This presentation contains certain forward-looking statements. These forward-looking statements may be identified by words such as “believes”, “expects”, “anticipates”, “projects”, “intends”, “should”, “seeks”, “estimates”, “future” or similar expressions or by discussion of strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation among others:

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5. Uncertainties in the discovery, development or marketing of new products or new uses of existing products;
6. Increased government pricing pressures;
7. Interruptions in production;
8. Loss of or inability to obtain adequate protection for intellectual property rights;
9. Litigation;
10. Loss of key executives or other employees; and...
11. Adverse publicity or news coverage

For marketed products discussed in this presentation, please see full prescribing information on our website – www.roche.com
Introduction
   Dr. Karl Mahler, Head of Investor Relations, Roche

Avastin in CRC: clinical trials and real life experience
   Prof. Dr. Alberto Sobrero, Head Medical Oncology Unit, Ospedale San Martino, Genova, Italy

New data on Avastin in mCRC including K-Ras subgroup analysis
   Dr. Niko André, International Medical Leader Avastin, Roche

GBG-26 study and phase II study of pertuzumab in mBC
   Prof. Dr. José Baselga, Chairman and Professor of Medicine, Medical Oncology Service, Vall d’Hebron University Hospital, Barcelona, Spain

Conclusion
   William M. Burns, CEO Roche Pharmaceuticals
Roche oncology products

Existing and future components of standards of care

- **Adjuvant**
  - Xeloda, Avastin

1st line
- Avastin, Xeloda

**CRC**

2nd line
- Xeloda, Avastin

**BC**

2nd line
- Xeloda, Avastin, Herceptin, pertuzumab

3rd line
- Tarceva

**NSCLC**

2nd line
- Tarceva

1st line
- Avastin, Tarceva

**Proven efficacy**

**In development**
Avastin in metastatic colorectal cancer

*Strong growth potential in Europe*

Avastin market penetration (Top 5 EU):

- 10 to 20% of XELOX segment
- 10 to 20% of FOLFOX segment
- 60% of FOLFIRI segment

First-line market:

- FOLFIRI
- FOLFOX
- XELOX
- Xeloda/5-FU

Avastin in mCRC

- Broadest possible label in EU: Avastin can be combined with any chemo in first and later lines (since January 2008)
- Excellent reimbursement in most EU countries
- Significant potential for growth in Europe/RoW
Avastin in CRC: clinical trials and real life experience

New data on Avastin in CRC including K-Ras subgroup analysis

GBG-26 study and phase II study of pertuzumab in mBC

Conclusion

Q&A
Avastin-based therapy: essential in clinical practice

Professor Alberto Sobrero
Head of Medical Oncology,
Hospital San Martino, Genoa, Italy
Colorectal cancer – a global challenge

2nd

Over 1 million new cases

Biggest cancer killer

Three positive controlled clinical trials in first-line mCRC

Combined Analysis of Efficacy: The Addition of Bevacizumab to Fluorouracil/Leucovorin Improves Survival for Patients With Metastatic Colorectal Cancer

Purpose
Bevacizumab (Avastin), a monoclonal antibody against vascular endothelial growth factor, has demonstrated colorectal cancer when administered alone. A combined analysis of three recent randomized clinical trials in first-line metastatic colorectal cancer (mCRC) was conducted to determine the efficacy and safety of bevacizumab in combination with standard chemotherapy.

Methods
A pooled analysis was performed on 721 patients who were randomized to receive either bevacizumab plus fluorouracil/leucovorin or fluorouracil/leucovorin alone. The primary endpoint was overall survival (OS) and secondary endpoints included progression-free survival (PFS) and safety.

Results
The analysis showed a significant improvement in OS for patients in the bevacizumab plus fluorouracil/leucovorin arm compared to the fluorouracil/leucovorin alone arm (median OS: 11.7 months vs. 10.3 months, respectively). The hazard ratio for death was 0.68 (95% CI: 0.55-0.85, p=0.0007). PFS was also improved in the bevacizumab plus fluorouracil/leucovorin arm compared to the fluorouracil/leucovorin alone arm (median PFS: 14.4 months vs. 9.7 months, respectively).

