



Don Stribling

VP Iressa, Key Brand Team

Iressa® in perspective

Iressa® registration status

- ✦ Approved in Japan, US and other markets
 - Argentina, Australia, Korea, Malaysia, Mexico, Singapore, Taiwan, Philippines
 - Future FDA commitments agreed and 1st study started
- ✦ European application filed Feb 2003 via central route
- ✦ RoW applications submitted and under review

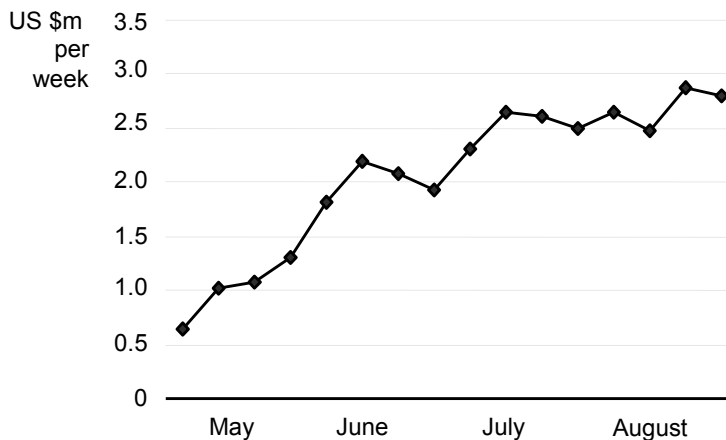


Iressa® US launch 19th May 03 Strong take-off

- 🔗 Orders placed date of FDA approval
 - Drug packed and shipped within 7 days
- 🔗 Smooth transition of patients from compassionate use programme
- 🔗 Dedicated support provided for patients in obtaining insurance coverage where possible
 - Patient Assistance Programme available from launch
- 🔗 Insurance companies almost universally covering Iressa®
- 🔗 All state Medicais currently reimburse Iressa®
- 🔗 On Dept of Defence Mail Order Formulary
- 🔗 Over 10,000 patients on treatment

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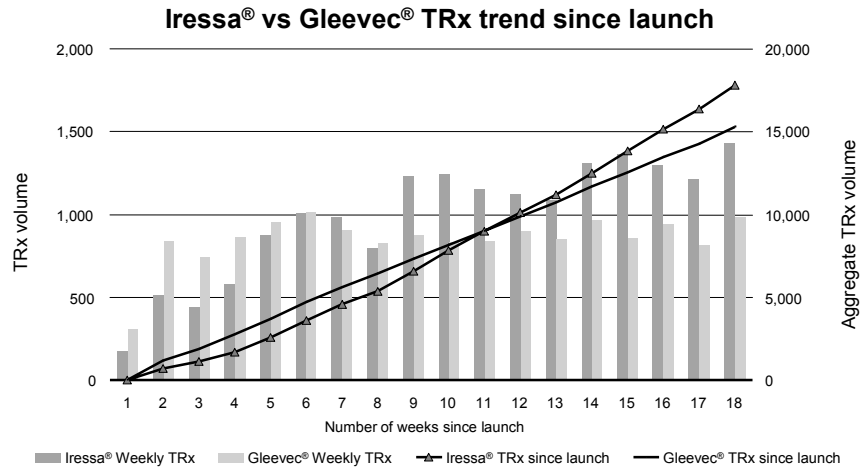
Iressa® US audited weekly sales from launch



