

*Committed to improving health outcomes for cancer patients*

**December 2006**



# Safe Harbour Statement

*This presentation contains forward-looking statements that are based on current management expectations. These statements may differ materially from actual future events or results due to certain risks and uncertainties, including without limitation, risks associated with drug development and manufacture, risks inherent in the extensive regulatory approval process mandated by the United States Food and Drug Administration and the Australian Therapeutic Goods Administration, delays in obtaining the necessary approvals for clinical testing, patient recruitment, delays in the conduct of clinical trials, market acceptance of PI-88, PI-166 and other drugs, future capital needs, general economic conditions and other risks and uncertainties detailed from time to time in the Company's filings with the Australian Stock Exchange and the United States Securities and Exchange Commission. Moreover, there can be no assurance that clinical data will remain scientifically, medically or commercially relevant or that others will not independently develop similar products or processes or design around patents owned or licensed by the Company, or that patents owned or licensed by the Company will provide meaningful protection or competitive advantages.*

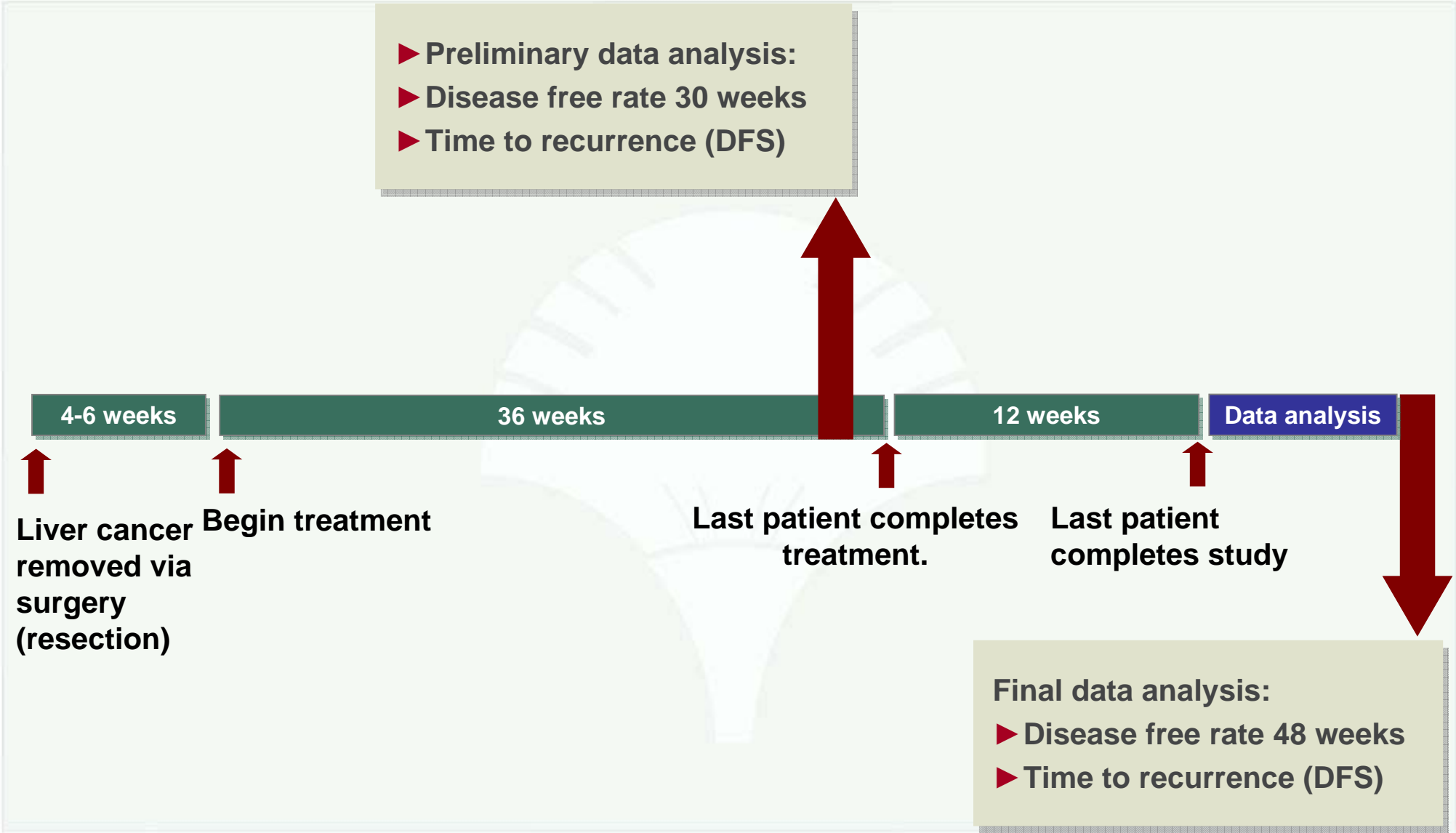




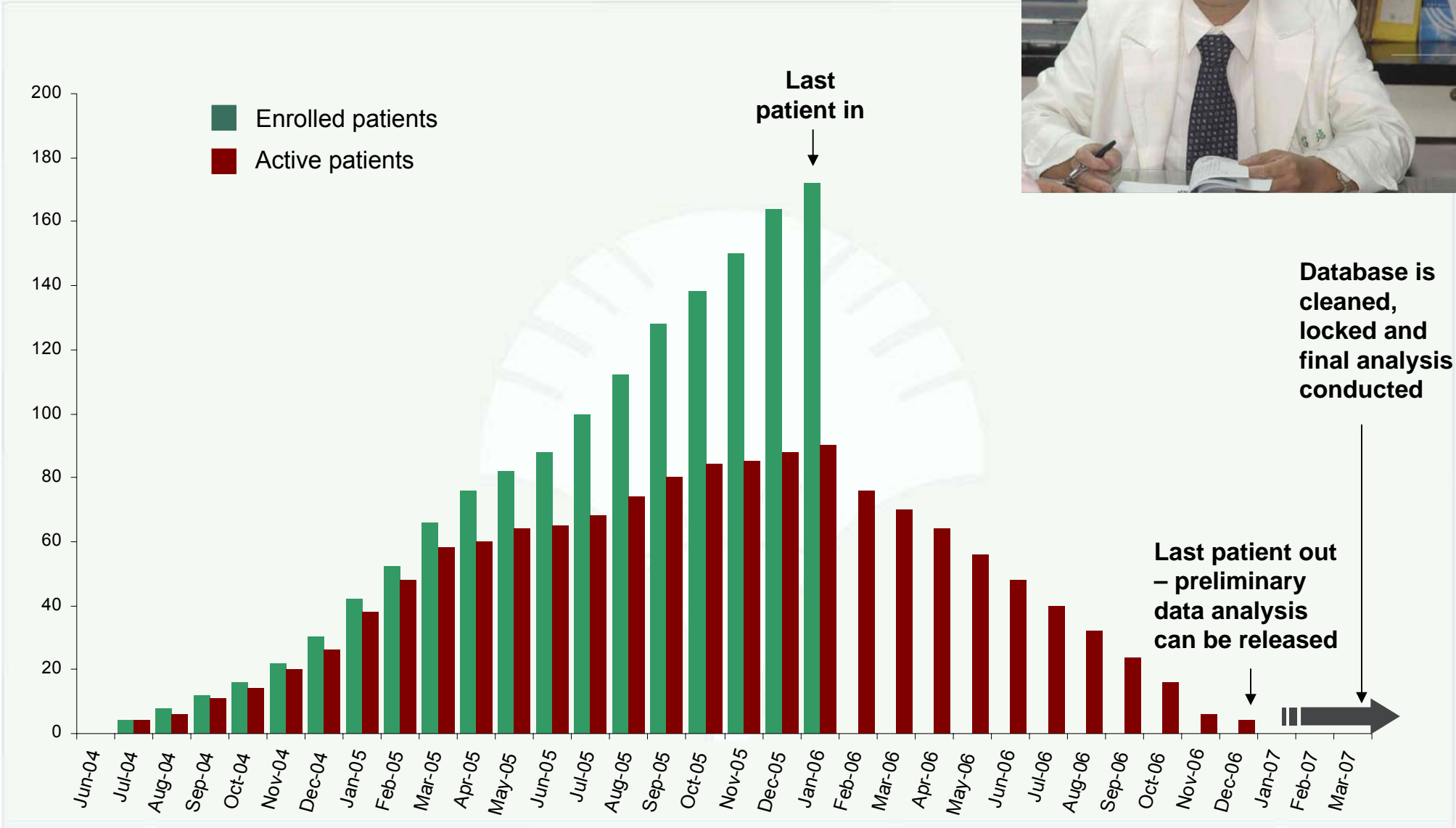
# PI-88 Liver Cancer Phase II Results



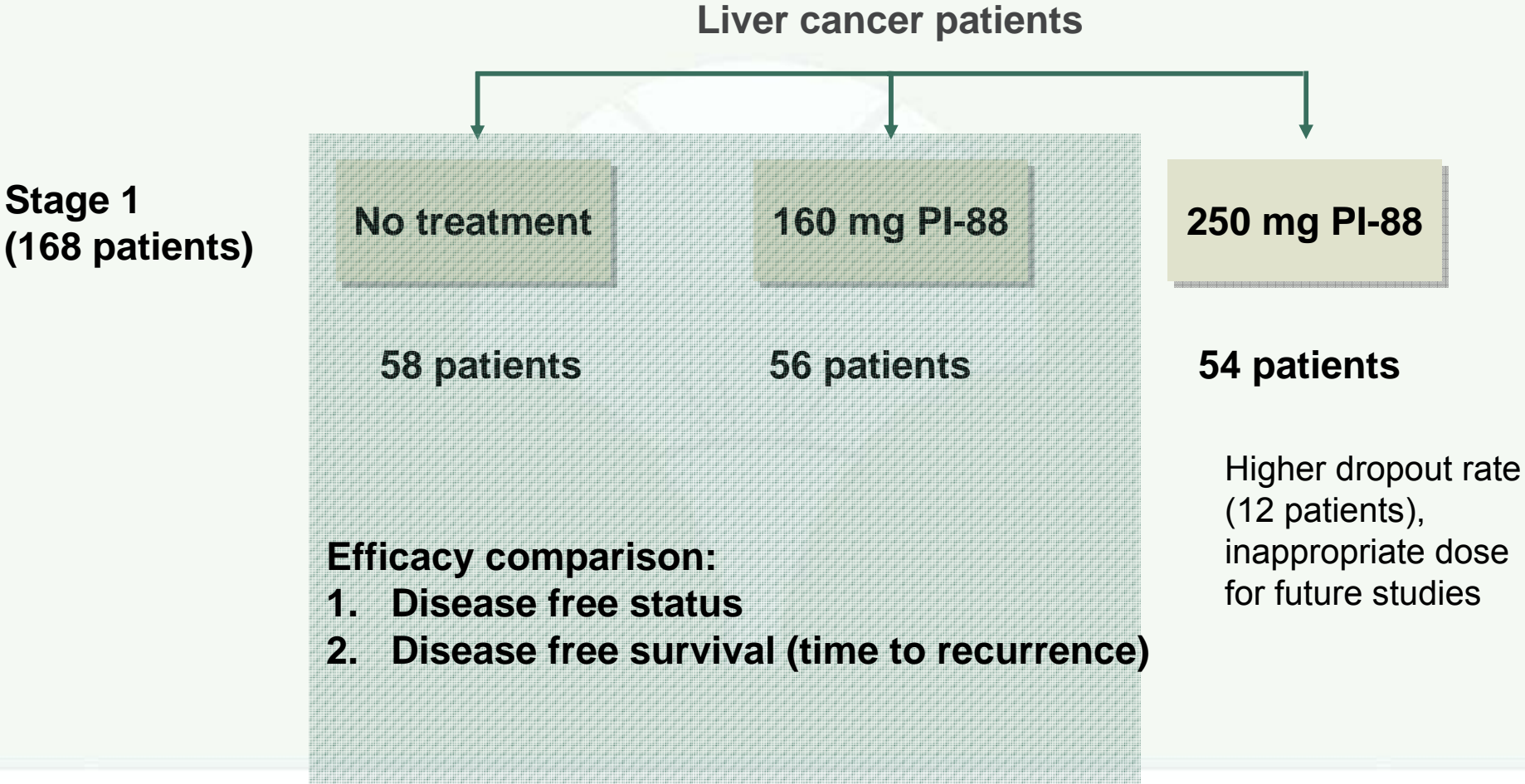
# Phase II post-resection liver cancer timeline



