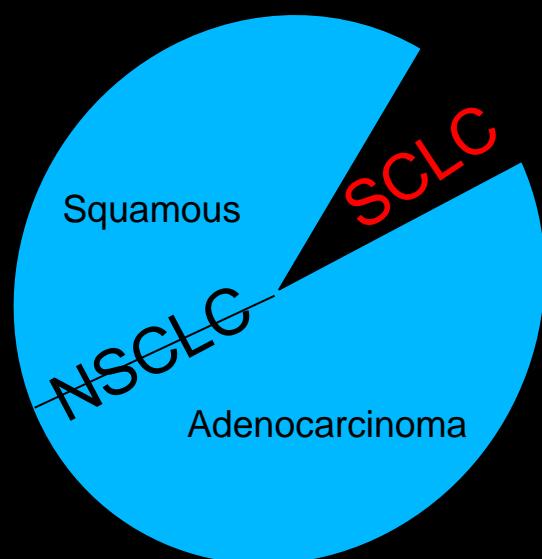
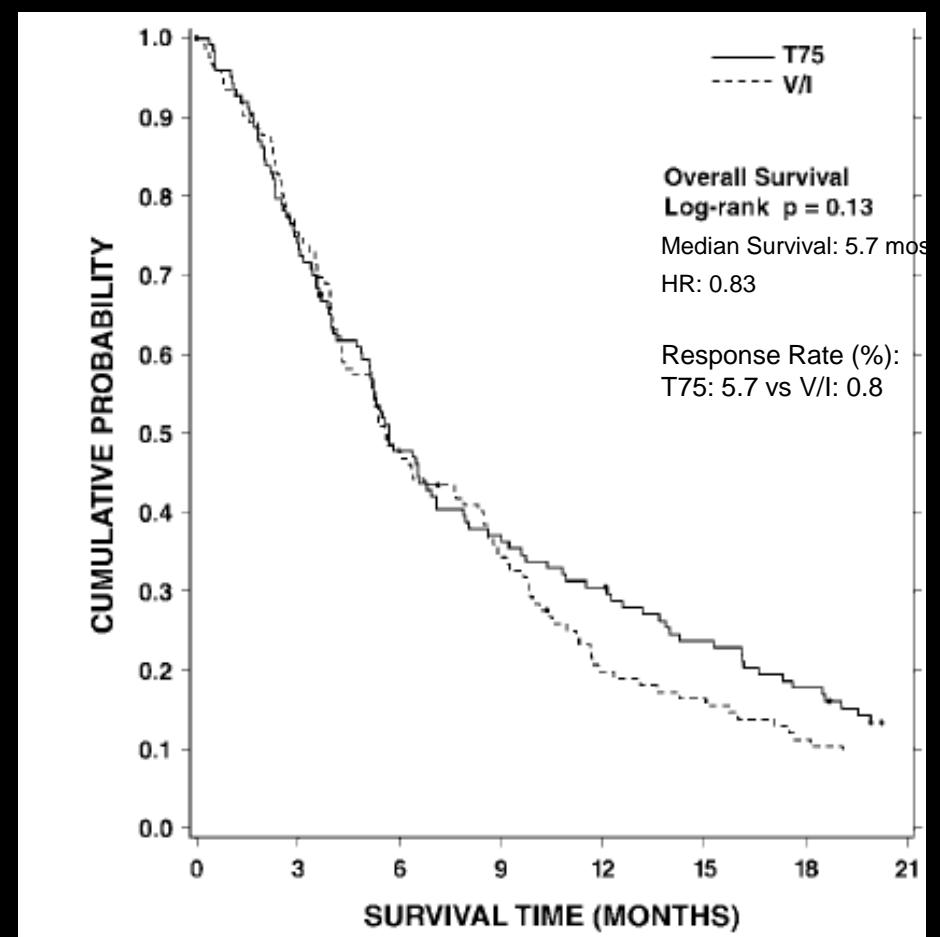


