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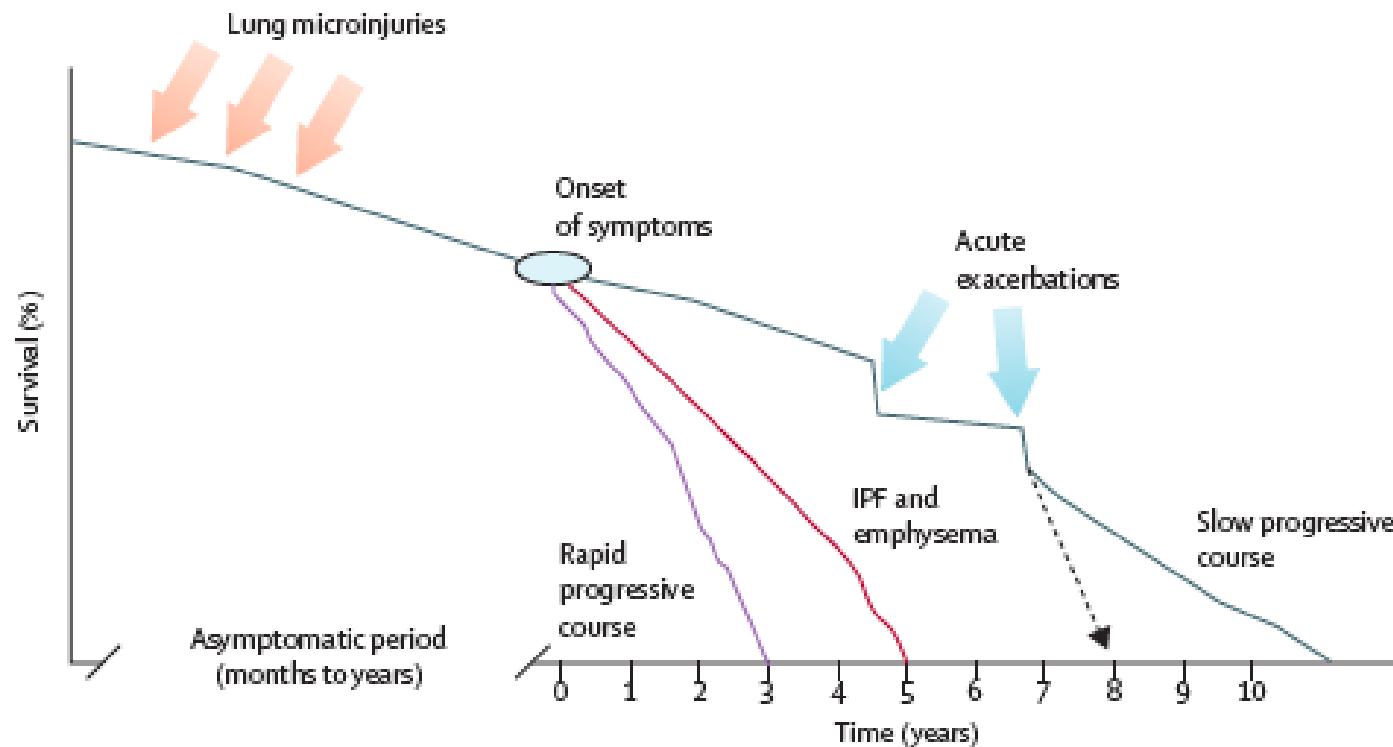
Pharmacological Management
Nintedanib + Case study

What is Idiopathic Pulmonary Fibrosis (IPF)