Bevacizumab plus Irinotecan, Fluorouracil, and Leucovorin for Metastatic Colorectal Cancer

Bevacizumab, a monoclonal antibody against vascular endothelial growth factor, has demonstrated survival benefits in patients with metastatic colorectal cancer (mCRC). This combination therapy has shown promising results in clinical trials.

Purpose
To evaluate the efficacy and safety of bevacizumab in combination with oxaliplatin-based chemotherapy as first-line therapy in mCRC.

Methods
A phase III randomized controlled trial randomized 450 patients with mCRC to receive bevacizumab in combination with oxaliplatin, 5-fluorouracil (5-FU), and leucovorin (FOLFOX-4) or to receive oxaliplatin, 5-FU, and leucovorin alone. The primary endpoint was progression-free survival (PFS) and secondary endpoints included overall survival (OS) and safety.

Results
The analysis showed a significant improvement in PFS for patients in the bevacizumab plus oxaliplatin, 5-FU, and leucovorin arm compared to the oxaliplatin, 5-FU, and leucovorin alone arm (median PFS: 10.6 months vs. 6.7 months, respectively). The hazard ratio for disease progression or death was 0.66 (95% CI: 0.53-0.82, p<0.001). There was no significant difference in OS between the two arms (median OS: 22.4 months vs. 20.3 months, respectively).

Bevacizumab plus Oxaliplatin, 5-Fluorouracil, and Leucovorin for Metastatic Colorectal Cancer

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Avastin adds strong benefit  
*The time patients live without their disease progressing (PFS)*

<table>
<thead>
<tr>
<th>Oxaliplatin-based CTx₁</th>
<th>Avastin + XELOX/FOLFOX4</th>
<th>(n=699)</th>
<th>9.4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo + XELOX/FOLFOX4</td>
<td>(n=701)</td>
<td>8.0</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Irinotecan-based CTx₂</th>
<th>Avastin + IFL</th>
<th>(n=402)</th>
<th>10.6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo + IFL</td>
<td>(n=411)</td>
<td>6.2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5-FU/LV-based CTx₃</th>
<th>Avastin + 5-FU/LV*</th>
<th>(n=249)</th>
<th>8.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-FU/LV or IFL alone*</td>
<td>(n=241)</td>
<td>5.6</td>
<td></td>
</tr>
</tbody>
</table>

*Combined analyses: included two phase II trials and one phase III trial*

1. Saltz et al. JCO 2008  
Avastin adds strong benefit
Overall survival

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Median OS (months)</th>
<th>HR</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avastin + XELOX/FOLFOX4</td>
<td>21.3</td>
<td>0.89</td>
<td>0.077</td>
</tr>
<tr>
<td>Placebo + XELOX/FOLFOX4</td>
<td>19.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avastin + IFL</td>
<td>20.3</td>
<td>0.66</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Placebo + IFL</td>
<td>15.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avastin + 5-FU/LV</td>
<td>17.9</td>
<td>0.74</td>
<td>0.0081</td>
</tr>
<tr>
<td>5-FU/LV or IFL alone*</td>
<td>14.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Combined analyses: included two phase II trials and one phase III trial

1. Saltz et al. JCO 2008
From clinical trials to clinical practice

Activity

Efficacy

Effectiveness
In clinical practice, Avastin provides PFS >10 months with many chemotherapy combinations

- Overall:
  - n=1,953: 10.1 months
  - n=1,914: 10.8 months

- Avastin + FOLFIRI:
  - n=280: 10.9 months
  - n=503: 11.6 months

- Avastin + FOLFOX:
  - n=1,092: 10.0 months
  - n=552: 11.3 months

- Avastin + XELOX:
  - n=94: 11.2 months
  - n=346: 10.8 months

- Avastin + 5-FU/Xeloda:
  - n=300: 8.6 months

- Avastin + 5-FU/LV:
  - n=132: 9.2 months

Data sources:
- First BEAT Berry, et al.
  - ASCO 2008 (poster 4025)
- BRiTE Kozloff et al.
  - ASCO GI 2007 (poster)
In clinical practice, Avastin provides OS of almost 2 years with many chemotherapy combinations.