Source: IMS Health, DDD weekly 2003

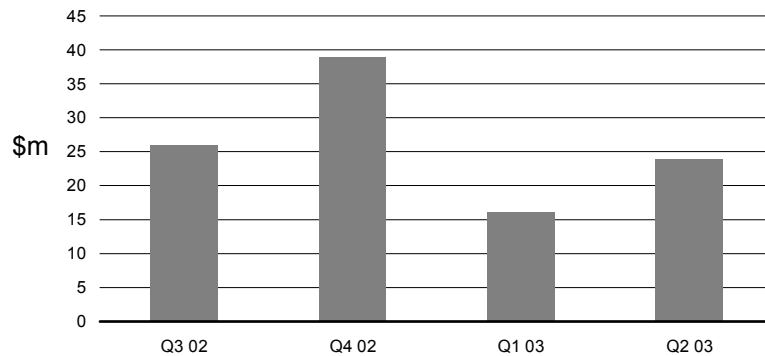
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Iressa® US Rx running 16% ahead of Gleevec® launch



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Iressa® 12 mths since launch in Japan

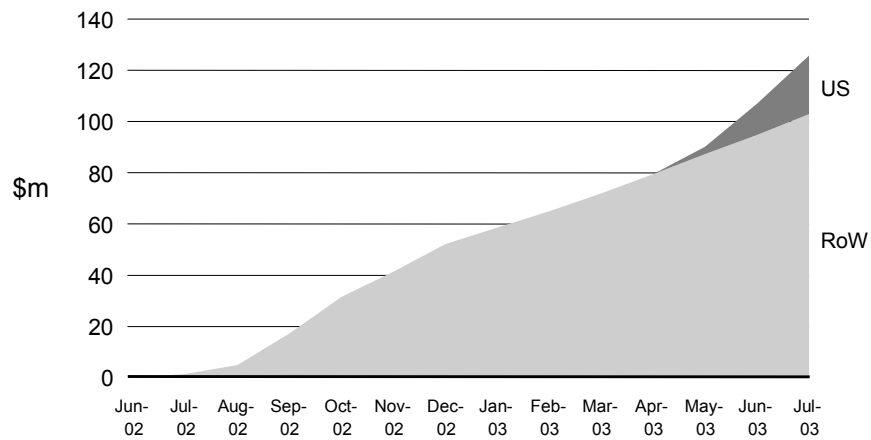


- 🔗 First year sales well ahead of other novel anticancer agents
- 🔗 Monthly sales growing through 2003
- 🔗 Iressa® holds over 70% market share in NSCLC*

*Source: IMS Health, IMS MIDAS Monthly

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Iressa® global cumulative sales from first launch



*Source: IMS Health, IMS MIDAS Monthly

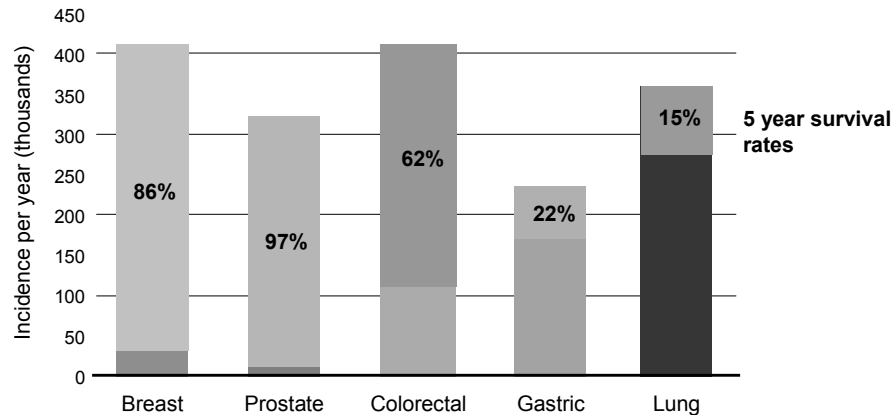
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Patient benefits in NSCLC

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Incidence and five year survival rates in G7 group