# Lung Cancer Status (circa 2000)

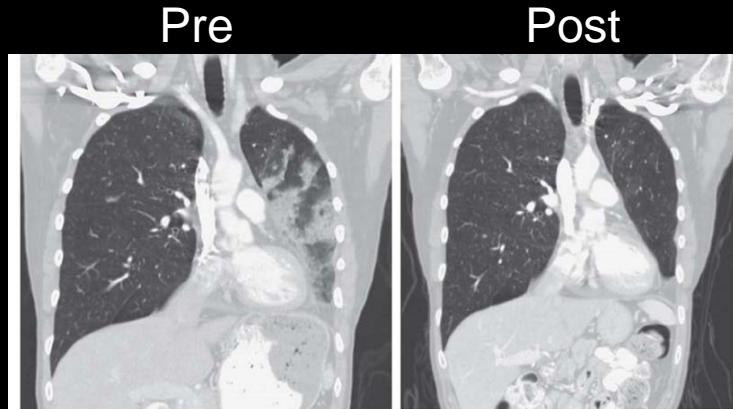
Lung cancer (circa 2000)



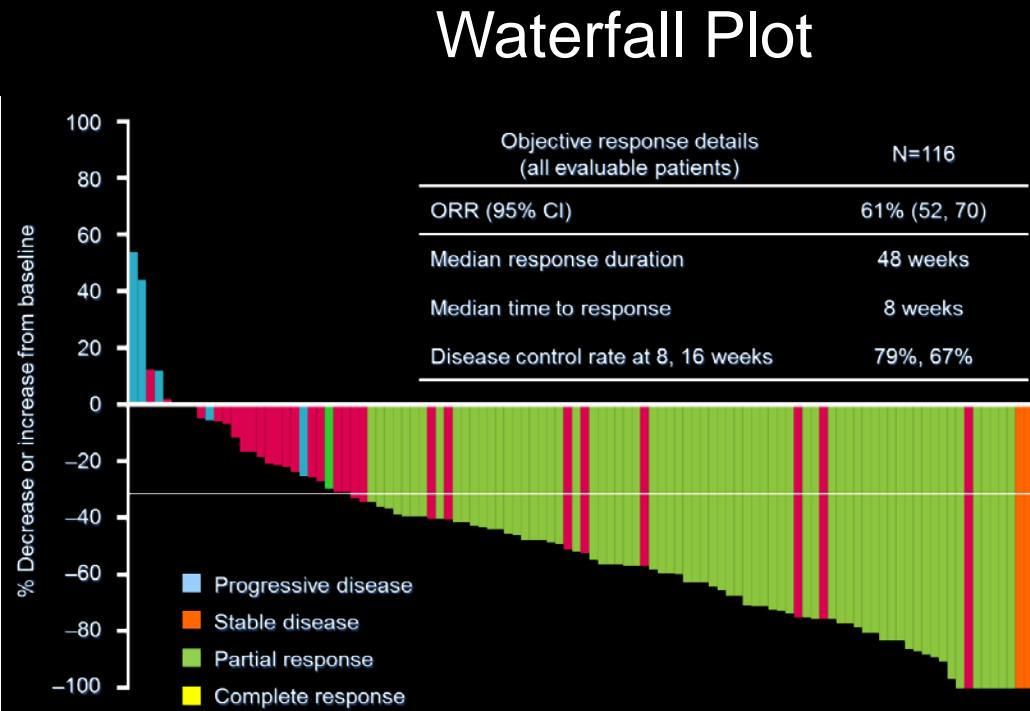