- ▶ A disease characterised by chronic/progressive lung fibrosis
 - ▶ Scar tissue builds up around the alveoli (air sacs of the lung)
 - ▶ Abnormal healing in the air sacs and repetitive injury
 - ▶ The lungs are stiff, thickened and scarred
 - ▶ The exchange of gases in the lungs is impaired
 - ▶ Unpredictable clinical course and high mortality.
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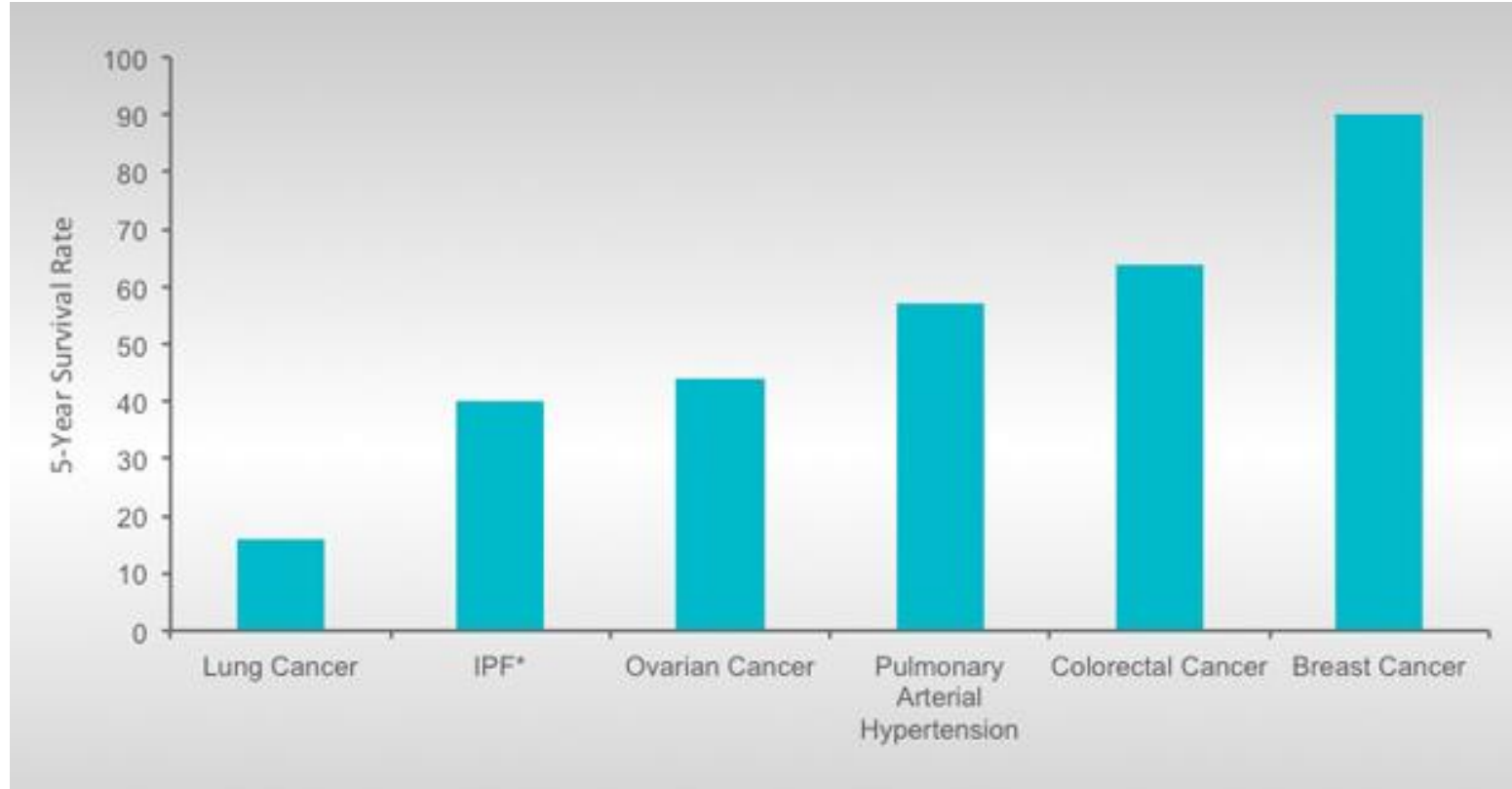
What is the course of IPF?

Prognosis approx 3 years from point of diagnosis – now changing with antifibrotic therapies



King TR et al, Lancet 2011

IPF: 2011 ATS/ERS guidance




*Reported 5-year survival rate is approximately 20% to 40%.

Aims of Treatment


- ▶ No curative treatment
- ▶ Aim of treatment is to slow rate of progression of IPF
- ▶ Rate of progression is very variable
 - Difficult to predict at time of diagnosis
 - Monitor change in lung function (FVC)
- ▶ Not all patients with IPF may need treatment