Berry, et al. ASCO 2008 (poster 4025)

- Overall: 22.7 months
- Avastin + FOLFIRI: 23.7 months
- Avastin + FOLFOX: 25.9 months
- Avastin + XELOX: 23.0 months
- Avastin + 5-FU/Xeloda: 18.0 months

Berry, et al. ASCO 2008 (poster 4025)
Considerable survival benefit with Avastin treatment throughout course of disease

A multivariate analysis of data from the BRiTE observational study confirmed Avastin post-progressive disease was the only variable that significantly increased survival (p<0.001)

Continuous VEGF inhibition results in tumor control

Roche


PD = progressive disease
Avastin enables effective and safe curative surgery in initially unresectable patients

Successful curative surgery (R0) following Avastin plus chemotherapy in the First BEAT trial

- Secondary resection was a planned secondary endpoint; data were assessed prospectively
- Overall, 225 patients (12%) received surgery with curative intent. Among these, R0 was achieved in 173 patients (77%)

Cunningham D, et al. ASCO GI 2008
Avastin has a well-established safety profile in phase III trials and clinical practice

<table>
<thead>
<tr>
<th>Selected adverse events (%)</th>
<th>NO16966 Placebo + CTx (n=675)*</th>
<th>NO16966 Avastin + CTx (n=694)*</th>
<th>BEAT Avastin + CTx (n=1,914)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proteinuria</td>
<td>NR</td>
<td>1</td>
<td>1.1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1</td>
<td>4</td>
<td>5.3</td>
</tr>
<tr>
<td>Bleeding</td>
<td>1</td>
<td>2</td>
<td>3.4</td>
</tr>
<tr>
<td>GI perforation</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>1.8</td>
</tr>
<tr>
<td>Wound-healing complications</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>1.1</td>
</tr>
<tr>
<td>ATEs</td>
<td>1</td>
<td>2</td>
<td>1.5</td>
</tr>
</tbody>
</table>

*Grade 3/4; †Grade 3–5 adverse event or serious adverse event
Stage II or III Colon Cancer

Stratification
Number of Positive Lymph Nodes

Randomization

mFOLFOX6

mFOLFOX6 + Bevacizumab

*Disease-free survival: primary endpoint*
Adding Beva to mFOLFOX-6 ➔ no increase in

- ATE
- hemorrhage
- GI perforations
- death from any cause
1. NSABP C-08: very selected “young” population
2. Minor additional toxicities (htn, proteinuria,”pain”)
3. Longer follow up needed
Conclusion

• Theory suggests that Avastin **SHOULD** work

• Clinical trials and real life experience proves Avastin **DOES** work

• Regulatory bodies have now **RECOGNIZED** Avastin’s importance in CRC management
Avastin in CRC: clinical trials and real life experience

