

## **Questions/Answer Session after Maintenance Therapy for Advanced NSCLC: When, What, Why & What's Left After Post-Maintenance Relapse?**

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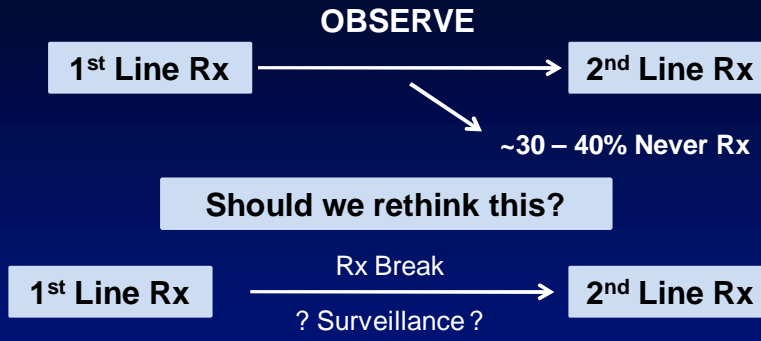
**University of North Carolina**



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## The Changing Treatment Paradigm in Advanced NSCLC

Standard of Care



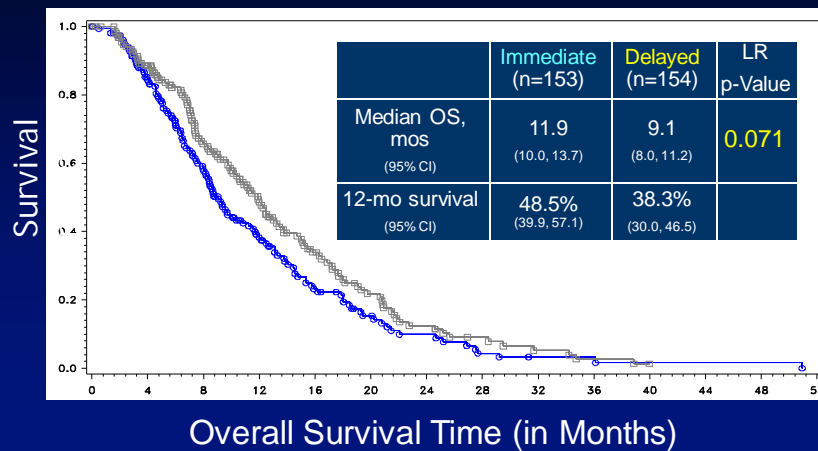
Fidias – Docetaxel  
 Ciuleanu – Pemetrexed  
 SATURN – Erlotinib  
 ATLAS – Erlotinib



All approved  
 2nd line agents

## Immediate vs. Delayed Taxotere (Fidias Trial): Overall Survival

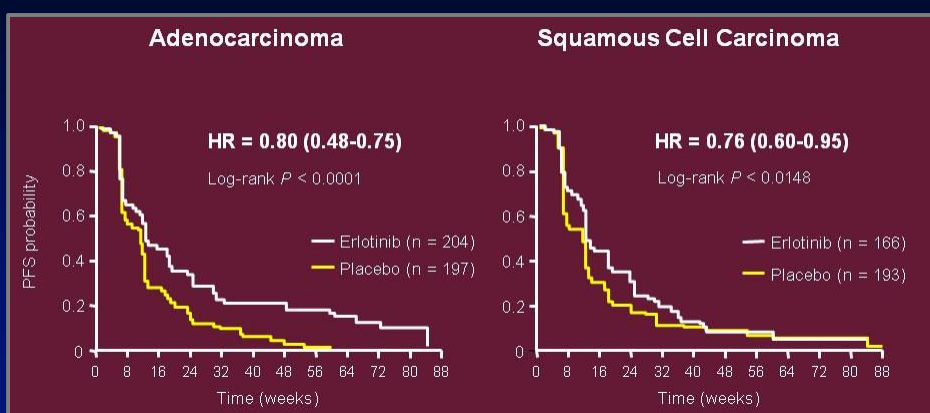
Total Randomized Population



Fidias, *J Clin Oncol* 2008

Should the statistically negative results of the Fidias trial of Immediate vs. delayed Taxotere (docetaxel) make us less inclined to use it than other treatment options in the maintenance therapy setting, particularly for patients with a squamous cell NSCLC?

## SATURN Trial of Maintenance Tarceva (Erlotinib) vs. Placebo: PFS by Histology



Capuzzo, *Proc ASCO* 2009

## Alimta (Pemetrexed) vs. Taxotere (Docetaxel) in 2<sup>nd</sup> line NSCLC

Previously treated  
Advanced NSCLC  
Perf. status 0-2  
N = 571

RANDOMIZED

### Alimta

**500 mg/m<sup>2</sup> i.v. q3wks (n=283)**  
(folic acid 350-1,000 µg daily +  
vitamin B<sub>12</sub> 1,000 µg q 9wks;  
dexamethasone 4mg bid on  
d-1,d0,d+1)

