
Week 12: Emotional Well-Being (n=144,194)	0.25 (3.728)	0.20 (4.115)
Week 12: Functional Well-Being (n=144,196)	1.00 (4.707)	-0.38 (4.806)
Week 12: FACT-L Subscale Score (n=144,196)	0.88 (4.501)	-0.06 (4.570)
Week 12: Lung Cancer Subscale Score (n=144,196)	0.19 (3.666)	-0.48 (4.004)
Week 12: Total FACT-G Score (n=144,191)	1.83 (11.637)	-0.84 (12.145)
Week 12: Trial Outcome Index (n=144,193)	2.20 (9.362)	-1.04 (10.051)
Week 12: Total FACT-L Score (n=144,191)	2.72 (14.226)	-0.90 (14.536)
Week 18: Physical Well-Being (n=86,143)	1.31 (4.798)	0.40 (4.890)
Week 18: Social Well-Being (n=86,143)	-0.01 (4.454)	-0.51 (5.894)
Week 18: Emotional Well-Being (n=86,143)	0.59 (3.984)	0.60 (3.723)
Week 18: Functional Well-Being (n=86,143)	1.06 (4.353)	0.18 (4.903)

	Placebo	Erlotinib, 150 mg/Day
Week 18: FACT-L Subscale Score (n=86,143)	1.48 (4.171)	0.27 (4.587)
Week 18: Lung Cancer Subscale Score (n=86,143)	0.49 (3.550)	-0.26 (4.125)
Week 18: Total FACT-G Score (n=86,143)	2.95 (12.047)	0.68 (12.668)
Week 18: Trial Outcome Index (n=86,143)	2.86 (9.638)	0.32 (10.350)
Week 18: Total FACT-L Score (n=86,143)	4.43 (14.523)	0.95 (15.386)
Week 24: Physical Well-Being (n=59,101)	1.29 (4.358)	0.16 (4.881)
Week 24: Social Well-Being (n=59,101)	-0.25 (4.804)	0.04 (6.092)
Week 24: Emotional Well-Being (n=59,100)	0.21 (5.118)	-0.05 (4.169)
Week 24: Functional Well-Being (n=59,100)	1.64 (4.550)	0.42 (4.373)
Week 24: FACT-L Subscale Score (n=59,101)	1.45 (5.018)	0.50 (5.048)
Week 24: Lung Cancer Subscale Score (n=59,101)	0.48 (4.051)	-0.12 (4.321)
Week 24: Total FACT-G Score (n=59,99)	2.89 (13.739)	0.52 (12.753)
Week 24: Trial Outcome Index (n=59,100)	3.42 (9.606)	0.43 (10.348)
Week 24: Total FACT-L Score (n=59,99)	4.34 (16.354)	1.10 (15.954)
Week 30: Physical Well-Being (n=37,66)	1.61 (4.205)	0.49 (5.129)
Week 30: Social Well-Being (n=37,66)	0.00 (5.510)	-0.19 (6.676)
Week 30: Emotional Well-Being (n=37,66)	-0.07 (4.902)	0.74 (4.775)
Week 30: Functional Well-Being (n=37,66)	2.17 (5.028)	0.83 (5.243)
Week 30: FACT-L Subscale Score (n=37,66)	1.79 (4.616)	0.99 (4.863)
Week 30: Lung Cancer Subscale Score (n=37,66)	0.69 (3.818)	0.38 (4.454)
Week 30: Total FACT-G Score (n=37,66)	3.71 (13.827)	1.88 (14.268)
Week 30: Trial Outcome Index (n=37,66)	4.47 (9.551)	1.70 (11.108)
Week 30: Total FACT-L Score (n=37,66)	5.50 (15.828)	2.86 (16.864)
Week 36: Physical Well-Being (n=25,47)	2.21 (4.791)	0.77 (5.093)
Week 36: Social Well-Being (n=25,47)	-0.36 (5.659)	-0.16 (7.053)
Week 36: Emotional Well-Being (n=25,47)	0.86 (4.892)	0.65 (3.717)
Week 36: Functional Well-Being (n=25,47)	1.31 (5.551)	1.10 (5.280)

