

## **Tarceva** **Proven to prolong survival**

*Don Maclean, LCL Tarceva*



(osi) pharmaceuticals Genentech

## **Tarceva – Key Objectives**

- Establish benefits of Tarceva in 2<sup>nd</sup> line
  - over chemotherapy
  - as treatment option in untreated patients
    - increase number of patients being treated
- Lower/ remove barriers to utilisation
- Launch successfully in pancreatic cancer
- Establish in 1<sup>st</sup> line and adjuvant NSCLC



## Tarceva Today

### *Overall survival in two tumor types*

- **NSCLC**

- locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen (monotherapy)
- approved US, EU and many other countries

- **Pancreatic cancer**

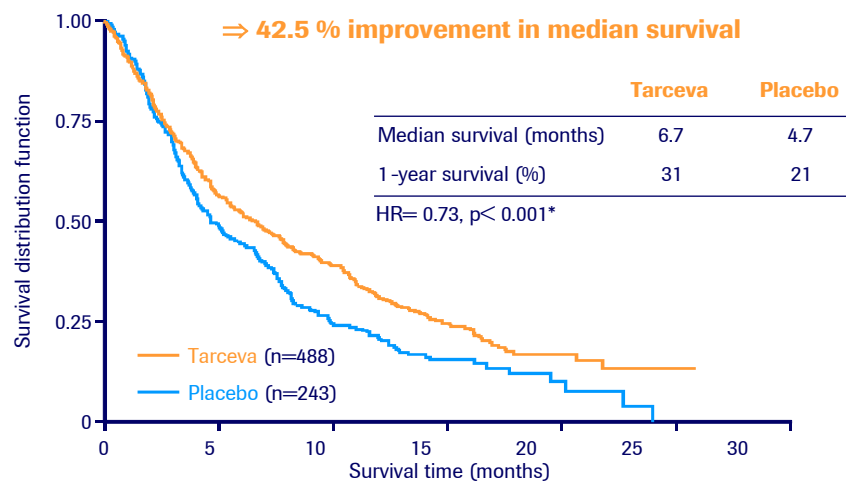
- in combination with gemcitabine for first-line treatment of locally advanced, unresectable or metastatic pancreatic cancer
- approved US, under review EU