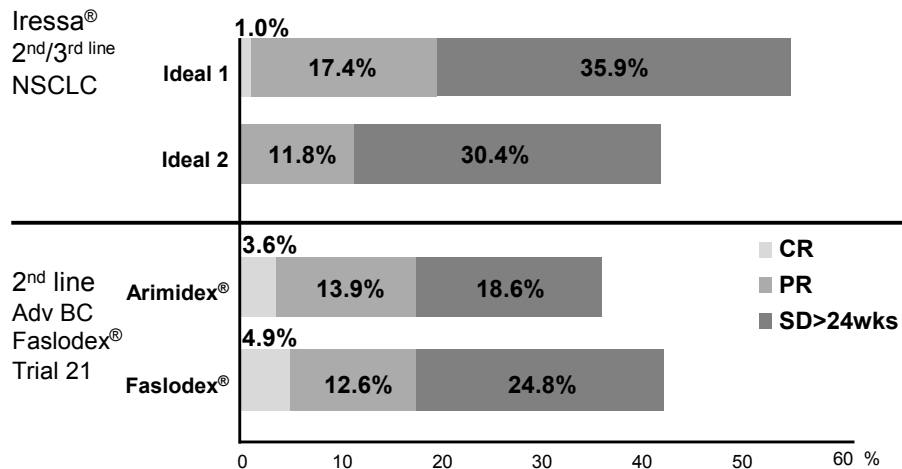
Prognosis for Breast and Prostate cancer transformed by early detection and anti-hormonal therapies



Incidence data from Decision Resources ONKOS series – top 7 markets USA, Japan, France, Germany, Italy, Spain, UK
 All Survival data from SEER Cancer Statistics Review 1973-1999, figures for 1992-1998 (age adjusted); National Cancer Institute: All races



Efficacy of anti-hormonal agents in second line cancer therapy



Iressa® disease control rates are in excess of best anti-hormonal agents in BrCa

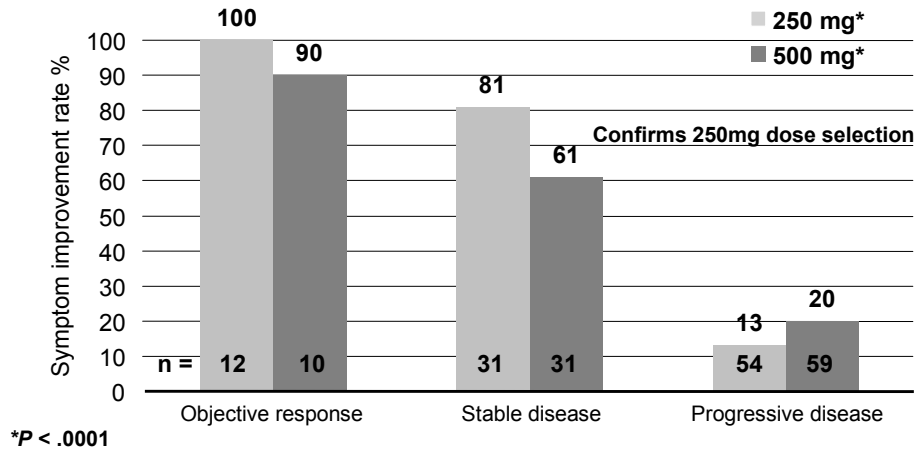
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Iressa® association of tumour and symptom response

Symptom response from 8-10 days
 Tumour response detected at 1 month – earliest assessment point
 Clinically significant benefit in patients with terminal disease