New data on Avastin in CRC including K-Ras subgroup analysis

GBG-26 study and phase II study of pertuzumab in mBC

Conclusion

Q&A
Roche oncology products

Existing and future components of standards of care

2nd line
Xeloda, Avastin

1st line
Avastin, Xeloda

Adjuvant
Xeloda, Avastin

CRC

Proven efficacy
In development

2nd line
Xeloda, Avastin, Herceptin, pertuzumab, TDM-1

1st line
Herceptin, Avastin, Xeloda, pertuzumab

Adjuvant
Herceptin, Avastin, Xeloda

BC

2nd line
Tarceva

1st line
Avastin, Tarceva

Adjuvant
Tarceva, Avastin

NSCLC
Avastin standard in major treatment guidelines

NCCN guidelines

Previously untreated metastatic CRC

Patients can tolerate intense therapy

Avastin + FOLFOX/XELOX

Avastin + FOLFIRI

Avastin + 5-FU/LV

Capecitabine ± Avastin

Infusional 5-FU/LV ± Avastin

Patients cannot tolerate intense therapy

Avastin + FOLFIRI

FOLFIRI

FOLFOX/XELOX

EORTC guidelines

Previously untreated metastatic CRC

First disease progression

Avastin + FOLFOX/XELOX

FOLFIRI

FOLFOX/XELOX

Second disease progression

Irinotecan + cetuximab

Irinotecan + cetuximab

FOLFIRI
Avastin in 1st-line mCRC
unprecedented survival benefit in mCRC

Median PFS
- IFL + Placebo
- IFL + Avastin

HR=0.54
(95% CI: 0.45–0.66)
p<0.001

Median OS
- IFL + Placebo
- IFL + Avastin

HR=0.66
(95% CI: 0.54–0.81)
p<0.001

What is K-Ras?

- Gene for Ras protein in EGFR signaling pathway
- K-Ras mutations are common in CRC (approx. 45%)
- Mutation of K-Ras gene leads to continuous activation of Ras protein
- Prevents cetuximab/panitumumab from being able to turn the pathway off

Adapted from Roberts Der. Oncogene 2007
Prognostic vs. Predictive

**Prognostic biomarker:**
Provides information about the patients overall cancer outcome, regardless of therapy

**Predictive biomarker:**
Provides information about the effect of a specific treatment on the patients disease

*K-Ras: Now emerging as a negative predictive marker for Cetuximab / Panitumumab*
How does this Negative Predictor Relate to Other Potential Predictors?

Responders

KRAS WT

KRAS MT

Non-responders

↑EGFR copy number
EGFR pathway “addiction”
Pharmacodynamic:
Skin rash
PET/CT early response

↑Sensitivity of assay
PTEN/PI3K/BRAF mutations
Mutations in EGFR pathways

Ground-laying research from pivotal Avastin trial AVF 2107

• Prospective tumor sampling performed in pivotal Avastin phase III study 2107*

• Samples were analyzed for a variety of established prognostic biomarkers (K-Ras, p53, bRAF)

• Results were correlated with benefit of Avastin-based therapy

• Analysis already published in 2005**

Our current understanding of K-Ras in mCRC

• Roche is committed to personalized healthcare

• Our current understanding of K-Ras in mCRC:
  – If K-Ras status is unknown, cetuximab’s use is potentially harmful
    • OPUS, CAIRO-2
  – In K-Ras wild-type Avastin has substantially better efficacy and is better tolerated than cetuximab
    • CRYSTAL vs. PACCE and AVF2107g
  – Avastin works independently of K-Ras
  – Avastin’s position as standard of care in mCRC is unchallenged
Avastin in CRC: clinical trials and real life experience

New data on Avastin in CRC including K-Ras subgroup analysis

GBG-26 study and phase II study of pertuzumab in mBC

Conclusion

Q&A
Herceptin and pertuzumab: Efficacy beyond progression in women with HER2-positive metastatic breast cancer

*Professor Dr. José Baselga*
Chairman and Professor of Medicine
Medical Oncology Service
Vall d’Hebron University Hospital
Barcelona, Spain
Herceptin extends survival by activating the immune system and suppressing HER2

Activation of the body’s immune system

Inhibition of HER2-mediated signalling

Barok M et al. J. Mol Cancer Ther. 2007;6:2065-72
Herceptin delivers high cure rates for women with HER2-positive early breast cancer

- HERA CTx→H 1 year
- B-31 / N9831 AC→PH
- BCIRG 006 AC→DH
- BCIRG 006 DCarboH

Size of square represents sample size; horizontal bars indicate 95% confidence intervals.