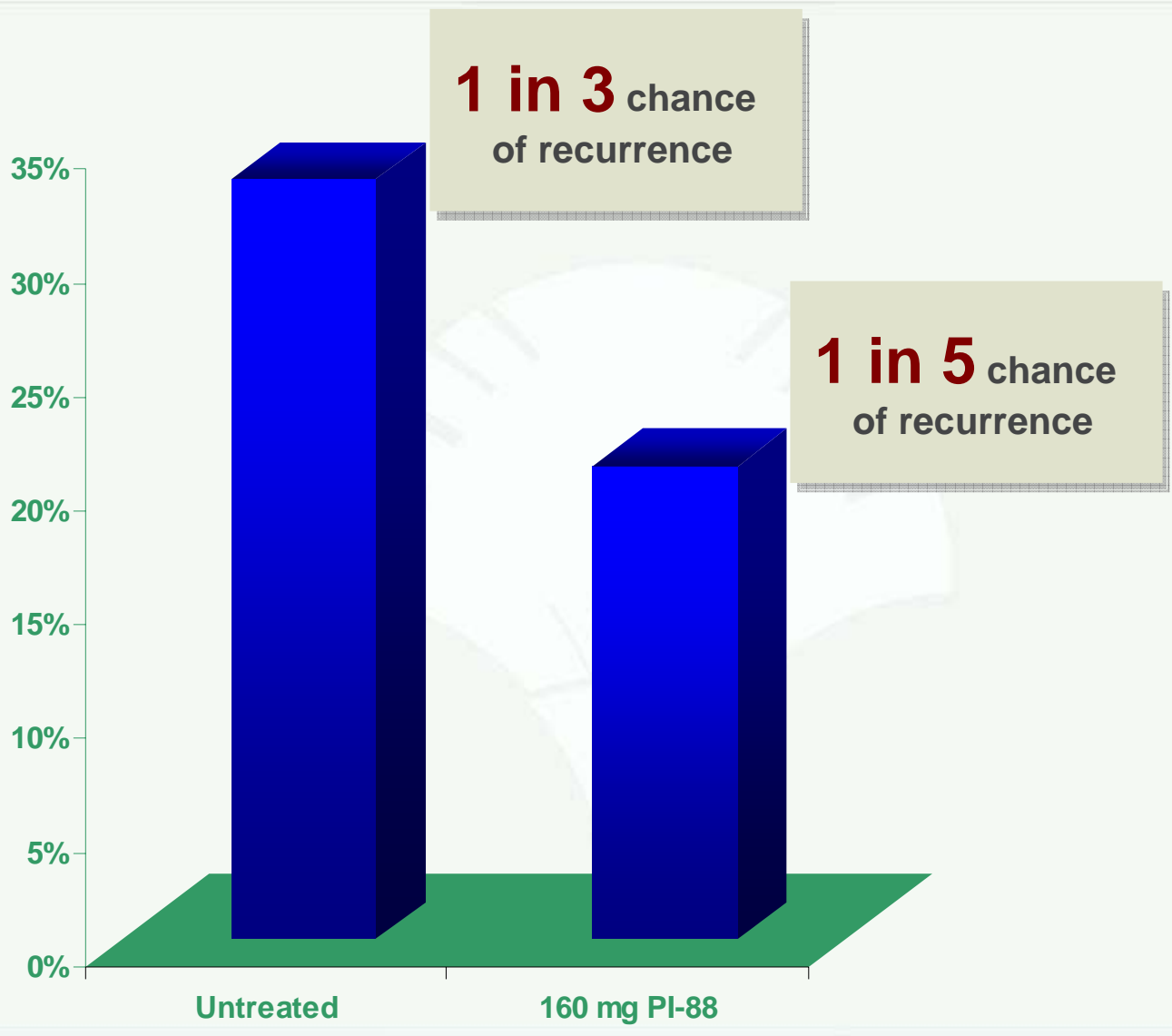
# Phase II timing of data releases



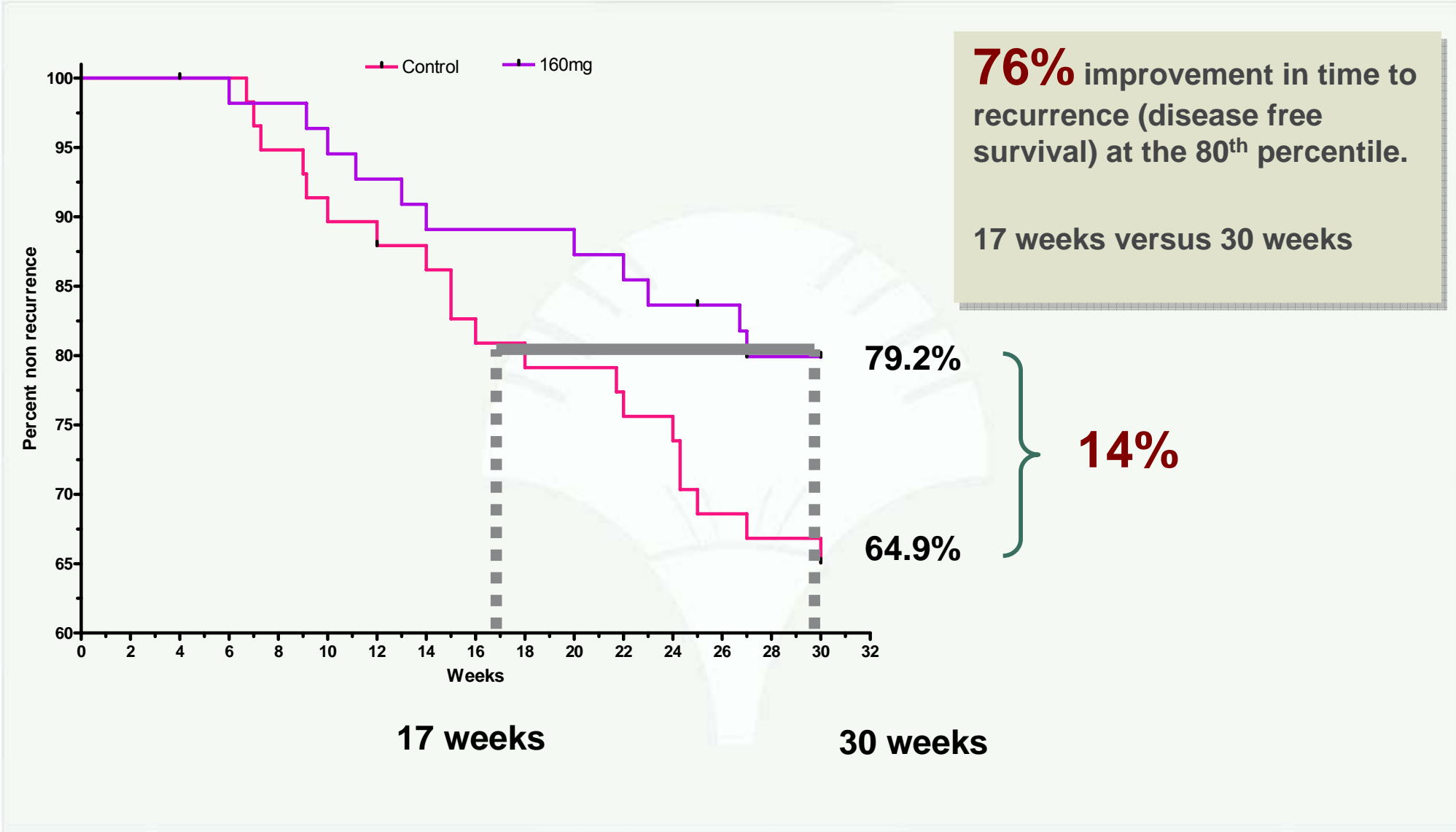
# Phase II post-resection liver cancer



# Risk of recurrence at 30 weeks