	Placebo	Erlotinib, 150 mg/Day
Week 36: FACT-L Subscale Score (n=25,47)	0.67 (4.864)	0.43 (5.459)
Week 36: Lung Cancer Subscale Score (n=25,47)	-0.10 (3.963)	-0.06 (4.535)
Week 36: Total FACT-G Score (n=25,47)	4.02 (14.439)	2.37 (13.991)
Week 36: Trial Outcome Index (n=25,47)	3.42 (11.186)	1.82 (10.443)
Week 36: Total Fact-L Score (n=25,47)	4.68 (17.636)	2.79 (16.662)
Week 42: Physical Well-Being (n=19,35)	1.82 (3.936)	0.27 (5.835)
Week 42: Social Well-Being (n=19,35)	-1.14 (6.006)	0.28 (7.784)
Week 42: Emotional Well-Being (n=19,35)	-0.11 (3.573)	0.59 (3.741)
Week 42: Functional Well-Being (n=19,35)	0.05 (3.582)	0.65 (5.580)
Week 42: FACT-L Subscale Score (n=19,35)	1.40 (4.321)	0.87 (4.974)
Week 42: Lung Cancer Subscale Score (n=19,35)	0.42 (2.858)	0.51 (4.301)
Week 42: FACT-G Score (n=19,35)	0.62 (10.871)	1.80 (15.245)
Week 42: Trial Outcome Index (n=19,35)	2.29 (7.037)	1.44 (12.405)
Week 42: FACT-L Score (n=19,35)	2.03 (12.466)	2.67 (18.499)
Week 48: Physical Well-Being (n=13,29)	0.46 (3.497)	1.37 (6.388)
Week 48: Social Well-Being (n=13,29)	-1.96 (7.987)	-0.68 (6.851)
Week 48: Emotional Well-Being (n=13,29)	-0.08 (3.095)	0.41 (4.166)
Week 48: Functional Well-Being (n=13,29)	-2.00 (3.894)	0.55 (5.448)
Week 48: FACT-L Subscale Score (n=12,29)	0.03 (4.445)	0.82 (5.967)
Week 48: Lung Cancer Subscale Score (n=12,29)	-0.79 (3.100)	0.34 (5.150)
Week 48: Total FACT-G Score (n=13,29)	-3.57 (12.233)	1.64 (14.463)
Week 48: Trial Outcome Index (n=12,29)	-1.79 (7.570)	2.26 (13.247)
Week 48: Total FACT-L Score (n=12,29)	-1.60 (11.354)	2.46 (18.177)
Week 60: Physical Well-Being (n=9,17)	1.89 (5.383)	1.82 (6.307)
Week 60: Social Well-Being (n=9,17)	-0.57 (7.368)	0.06 (9.116)
Week 60: Emotional Well-Being (n=9,17)	-1.56 (2.789)	0.28 (4.478)
Week 60: Functional Well-Being (n=9,17)	-0.56 (3.877)	-0.53 (7.434)