Antifibrotic Treatments

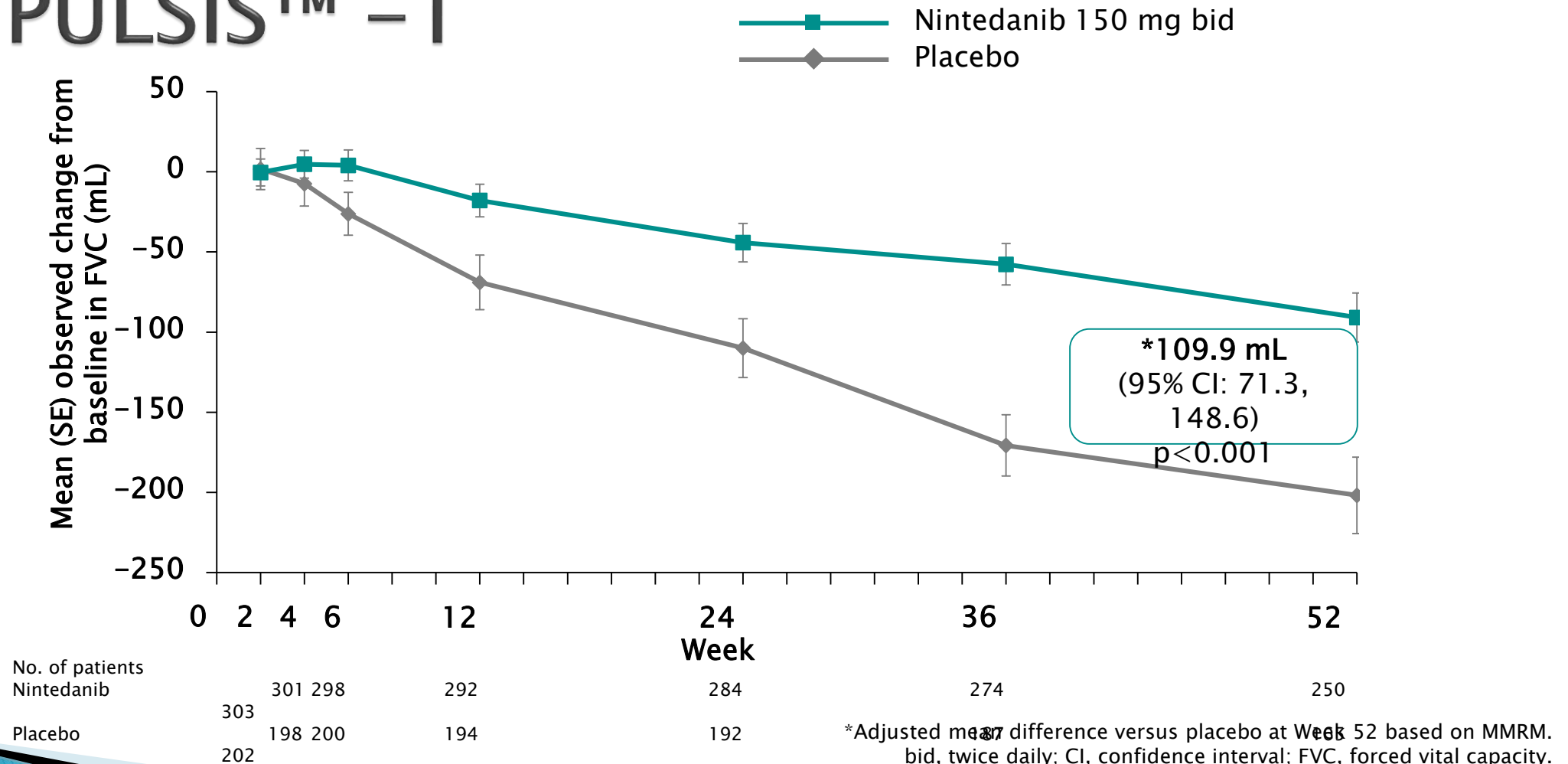
Pirfenidone and Nintedanib

- ▶ Evidence base for both medications is similar. 50% reduction in the rate of deterioration of lung function
 - ▶ Unless there is a clinical reason to offer one drug over the other patients can choose which drug to commence
 - ▶ Information on both drugs given to patient who can then make a treatment choice
 - ▶ The drugs are not used concurrently
 - ▶ Provided the patient is within criteria if they fail on one drug they can be offered the alternative
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Nintedanib