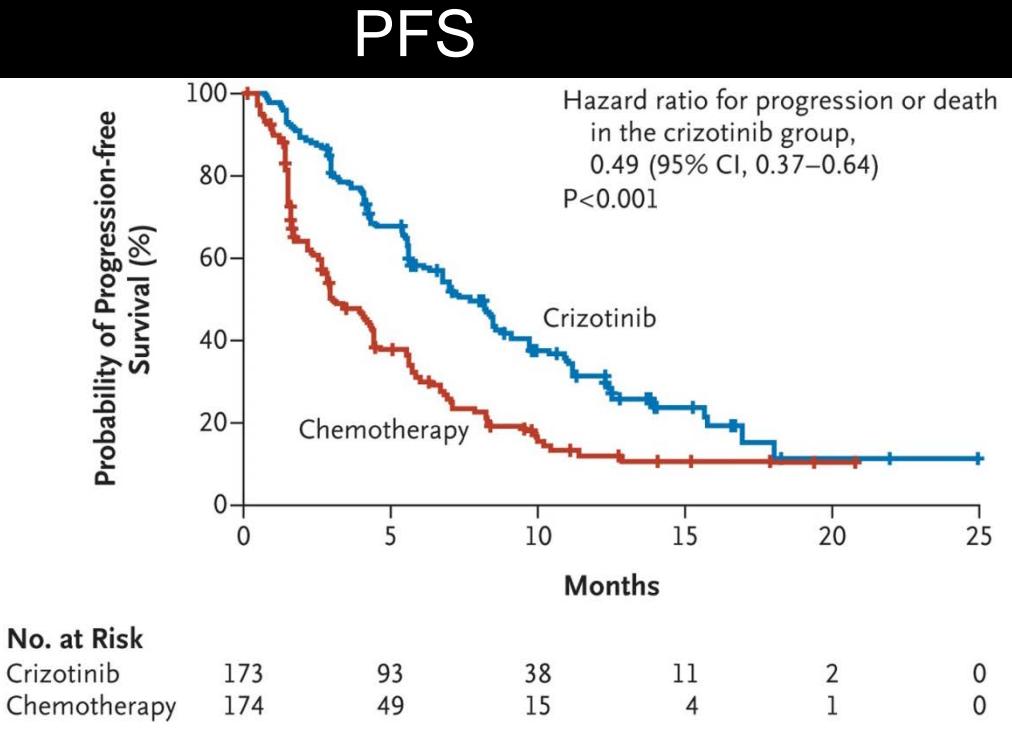
TAX 320: 2L NSCLC–Taxotere (T75)  
vs Vinorelbine or Ifosfamide (V/I)