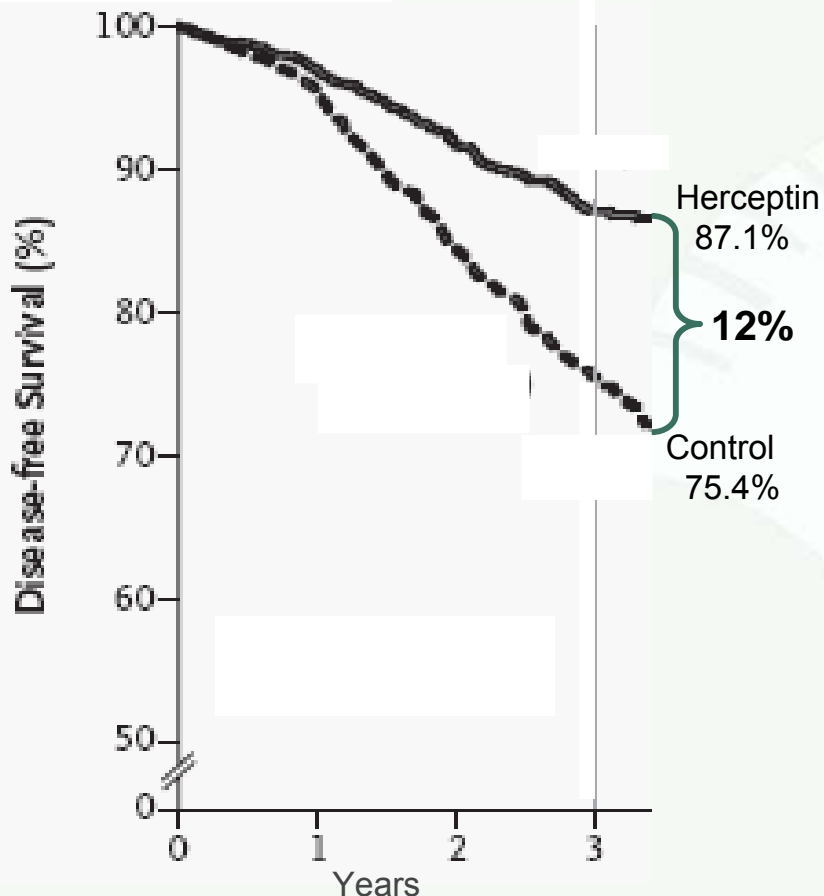
# Improvement in time to recurrence



**76%** improvement in time to recurrence (disease free survival) at the 80<sup>th</sup> percentile.  
17 weeks versus 30 weeks