OS, overall survival; H, Herceptin®; AC, doxorubicin, cyclophosphamide; P, paclitaxel; D, docetaxel; Carbo, carboplatin; HR, hazard ratio

Slamon D et al. Abstract # 52, SABCS 2006
Herceptin extends survival for women with HER2-positive metastatic breast cancer

Marty M et al. JCO 2005;23:4265-74
GBG-26 is the first randomised Phase III study to investigate continuation of Herceptin beyond progression

Progression under Herceptin-based first-line therapy
+ taxane (n=114)
monotherapy or non-taxane (n=42)

R

Xeloda
+ continuation of Herceptin
(n=78)

Xeloda
(n=78)

R, randomisation

von Minckwitz et al. Abstract # 1025, ASCO 2008
Continuation of Herceptin nearly doubles the response rate

P-value:
OR 0.011
CB 0.0068

75.3%
(64.2–84.4)

54
(42.1–65.7)

27.0
(17.3–38.6)

48.0
(36.5–59.7)

NC
>24wks

CR+PR

OR , Overall Response = CR+PR; CB, Clinical Benefit = CR+PR+NC>24wks
Continuation of Herceptin prolongs time to progression

HR=0.69 (two-sided p=0.034; one-sided p=0.015)

von Minckwitz et al 2008

Median TTP in months
TTP, time to progression; HR hazard ratio
Continuation of Herceptin suggests improvement of overall survival

HR=0.76 (two-sided p=0.26; one-sided p=0.13)

Herceptin + Xeloda (n=78)
Xeloda (n=78)

von Minckwitz et al 2008

Median survival in months
OS, overall survival
Continuation of Herceptin further delays disease progression

GBG-26 shows that Herceptin beyond disease progression:

• Prolongs survival without disease progression by nearly 3 months
  – Time to progression increased from 5.6 to 8.2 months

• Doubles the number of patients responding to treatment
  – 27% for Xeloda alone
  – 48% for Herceptin + Xeloda
Capecitabine vs. capecitabine + trastuzumab in patients with HER2-positive metastatic breast cancer progressing during trastuzumab treatment: The TBP phase III study (GBG-26/BIG 3-05)

Poster no.: 6  Abstract no.: 1025

**Presenter:** G Von Minckwitz

**Poster presentation:** 08:00-12:00 in E450b

**Poster discussion session:** 11:00-12:00 in E354a

Final data from the GBG-26 trial will be reported on Tuesday, June 3
Herceptin and pertuzumab bind to distinct epitopes on HER2 extracellular domain

- Activates antibody-dependent cellular cytotoxicity
- Potent inhibitor of HER2-mediated signalling pathways
- Inhibits shedding and, thus, formation of p95

- Pertuzumab inhibits the pairing of HER2 with other HER receptors
- Potent inhibitor of HER-mediated signalling pathways
- Activates antibody-dependent cellular cytotoxicity
The phase II study BO17929

Efficacy and safety of pertuzumab in combination with Herceptin

Heavily pre-treated patients having received Herceptin and chemotherapy

→

Herceptin + pertuzumab

*66 patients having received Herceptin in combination with chemotherapy and whose disease progressed
Cardiac safety summary

• LVEF was assessed regularly in all patients

• No patients withdrew due to cardiac adverse events

• Only 3 patients (out of 66) had a LVEF decline (<50% and >10%)
  – 1 patient of the 3 did not meet protocol definition of adverse event
  – All three patients continued on treatment
Pertuzumab in combination with Herceptin shrinks tumours in nearly 1 out of 4 women

<table>
<thead>
<tr>
<th>Efficacy</th>
<th>(n=66)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective response rate (%)</strong></td>
<td>24.2</td>
</tr>
<tr>
<td>Complete response (%)a</td>
<td>7.6</td>
</tr>
<tr>
<td>Partial response (%)a</td>
<td>16.7</td>
</tr>
<tr>
<td>Stable disease for ≥8 cycles (%) (approx. 6 months)</td>
<td>25.8</td>
</tr>
<tr>
<td>Clinical benefit rateb (%)</td>
<td>50.0</td>
</tr>
<tr>
<td>Progression free survival (weeks)</td>
<td>24.0</td>
</tr>
</tbody>
</table>