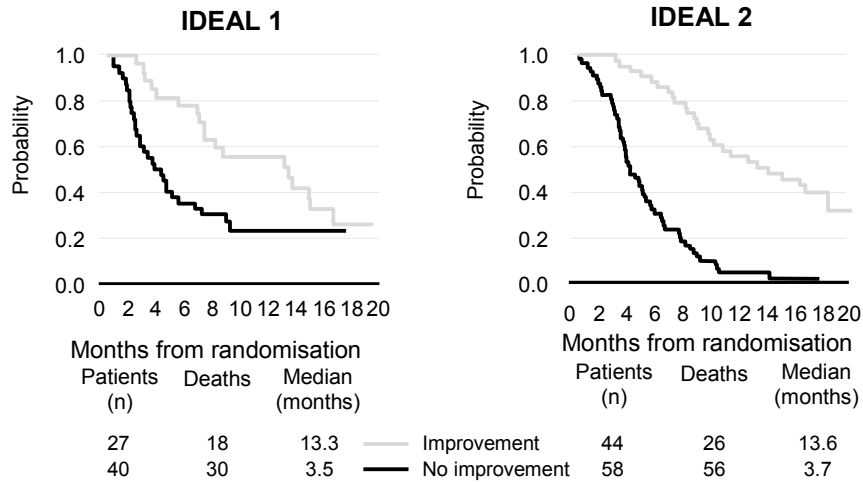
IDEAL 2



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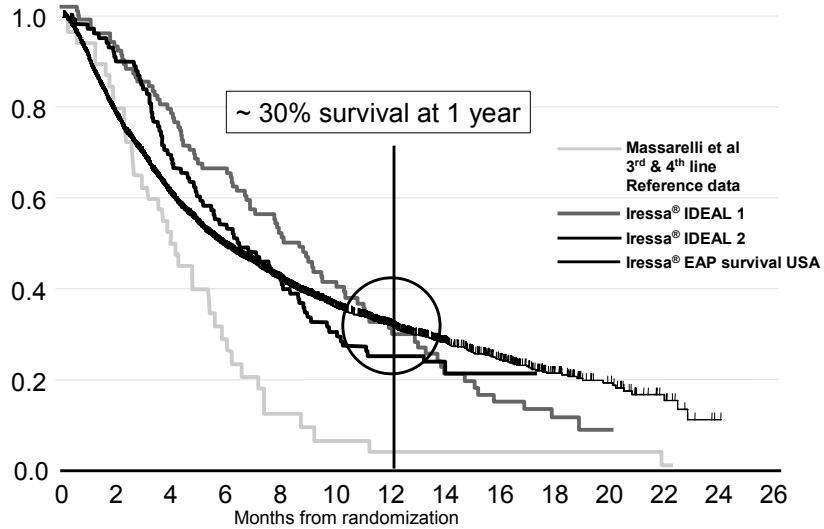
Iressa® symptom improvement correlates with overall survival

Symptom improvement is a useful prognostic marker



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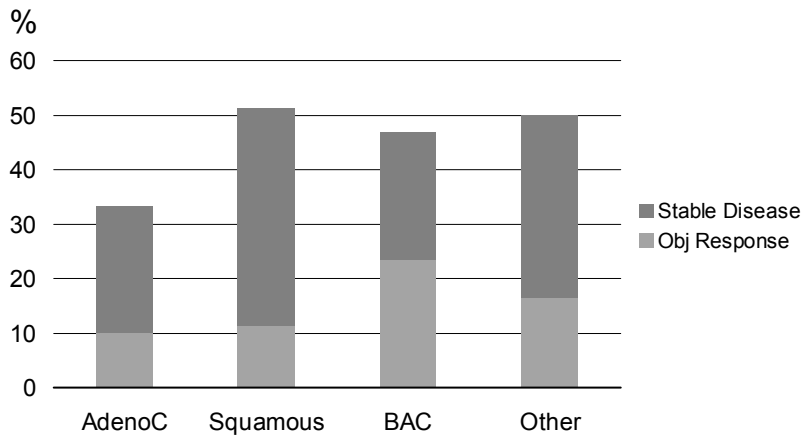
Iressa® survival: Promising a better future for patients



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NSCLC: Response by cell type