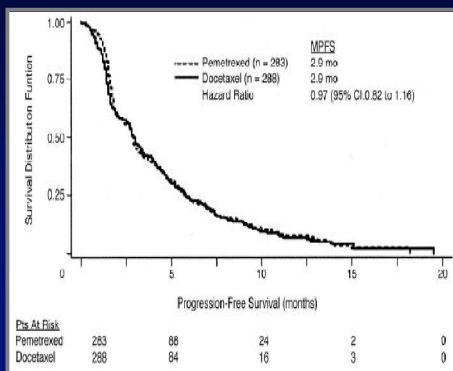
### Taxotere

**75 mg/m<sup>2</sup> i.v. q3wks (n=288)**  
(dexamethasone 8 mg bid on  
d-1,d0,d+1)

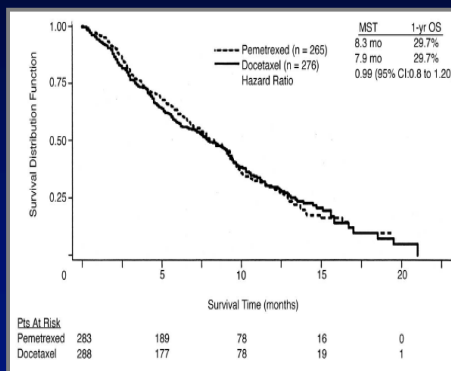
Hanna, *J Clin Oncol* 2004

## Equivalent Efficacy for Alimta (Pemetrexed) and Docetaxel (Taxotere)

### Progression-Free Survival



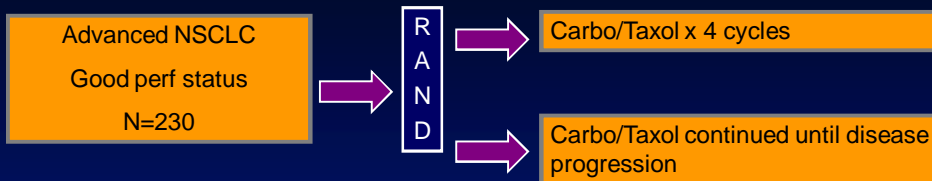
### Overall Survival



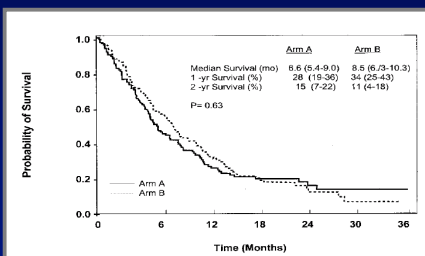
Hanna, *J Clin Oncol* 2004

Is there a meaningful difference in quality of life for patients who receive maintenance therapy compared with those who are observed after first line therapy?

## How Long to Treat? Four Cycles vs. Ongoing



Socinski,  
*J Clin Oncol* 2002



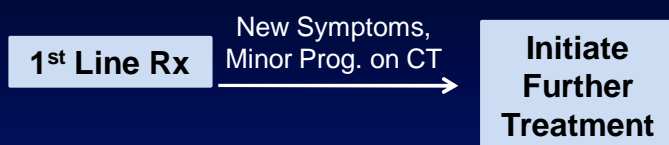
- All efficacy endpoints equal
- Only difference is more neurotoxicity with additional Rx

How can we compare “continuation maintenance therapy” to “switch maintenance therapy” in light of older and recent research findings in this setting?

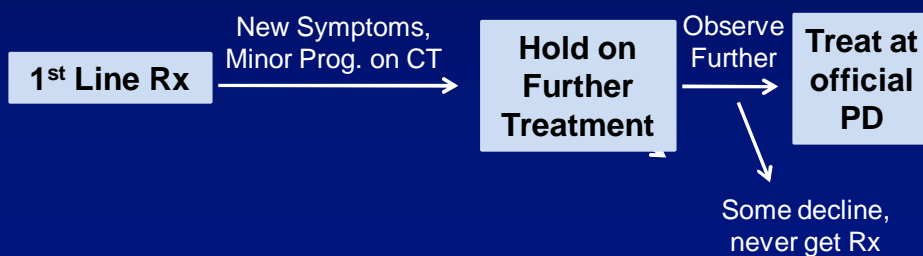
What is the significance of the fact that the Fidas trial of early vs. delayed Taxotere *required* patients to have significant disease progression before starting delayed chemotherapy?

## Requirement for Disease Progression May Delay Chemo Start vs. Routine Practice

### Routine Clinical Practice

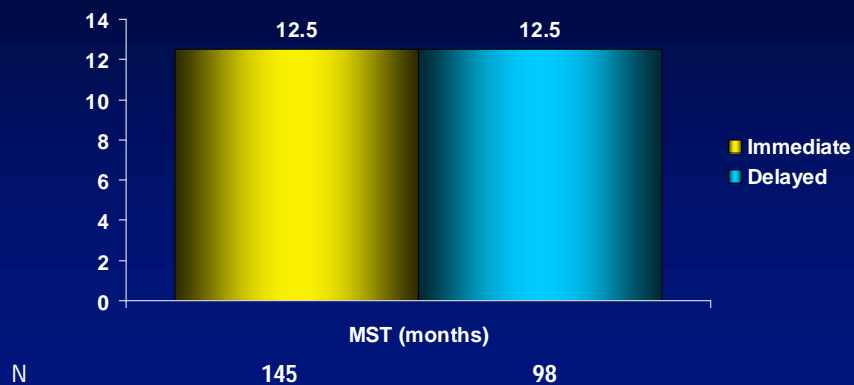


### Clinical Trial Requirement



Aside from presence of cancer-related symptoms, what criteria would you use to decide whether to recommend maintenance therapy or observation for an individual who hasn't progressed after first line chemo for advanced NSCLC?

## Survival for Patients Actually Receiving Docetaxel on Immediate & Delayed Arms (Fidias)



Fidias, *J Clin Oncol* 2008

Can we really compare these two groups, if the immediate arm includes patients with the more aggressive disease that dropped out from the delayed chemotherapy arm before starting Taxotere?

(are we really comparing apples to apples?)

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