	Placebo	Erlotinib, 150 mg/Day
Week 60: FACT-L Subscale Score (n=9,17)	1.61 (5.882)	0.43 (6.275)
Week 60: Lung Cancer Subscale Score (n=9,17)	-0.22 (4.438)	0.47 (5.535)
Week 60: Total FACT-G Score (n=9,17)	-0.79 (12.270)	1.64 (17.542)
Week 60: Trial Outcome Index (n=9,17)	1.11 (11.044)	1.76 (14.316)
Week 60: Total FACT-L Score (n=9,17)	0.82 (15.700)	2.07 (22.086)
Week 72: Physical Well-Being (n=6,8)	1.33 (6.318)	2.63 (7.130)
Week 72: Social Well-Being (n=6,8)	0.31 (6.723)	0.30 (3.733)
Week 72: Emotional Well-Being (n=6,8)	-1.50 (3.619)	-0.13 (4.853)
Week 72: Functional Well-Being (n=6,8)	-1.67 (5.354)	-1.13 (5.384)
Week 72: FACT-L Subscale Score (n=6,8)	-0.50 (7.396)	1.03 (4.818)
Week 72: Lung Cancer Subscale Score (n=6,8)	-1.17 (5.193)	1.78 (4.141)
Week 72: Total FACT-G Score (n=6,8)	-1.53 (11.929)	1.67 (14.651)
Week 72: Trial Outcome Index (n=6,8)	-1.50 (13.097)	3.28 (13.738)
Week 72: Total FACT-L Score (n=6,8)	-2.03 (16.140)	2.70 (17.579)
Week 84: Physical Well-Being (n=1,0)	1.33 (NA) [1]	NA (NA) [2]
Week 84: Social Well-Being (n=1,0)	-2.00 (NA) [1]	NA (NA) [2]
Week 84: Emotional Well-Being (n=1,0)	-3.00 (NA) [1]	NA (NA) [2]
Week 84: Functional Well-Being (n=1,0)	-1.00 (NA) [1]	NA (NA) [2]
Week 84: FACT-L Subscale Score (n=1,0)	6.0 (NA) [1]	NA (NA) [2]
Week 84: Lung Cancer Subscale Score (n=1,0)	2.0 (NA) [1]	NA (NA) [2]
Week 84: Total FACT-G Score (n=1,0)	-4.67 (NA) [1]	NA (NA) [2]
Week 84: Trial Outcome Index (n=1,0)	2.33 (NA) [1]	NA (NA) [2]
Week 84: Total FACT-L Score (n=1,0)	1.33 (NA) [1]	NA (NA) [2]
Off Trtmt: Physical Well-Being (n=264,214)	-1.07 (4.750)	-2.19 (5.506)
Off Trtmt: Social Well-Being (n=263,216)	-0.66 (4.973)	0.09 (4.824)

	Placebo	Erlotinib, 150 mg/Day
Off Trtmt: Emotional Well-Being (n=264,216)	-2.04 (4.225)	-1.56 (4.745)
Off Trtmt: Functional Well-Being (n=264,216)	-1.20 (5.170)	-1.98 (5.355)
Off Trtmt: FACT-L Subscale Score (n=263,212)	-1.27 (4.458)	-1.32 (4.708)
Off Trtmt: Lung Cancer Subscale Score (n=263,212)	-1.74 (3.882)	-1.78 (4.199)
Off Trtmt: Total FACT-G Score (n=260,213)	-4.91 (12.576)	-5.71 (13.588)
Off Trtmt: Trial Outcome Index (n=261,210)	-4.03 (10.658)	-6.05 (11.785)
Off Trtmt: Total FACT-L Score (n=258,209)	-6.26 (15.146)	-7.10 (16.194)

[1] SD not calculated as only 1 participant was analyzed.
[2] Zero participants were analyzed

Reported Adverse Events

Time Frame	Adverse events (AEs) were recorded from Day 1 (after randomization) through the end of study, up to 27 months. Serious adverse events (SAEs) were recorded from Day 1 (after randomization) through the second data cut-off, up to 71 months.
Additional Description	All participants who received at least 1 dose of investigational treatment and had at least 1 safety follow-up, whether prematurely withdrawn or not, were included in the safety analysis.

Reporting Groups

	Description
Placebo	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive a placebo, PO as tablets, daily, from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.
Erlotinib, 150 mg/Day	Participants completed 4 cycles (3 or 4 week cycles) of a standard platinum based non-investigational chemotherapy according to local practice and in concordance with the local labeling instructions (chemotherapy run-in period). Participants who completed all 4 cycles of chemotherapy run-in without PD according to RECIST were randomized to receive erlotinib, 150 mg/day, PO as tablets from randomization until PD, death, unacceptable toxicity, or end of study, up to 27 months.