Analysis of 127 EAP patients with available tumour samples

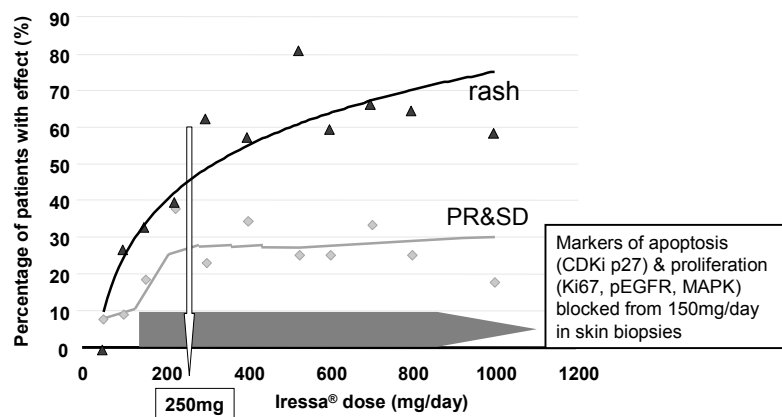


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Profile of EGFR TK Inhibitors



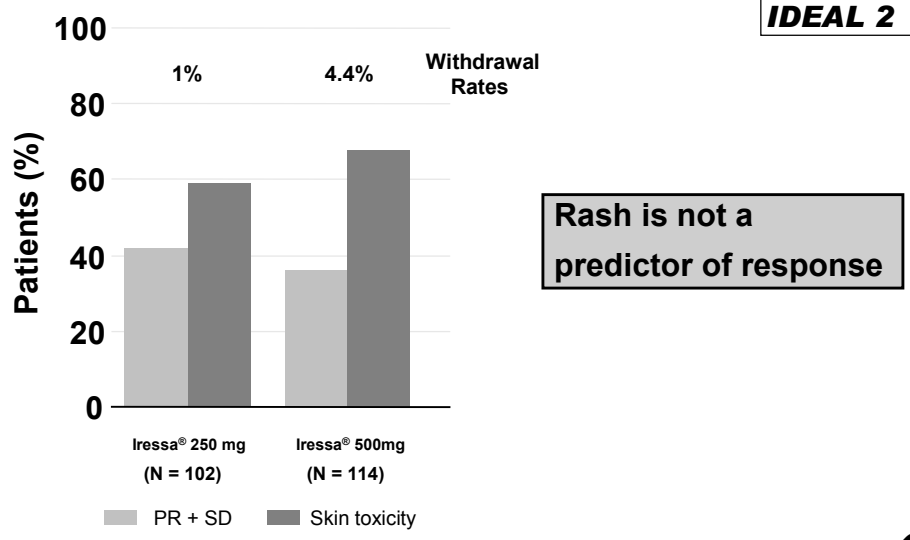
EGF-RTKi are not cytotoxic agents - inappropriate to dose at MTD