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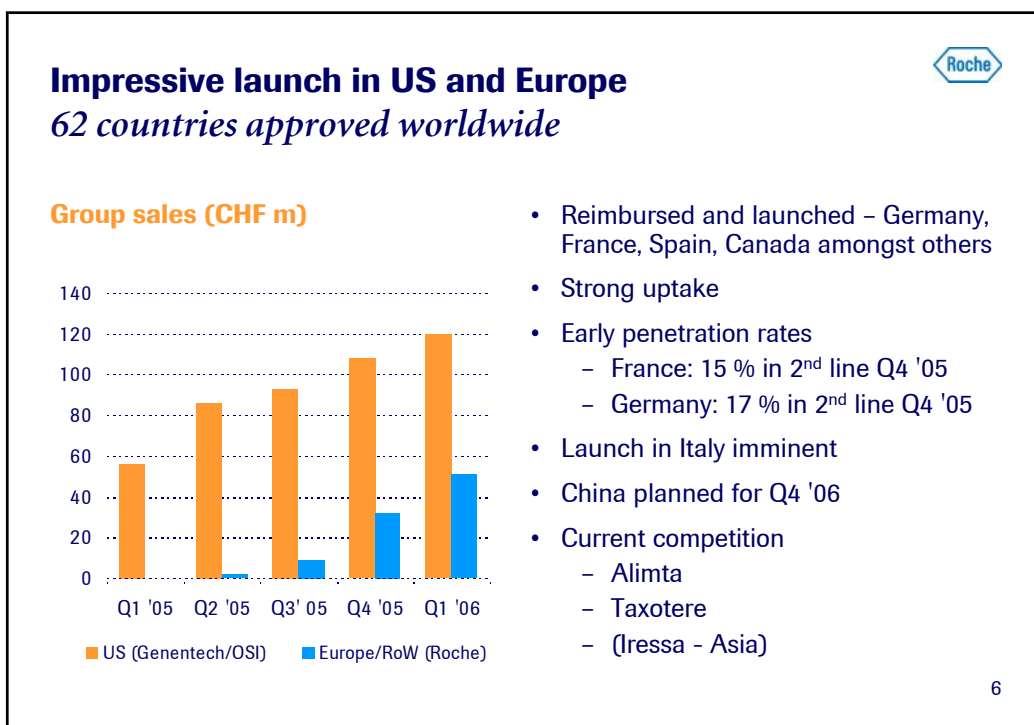
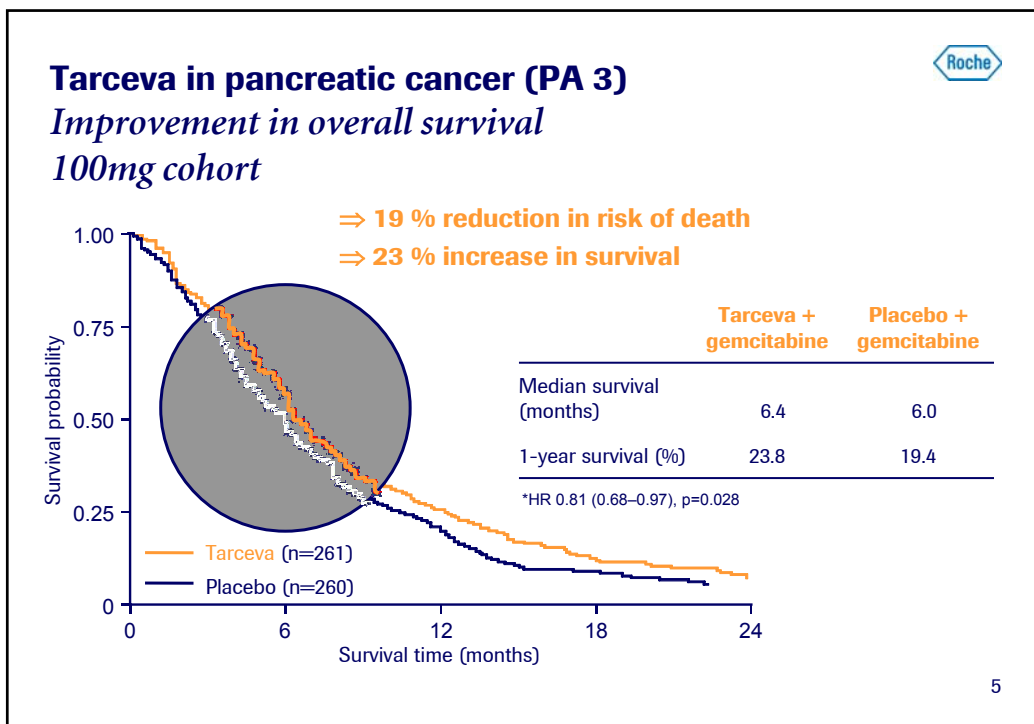
## Tarceva in NSCLC (BR.21)

### *Improvement in overall survival*



\*HR and p (log-rank test) adjusted for stratification factors at randomisation and HER1/EGFR status  
Shepherd F, et al. N Engl J Med 2005;353:123-32

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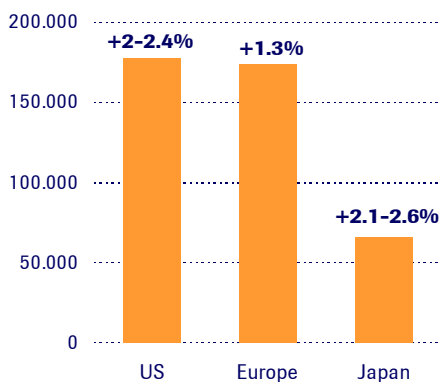




## Market

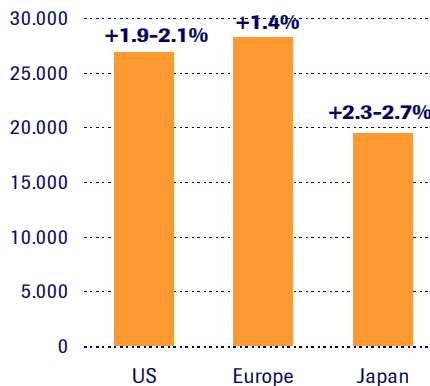
### High medical need in NSCLC & pancreatic cancer