**14%**

# Analogy: Herceptin, major breakthrough in post-resection breast cancer



Herceptin plus standard post-resection chemotherapy regimen approved based on:

- ▶ **12%** improvement in disease-free rate
- ▶ Estimation of **33%** improvement in time to recurrence (DFS)

“...the most stunning results I have seen in adjuvant trial during my whole professional career”

“biology has spoken and we should listen”

Chairman of ASCO 2005, Dr George Sledge

PI-88's Phase II preliminary data analysis

- ▶ recurrence rate **14%** improvement
- ▶ time to recurrence (disease-free survival) **76%** improvement

3500 patients from 2 Phase III trials

Romond et al, *N. Engl. J. Med.* 2005, **353**, 1673



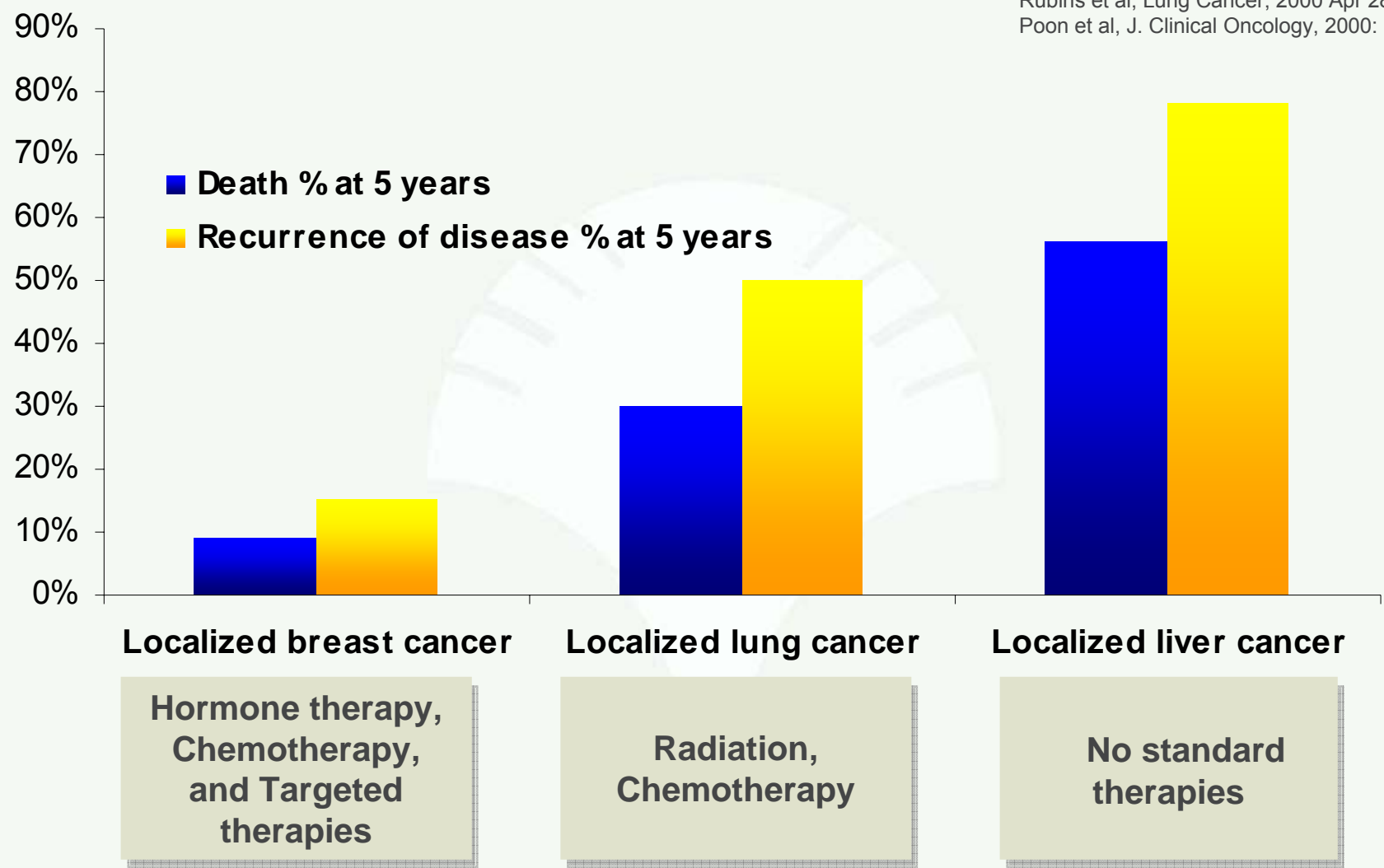


# PI-88 moves to Phase III

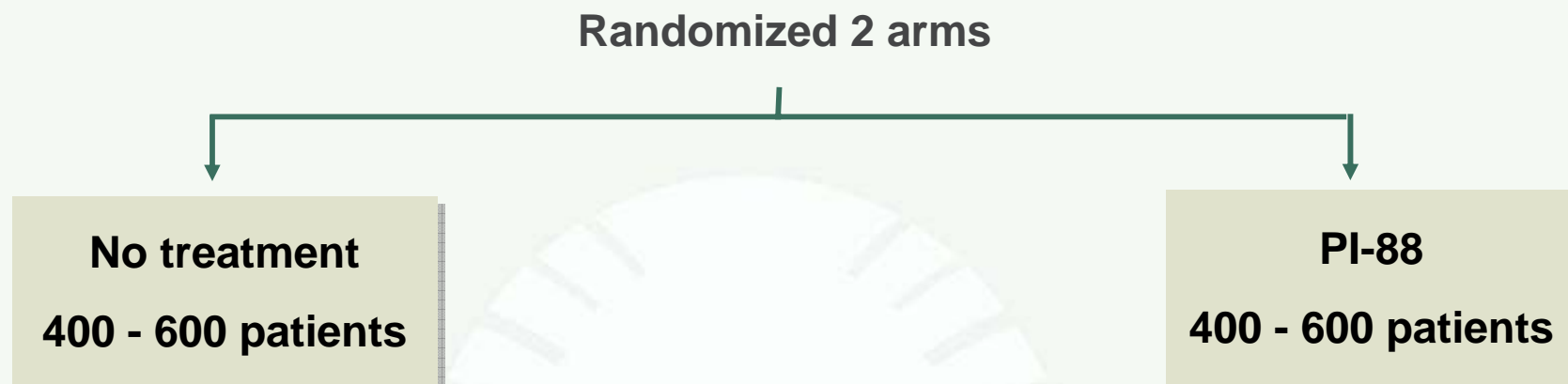


# High unmet need and no standard therapies for post-resection liver cancer

Clarke et al, Lancet. 2005 Dec 17;366(9503): 2087-106  
Rubins et al, Lung Cancer, 2000 Apr 28 (1): 21-27  
Poon et al, J. Clinical Oncology, 2000: 1094-1101



# PI-88 Phase III indicative design



- ▶ FDA recommended – 1 pivotal trial and accelerated approval based on disease free survival (time to first recurrence)
- ▶ International CRO to conduct the trial in US and Asian centers
- ▶ Phase II outcome will be used to guide the Phase III design
- ▶ Final trial design (patient number and endpoints) will be defined in the SPA process



# Timeline to first registration – liver cancer

| Potential Timeframes |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |      |    |    |    |
|----------------------|----|------|----|----|----|------|----|----|----|------|----|----|----|------|----|----|----|------|----|----|----|
| 2006                 |    | 2007 |    |    |    | 2008 |    |    |    | 2009 |    |    |    | 2010 |    |    |    | 2011 |    |    |    |
| Q3                   | Q4 | Q1   | Q2 | Q3 | Q4 | Q1   | Q2 | Q3 | Q4 | Q1   | Q2 | Q3 | Q4 | Q1   | Q2 | Q3 | Q4 | Q1   | Q2 | Q3 | Q4 |