Iressa® through dose ranging to maximise benefit:risk profile

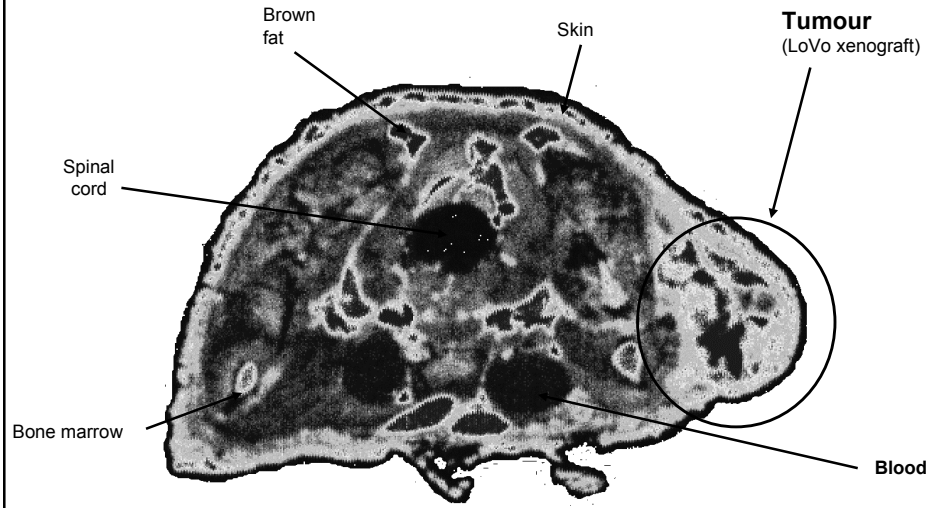


Iressa®: 250mg optimal dose in advanced NSCLC



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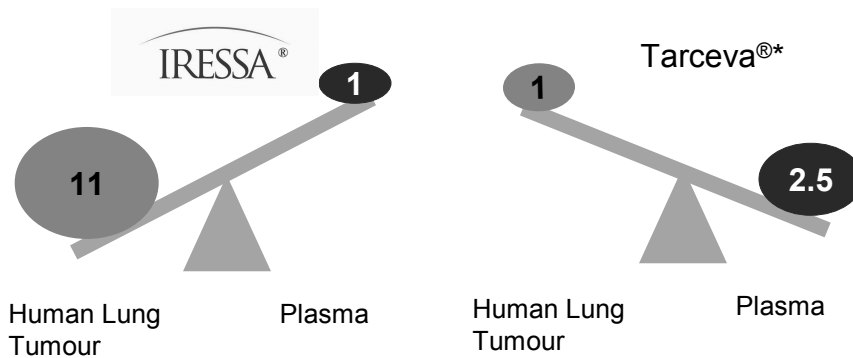
Iressa®: pronounced concentration into tumour tissue (RED)



Autoradiogram of section through nude mouse 4 hours following oral dosing

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Tumour penetration of EGFR TKis in mouse xenograft model



*Pollack et al

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Iressa®: 250mg optimal dose in advanced NSCLC

- ✦ Iressa® fully inhibits EGFR Tkinase
- ✦ Clear evidence 500mg no better than 250mg in efficacy
- ✦ Better safety profile
- ✦ Convenient once daily oral dosing
- ✦ 250mg is right dose in NSCLC

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Life Cycle Management Plans

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FDA Phase 4 commitments - integral part of NSCLC expansion

- ✦ Survival study of Best Supportive Care (BSC) +/- Iressa® in refractory patients (ISEL study)
 - Start date July 2003
 - First patients entered on target

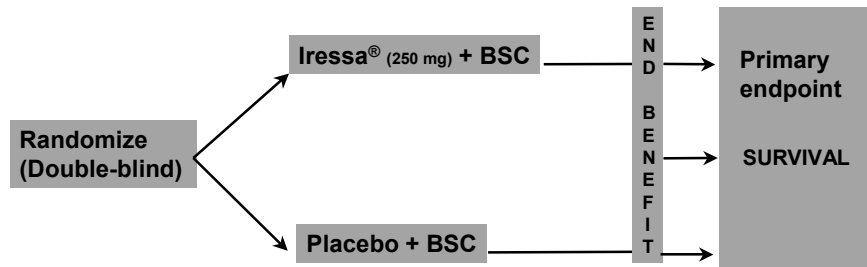
- ✦ Symptom improvement study of BSC +/- Iressa® in refractory patients
 - End 2003