NSCLC: diagnosed incidence cases in 2004



Source: Decision Resources

Pancreas: diagnosed incidence cases in 2003

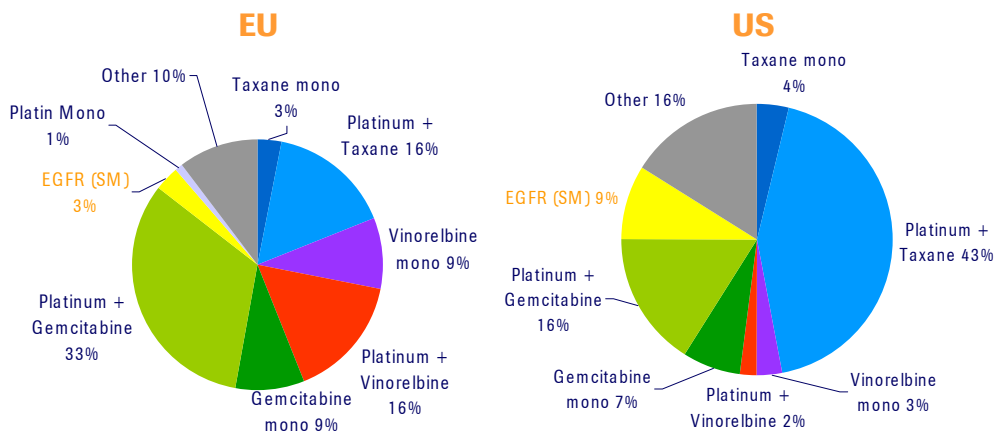


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## The Non-Small Cell Lung Cancer market - 1<sup>st</sup> line

### Different treatment algorithms in US & EU



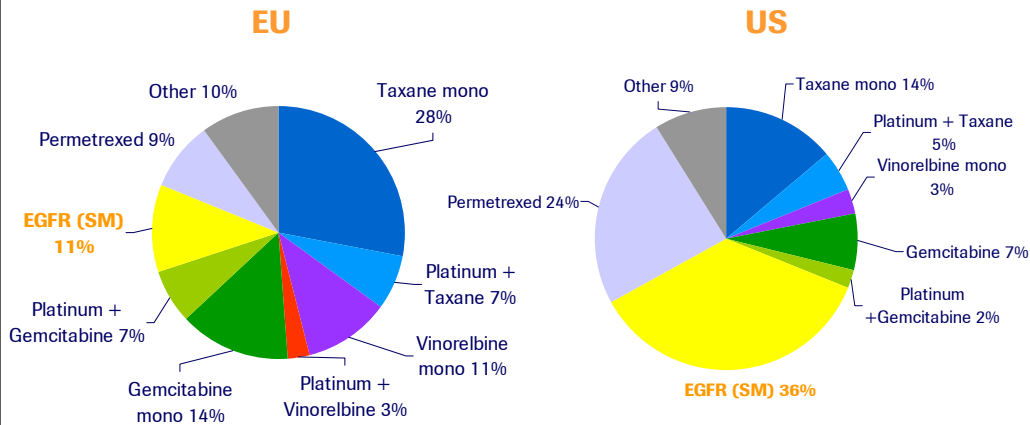
Source: Synovate Healthcare 2005

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## The Non-Small Cell Lung Cancer market – 2<sup>nd</sup> line

*Rapid penetration of Tarceva following launch*

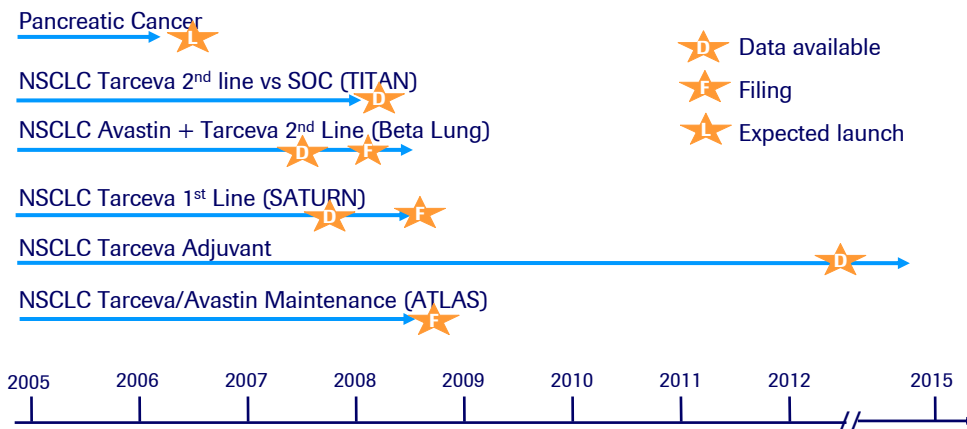


Source: Synovate Healthcare 2005

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## Tarceva - current and future filings