**Phase II**

Data Analysis

**SPA Process**

**Phase III**

**Filing**

1<sup>st</sup> Pt recruited

Last Pt recruited

PRODUCT LAUNCH



# Opportunity: PI-88 Addressable Market

- ▶ Pricing likely to be similar to Avastin, Sutent and Nexavar (USD\$4- 5k/mth)
- ▶ Angiogenesis inhibitors are expected to be worth in excess of USD\$10B\* by 2010
- ▶ PI-88 has a novel mechanism and will be an attractive combination therapy

|  | Liver Cancer | Melanoma | Lung Cancer (NSCL) | Prostate Cancer | Multiple Myeloma |
|--|--------------|----------|--------------------|-----------------|------------------|
| <b>Incidence (number of patients/year)<br/>WW – including US, EU, Japan, China and SE Asia</b> | 677,000      | 115,000  | 830,000            | 540,000         | 90,000           |
| <b>Target PI-88 treated patients</b>   | 25%          | 15%      | 27%                | 30%             | 100%             |
| <b>Approx. treatment time (months)</b>   | 12           | 9        | 10                 | 12              | 6                |
| <b>Total PI-88 addressable market (USD)</b>  | 9.1B         | 0.7B     | 10B                | 8.7B            | 2.4B             |

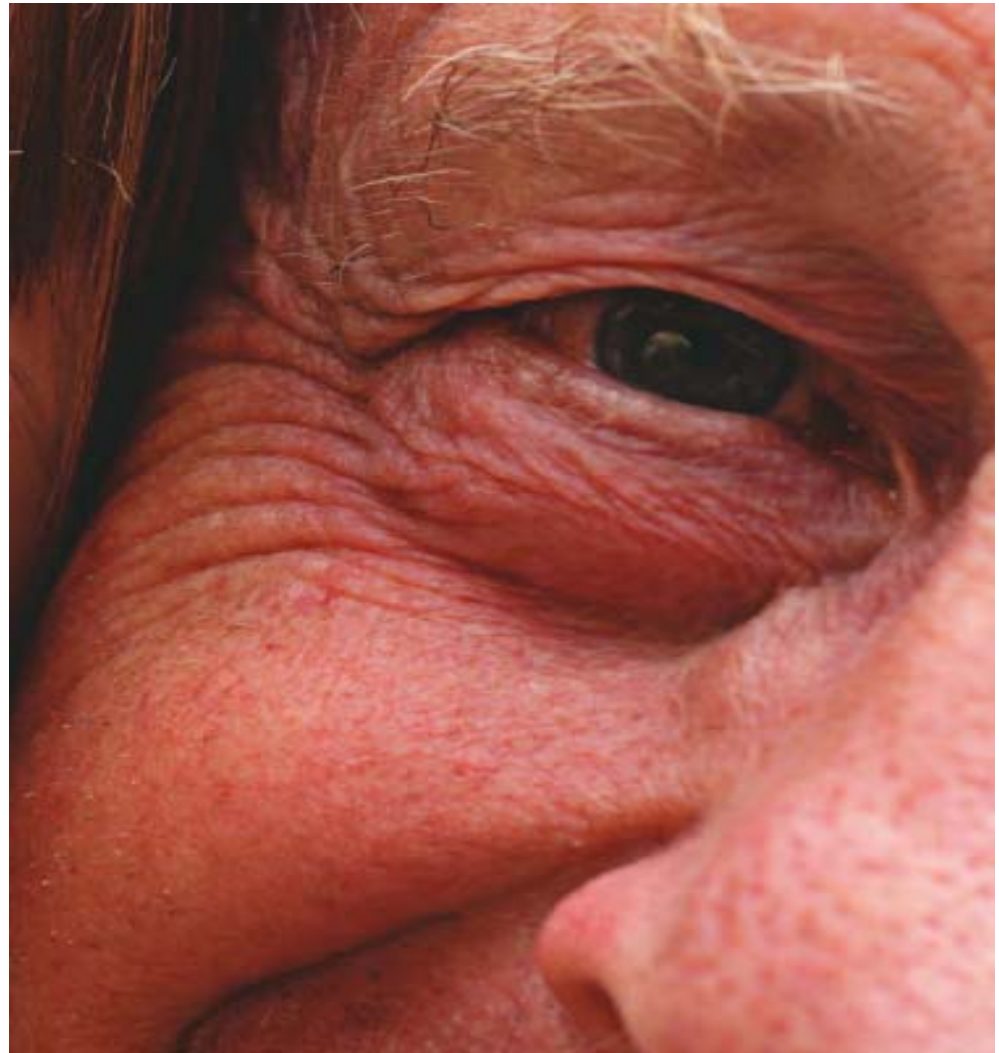


# The Strategy

- ▶ **Post Phase II results:**
  - Phase III clinical program set
  - Path to registration set
  - Focus on speed to market and pursue product launch
- ▶ **Maintain flexibility**
  - Licensing
  - Co-marketing/co-development
  - Distribution agreements
  - Market in some territories
- ▶ **Expand the pipeline by moving drug discovery compounds into clinical development**

*Each day that passes is one day longer that the product is not available to liver cancer patients*





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