Serious Adverse Events

	Placebo	Erlotinib, 150 mg/Day
	Affected/At Risk (%)	Affected/At Risk (%)
Total	34/445 (7.64%)	49/433 (11.32%)
Blood and lymphatic system disorders		
Anaemia [A] *	0/445 (0%)	1/433 (0.23%)
Cardiac disorders		
Aortic aneurysm [A] *	0/445 (0%)	1/433 (0.23%)
Cardiac failure [A] *	0/445 (0%)	1/433 (0.23%)
Cardiac tamponade [A] *	1/445 (0.22%)	0/433 (0%)
Cardio-respiratory arrest [A] *	0/445 (0%)	2/433 (0.46%)
Left ventricular dysfunction [A] *	0/445 (0%)	1/433 (0.23%)
Myocardial infarction [A] *	1/445 (0.22%)	0/433 (0%)
Eye disorders		
Diplopia [A] *	1/445 (0.22%)	0/433 (0%)
Gastrointestinal disorders		
Diarrhoea [A] *	0/445 (0%)	4/433 (0.92%)
Dysphagia [A] *	1/445 (0.22%)	0/433 (0%)
Gastric perforation [A] *	0/445 (0%)	1/433 (0.23%)
Gastric ulcer perforation [A] *	0/445 (0%)	1/433 (0.23%)
Haematemesis [A] *	0/445 (0%)	1/433 (0.23%)
Vomiting [A] *	2/445 (0.45%)	0/433 (0%)
General disorders		
Asthenia [A] *	1/445 (0.22%)	0/433 (0%)
Chest pain [A] *	0/445 (0%)	1/433 (0.23%)

	Placebo	Erlotinib, 150 mg/Day
	Affected/At Risk (%)	Affected/At Risk (%)
Drowning [A] *	0/445 (0%)	1/433 (0.23%)
Pyrexia [A] *	0/445 (0%)	1/433 (0.23%)
Sudden death [A] *	0/445 (0%)	1/433 (0.23%)
Hepatobiliary disorders		
Cholelithiasis [A] *	0/445 (0%)	1/433 (0.23%)
Infections and infestations		
Bronchitis [A] *	2/445 (0.45%)	0/433 (0%)
Catheter sepsis [A] *	1/445 (0.22%)	0/433 (0%)
Cellulitis [A] *	0/445 (0%)	2/433 (0.46%)
Colitis [A] *	0/445 (0%)	1/433 (0.23%)
Empyema [A] *	1/445 (0.22%)	0/433 (0%)
Lower respiratory tract infection [A] *	1/445 (0.22%)	1/433 (0.23%)
Lung abscess [A] *	0/445 (0%)	1/433 (0.23%)
Nocardiosis [A] *	1/445 (0.22%)	0/433 (0%)
Pneumonia [A] *	4/445 (0.9%)	7/433 (1.62%)
Pyelonephritis acute [A] *	0/445 (0%)	1/433 (0.23%)
Respiratory tract infection [A] *	1/445 (0.22%)	1/433 (0.23%)
Sepsis [A] *	0/445 (0%)	1/433 (0.23%)
Staphylococcal abscess [A] *	0/445 (0%)	1/433 (0.23%)
Upper respiratory tract infection [A] *	0/445 (0%)	1/433 (0.23%)
Injury, poisoning and procedural complications		
Femur fracture [A] *	2/445 (0.45%)	0/433 (0%)

	Placebo	Erlotinib, 150 mg/Day
	Affected/At Risk (%)	Affected/At Risk (%)
Spinal compression fracture [A] *	0/445 (0%)	1/433 (0.23%)
Investigations		
Alanine aminotransferase increased [A] *	0/445 (0%)	1/433 (0.23%)
Aspartate aminotransferase increased [A] *	0/445 (0%)	1/433 (0.23%)
Metabolism and nutrition disorders		
Anorexia [A] *	0/445 (0%)	1/433 (0.23%)
Dehydration [A] *	0/445 (0%)	1/433 (0.23%)
Musculoskeletal and connective tissue disorders		
Muscular weakness [A] *	1/445 (0.22%)	0/433 (0%)
Pain in extremity [A] *	1/445 (0.22%)	0/433 (0%)
Nervous system disorders		
Cerebrovascular accident [A] *	1/445 (0.22%)	1/433 (0.23%)
Dizziness [A] *	0/445 (0%)	1/433 (0.23%)
Intracranial pressure increased [A] *	0/445 (0%)	1/433 (0.23%)
Neuralgia [A] *	0/445 (0%)	1/433 (0.23%)
Neuropathy peripheral [A] *	0/445 (0%)	1/433 (0.23%)
Peripheral motor neuropathy [A] *	0/445 (0%)	1/433 (0.23%)
Sciatica [A] *	1/445 (0.22%)	0/433 (0%)
Syncope [A] *	0/445 (0%)	1/433 (0.23%)
Psychiatric disorders		
Depression [A] *	0/445 (0%)	1/433 (0.23%)
Panic attack [A] *	0/445 (0%)	1/433 (0.23%)
Renal and urinary disorders		