Complete response patients still on CR at the end of the study period
At data cut-off 21 (31.8%) patients have not yet progressed

\(^a\)Median duration of response was 25.1 weeks (12.4-66.6)

\(^b\)At data cut-off 21 (31.8%) patients have not yet progressed
Final data from the B017929 trial will be reported on Tuesday, June 3

Results of a Phase II trial of trastuzumab and pertuzumab in patients with HER2-positive metastatic breast cancer who had progressed during trastuzumab therapy

Poster no.: 7  Abstract no.: 1026

Presenter: K Gelmon

Poster presentation: 08:00-12:00 in E450b

Poster discussion session: 11:00-12:00 in E354a
CLEOPATRA: Phase III study of Herceptin plus pertuzumab in HER2-positive mBC

An international Phase III randomised, double-blind, placebo-controlled study (approximately 250 sites worldwide)

Endpoints
• Progression-free survival
• Overall survival
• Quality of life
• Biomarker analysis
NEOSPHERE: Neoadjuvant treatment with Herceptin and pertuzumab

HER2+ LABC and large stage 2 (n=400)

- Trastuzumab + docetaxel
  - Surgery
  - FEC + trastuzumab

- Trastuzumab + pertuzumab + docetaxel
  - Surgery
  - FEC + trastuzumab

- Trastuzumab + pertuzumab
  - Surgery
  - Docetaxel + trastuzumab
  - FEC + trastuzumab

- Pertuzumab + docetaxel
  - Surgery
  - FEC + trastuzumab

Endpoints
- PCR
- Biomarker analysis
Conclusions

• Herceptin is the foundation of care for women with HER2-positive breast cancer
  – Herceptin offers the best chance of a cure in eBC
  – Herceptin extends life in mBC
  – Continuation of Herceptin delays disease progression in mBC

• Pertuzumab + Herceptin phase II trial results in HER2-positive mBC are impressive

• The combination of Herceptin plus pertuzumab and chemotherapy has the potential to become a new standard of care in HER2-positive mBC
  – CLEOPATRA phase III trial recruitment ongoing
Avastin in CRC: clinical trials and real life experience

New data on Avastin in CRC including K-Ras subgroup analysis

GBG-26 study and phase II study of pertuzumab in mBC

Conclusion

Q&A
# Avastin

**Offers proven and meaningful progression-free and overall survival benefit**

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Progression-free survival (median)</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal cancer first-line</td>
<td>Typically &gt;10 months</td>
<td>Only biologic with statistically significant OS benefit</td>
</tr>
<tr>
<td>Colorectal cancer second-line</td>
<td>&gt; 7 months</td>
<td>Only biologic with statistically significant OS benefit</td>
</tr>
<tr>
<td>NSCLC first-line</td>
<td>&gt; 6 months</td>
<td>Only biologic with statistically significant OS benefit and survival beyond 1 year</td>
</tr>
<tr>
<td>Breast cancer first-line</td>
<td>&gt; 11 months</td>
<td>1-year survival rate significantly improved</td>
</tr>
</tbody>
</table>

1-year survival rate significantly improved

Breast cancer first-line

Only biologic with statistically significant OS benefit
Conclusion

**Herceptin and pertuzumab**
- Herceptin: foundation of care in HER2-positive breast cancer
- Herceptin combined with pertuzumab: potential to raise the standard of care

**Avastin**
- mCRC: best chance to prolong survival for all patients
- Adjuvant CC: safety established – efficacy readout by 2009
- mBC: significant benefit demonstrated in two phase III studies
- mNSCLC: safe and efficacious, survival extended to beyond 1 year
- Glioblastoma: new hope in a difficult indication
Avastin in CRC: clinical trials and real life experience

New data on Avastin in CRC including K-Ras subgroup analysis

GBG-26 study and phase II study of pertuzumab in mBC

Conclusion

Q&A
We Innovate Healthcare