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## Tarceva: targeting all lines of treatment in NSCLC

*Also in combination with Avastin*

- **Phase III**

- **Adjuvant** (Stage I-IIIa), chemo (+/-) then Tarceva 2 years (OS)
- **1<sup>st</sup> line** Chemotherapy followed by Tarceva (Roche - SATURN)
- **1<sup>st</sup> line** (non-squamous) Chemotherapy + Avastin followed by Avastin + Tarceva (Genentech - ATLAS)
- **2<sup>nd</sup> line** Tarceva vs. pemetrexed or docetaxel (Roche - TITAN)
- **2<sup>nd</sup> line** Avastin + Tarceva vs. Tarceva (Genentech - BETA Lung)

- **Phase II**

- **2<sup>nd</sup> line** AT vs. A + docetaxel/ pemetrexed vs. docetaxel/ pemetrexed (Genentech)
- **2<sup>nd</sup> line** Marker discover/Clinical outcome (Roche - MERIT)

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## Combining targeted therapies without chemo

*Promising efficacy and favorable safety profile*

	Median PFS	Alive at 6 months
NSCLC 2 <sup>nd</sup> line, after platinum-based CT (n=120) → Avastin + Tarceva	4.4 months (HR= 0.72)	78 %
NSCLC 2 <sup>nd</sup> line, after platinum-based CT (n=120) → Avastin + CT (pemetrexed or docetaxel)	4.8 months (HR= 0.66)	72 %
NSCLC 2 <sup>nd</sup> line, after platinum-based CT (n=120) → CT (pemetrexed or docetaxel)	3.0 months	62 %

- Exploratory phase II trial
- **Primary endpoint:** PFS vs. chemotherapy alone
- Adverse events: No unexpected side effects

**Phase III Tarceva + Avastin in 2<sup>nd</sup> line NSCLC ongoing, data available 2008**

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## **Tarceva product strategy**

### *In summary*

- Where to go
  - NSCLC is the primary focus
  - Pancreas under HA review
- How to get there
  - 5 global phase III trials running in NSCLC
  - 1<sup>st</sup> line, combination with Avastin and Adjuvant
- What are the challenges
  - Large global trials
  - Patient selection
  - Competitive market now in 2<sup>nd</sup> line

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## **Appendix**

## Product profile



### Tarceva

<b>Indication</b>	NSCLC – metastatic/locally advanced, relapsed Pancreatic Ca – metastatic, locally advanced
<b>Dosing</b>	150mg in NSCLC; 100mg in pancreatic Ca (with gemcitabine)
<b>Adverse reactions</b>	Rash, diarrhea
<b>Incidence NSCLC</b>	~ 177,000 (US); ~ 174,000 (Europe)
<b>Incidence pancreatic Ca</b>	~27,000 (US); ~28,000 (Europe)
<b>Current sales</b>	2005 - CHF 387m global 2006 Q1 – CHF 228m global
<b>Further development</b>	1 <sup>st</sup> line NSCLC, combination with Avastin, adjuvant NSCLC

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## Tarceva development history



- Pre-1996** Discovery and preclinical development of Tarceva
- Q3 1997** First in-vitro data published in *Cancer Research*
- Q2 1999** Positive phase I data presented  
Large-scale, multi-center, phase II trials started
- Q2 2000** Full development rights returned to OSIP
- Q1 2001** OSIP, Genentech and Roche sign joint agreement for development of Tarceva
- Q2 2001** Positive phase II data presented ASCO
- Q3/4 2001** Phase III trials started (NSCLC and pancreatic Ca)
- Q1 2003** BR.21 completed accrual
- Sept 2003** 1<sup>st</sup> line trials in combination with chemo negative (Talent & Tribute)
- April 2004** BR.21 – Positive (2<sup>nd</sup>/3<sup>rd</sup> line NSCLC)
- Sept 2004** PA.3 – Positive (1<sup>st</sup> line pancreatic Cancer)

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