	Placebo	Erlotinib, 150 mg/Day
	Affected/At Risk (%)	Affected/At Risk (%)
Renal failure acute [A] *	0/445 (0%)	1/433 (0.23%)
Urogenital haemorrhage [A] *	0/445 (0%)	1/433 (0.23%)
Respiratory, thoracic and mediastinal disorders		
Bronchospasm [A] *	1/445 (0.22%)	0/433 (0%)
Chronic obstructive pulmonary disease [A] *	1/445 (0.22%)	0/433 (0%)
Dyspnoea [A] *	2/445 (0.45%)	2/433 (0.46%)
Epistaxis [A] *	1/445 (0.22%)	0/433 (0%)
Haemoptysis [A] *	2/445 (0.45%)	1/433 (0.23%)
Interstitial lung disease [A] *	0/445 (0%)	2/433 (0.46%)
Pleural effusion [A] *	1/445 (0.22%)	1/433 (0.23%)
Pleural fistula [A] *	0/445 (0%)	1/433 (0.23%)
Pneumonia aspiration [A] *	1/445 (0.22%)	0/433 (0%)
Pulmonary embolism [A] *	2/445 (0.45%)	0/433 (0%)
Pulmonary fibrosis [A] *	0/445 (0%)	1/433 (0.23%)
Respiratory failure [A] *	0/445 (0%)	1/433 (0.23%)
Skin and subcutaneous tissue disorders		
Rash [A] *	0/445 (0%)	2/433 (0.46%)
Vascular disorders		
Arterial thrombosis [A] *	1/445 (0.22%)	0/433 (0%)
Arteritis [A] *	1/445 (0.22%)	0/433 (0%)
Deep vein thrombosis [A] *	1/445 (0.22%)	0/433 (0%)
Iliac artery thrombosis [A] *	0/445 (0%)	1/433 (0.23%)

	Placebo	Erlotinib, 150 mg/Day
	Affected/At Risk (%)	Affected/At Risk (%)
Peripheral ischaemia [A] *	1/445 (0.22%)	1/433 (0.23%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (11.0)

Other Adverse Events
Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Placebo	Erlotinib, 150 mg/Day
	Affected/At Risk (%)	Affected/At Risk (%)
Total	152/445 (34.16%)	283/433 (65.36%)
Gastrointestinal disorders		
Diarrhoea [A] *	20/445 (4.49%)	87/433 (20.09%)
Nausea [A] *	27/445 (6.07%)	33/433 (7.62%)
General disorders		
Chest pain [A] *	28/445 (6.29%)	14/433 (3.23%)
Fatigue [A] *	26/445 (5.84%)	39/433 (9.01%)
Metabolism and nutrition disorders		
Anorexia [A] *	22/445 (4.94%)	39/433 (9.01%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] *	38/445 (8.54%)	36/433 (8.31%)
Dyspnoea [A] *	37/445 (8.31%)	33/433 (7.62%)
Haemoptysis [A] *	21/445 (4.72%)	22/433 (5.08%)
Skin and subcutaneous tissue disorders		
Acne [A] *	0/445 (0%)	27/433 (6.24%)
Pruritus [A] *	12/445 (2.7%)	32/433 (7.39%)
Rash [A] *	26/445 (5.84%)	211/433 (48.73%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (11.0)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

Results Point of Contact:

Name/Official Title: Medical Communications
Organization: Hoffman-LaRoche
Phone: 800-821-8590
Email: genentech@druginfo.com