- ✦ Iressa® vs docetaxel 2nd line
 - End 2003

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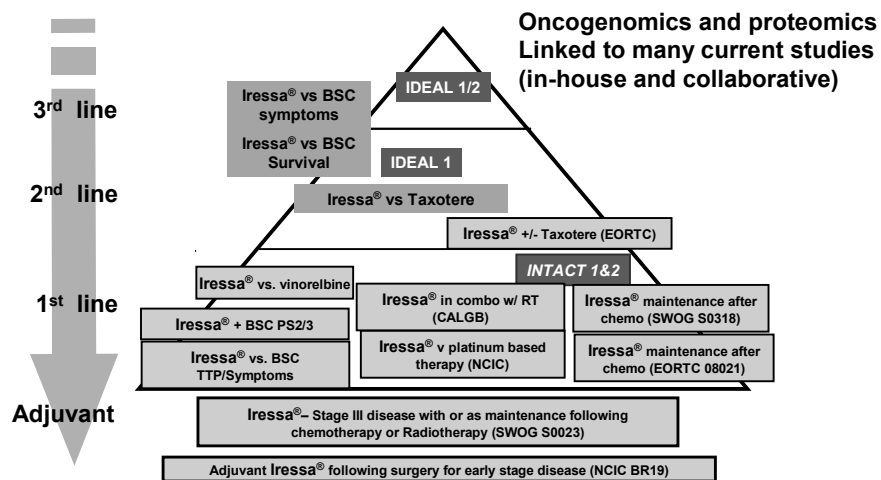
Trial 0709 (ISEL) - Design

Patients with advanced NSCLC who have received 1–2 prior chemotherapy regimens and are refractory or intolerant to their most recent regimen



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Iressa® NSCLC: way forward from 2nd & 3rd line



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Iressa[®] potential

Key elements of long term potential:

- 🔗 Positioning in treatment protocols
- 🔗 Range of tumour types

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Iressa[®] progression into other tumours

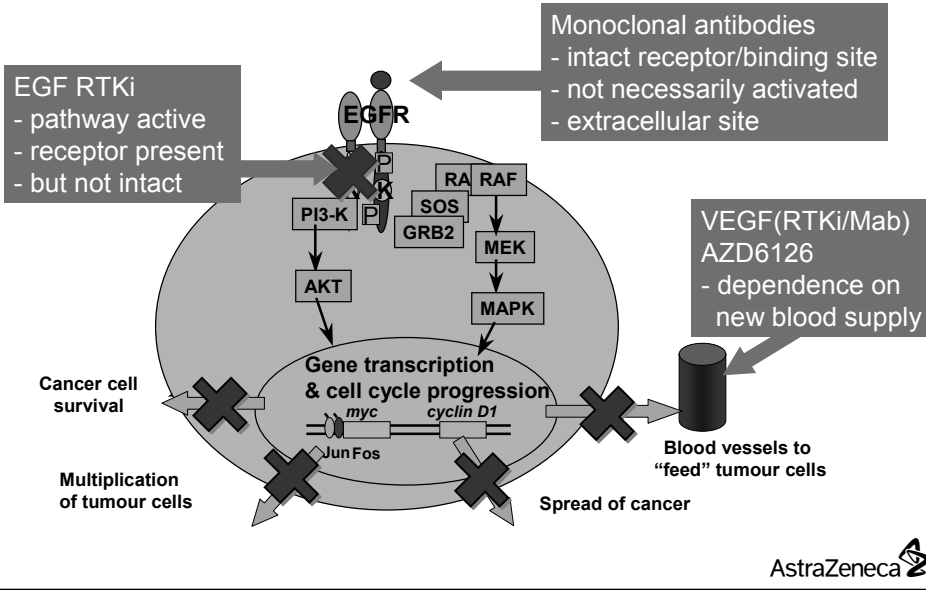
Defining dose and efficacy in:

- 🔗 Head and Neck: Phase II at 500mg 10.6% CR & PR: 42.6% SD
 - monotherapy Ph III trial due to start 4Q 2003 confirming dose and efficacy
 - Ph II 1st line in planning stages
- 🔗 Colorectal: Iressa[®] 500mg + Folfox 74% response rate (Sikic)
 - Ph II Combination studies to start Q1 2004
- 🔗 Breast: Phase II at 500mg 14.3% and 54.5% disease control in two studies
 - Ph II Nolvadex[®] + Iressa[®] started July 2003
- 🔗 16 other tumour types being tested in collaborative and investigator sponsored studies
 - Valuable signal generation

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EGF RTK inhibitors vs other targeted therapies

- likely different responding populations and potential synergies



The benefits of an Oncology portfolio