# Antitumor effects of TKI in NSCLC ALK+



Kwak EL et al. N Engl J Med 2010;363:1693-1703

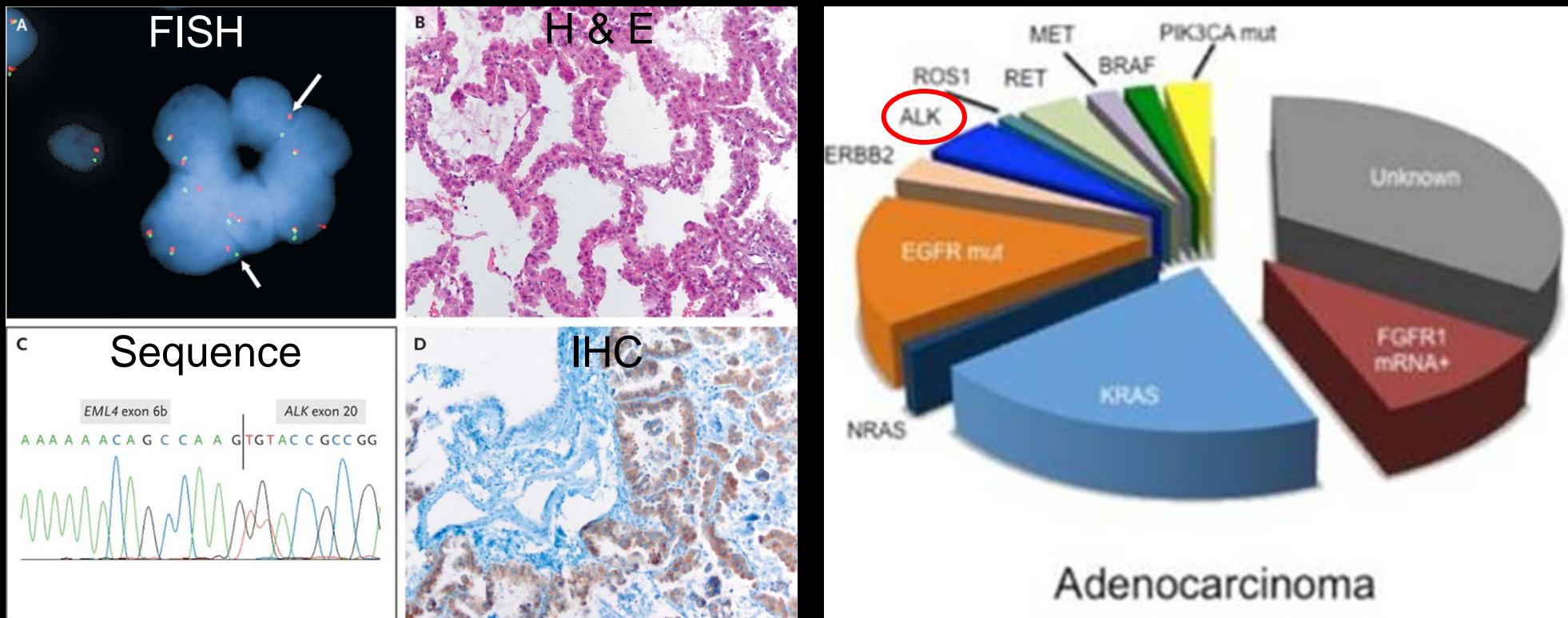


Camidge et al, TLO 2012

# Why TKIs have such incredible responses in specific populations?

## ALK Rearrangement as Example

### EML4-ALK-Positive NSCLC



#### **DX EML4-ALK-Positive NSCLC:**

A: break-apart FISH Vysis LSI ALK Dual Color, Break Apart Rearrangement Probe (Abbott Molecular). B: H&E. C: sequence of a RT/PCR assay of *EML4-ALK*. Panel D: IHC analysis of ALK protein expression.

**Kwak EL et al. N Engl J Med 2010;363:1693-1703**

# National Cancer Policy Forum Workshop Agenda: Policy Issues in the Development and Adoption of Molecularly Targeted Therapies for Cancer (day 1)

- Overview of the Workshop
- Session 1: Challenges in developing clinical biomarker tests
  - Single analyte tests
  - NGS
  - Circulating tumor DNA
  - RNAseq test
- Break
- Session 2A: Evidentiary Standards: Regulatory Science
  - Overview of FDA Regulations for Diagnostics
  - Evolving paradigm for Companion Diagnostics and other Diagnostic Tests at FDA
  - Clinical Utility of Diagnostic Tests
- Lunch Break

# National Cancer Policy Forum Workshop Agenda: Policy Issues in the Development and Adoption of Molecularly Targeted Therapies for Cancer (day 1, cont'd)

- Session 2B: Evidentiary Standards: Reimbursement
  - MolDX approach
  - Payers Perspectives
- Session 3A: Generating Evidence: Clinical Trial Designs
  - LungMap
  - Evaluation of NGS for companion diagnostics use
- Break
- Session 3B: Generating Evidence: Other Mechanisms
  - Actionable Genome Consortium
  - Coverage with evidence development
  - Facilitated drug access program and registry
  - Benefits and limitations/challenges of registries/databases
- Wrap up Day 1 and Adjourn

# National Cancer Policy Forum Workshop Agenda: Policy Issues in the Development and Adoption of Molecularly Targeted Therapies for Cancer (day 2)

- Session 4: Practice Guidelines & Implementation into Clinical Practice
  - Guidelines Development
  - Treatment Pathways
  - Adoption of genomics in oncology care
  - Return of sequencing results to patients
- Break
- Session 5: The business model for test development
  - Examples
- Workshop Wrap Up
- Adjourn