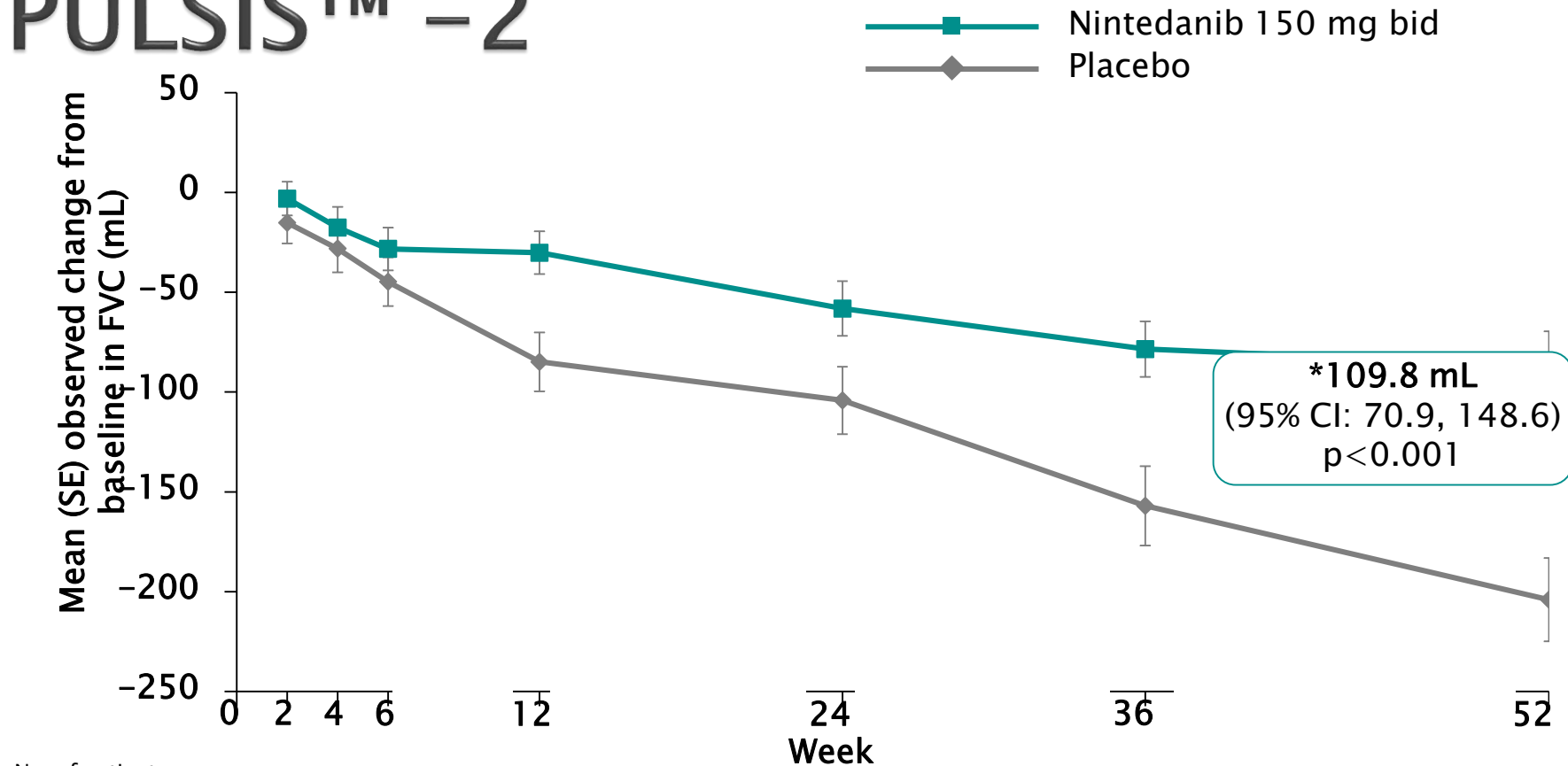
- ▶ It inhibits receptor tyrosine kinases implicated in the pathogenesis of IPF
 - ▶ Nintedanib significantly reduced the decline in forced vital capacity versus placebo in the INPULSIS Trials
 - ▶ 50% reduction in the rate of decline in forced vital capacity
 - ▶ The time to first acute exacerbation was significantly reduced with nintedanib
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CHANGE FROM BASELINE IN FVC OVER TIME: IMPULSIS™ –1



CHANGE FROM BASELINE IN FVC OVER TIME:

IMPULSIS™ -2




No. of patients							
Nintedanib		315	315	312	303	295	269
		323	210	207	209	203	203
Placebo		215	210	207	209	203	203
		215	210	207	209	203	203

*Adjusted mean difference versus placebo at Week 52 based on MMRM. bid, twice daily; CI, confidence interval; FVC, forced vital capacity.

Nintedanib received NICE approval in January 2016

Nintedanib can be offered to patients who meet the following criteria:–

- * Forced vital capacity of between 50% and 80% of predicted
 - * ILD MDT diagnosis of probable or definite IPF
 - * Disease progression
 - * Treatment is stopped if disease progresses – defined as a 10% or greater decline in FVC over any 12 month
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Dosing

- ▶ OFEV[®] (nintedanib) capsules should be
 - Taken approximately 12 hours apart with food
 - Swallowed whole with a glass of water
 - Dose 150 mgs or reduced dosage 100 mgs



1 Tablet Twice Daily



1 tablet in the morning

1 tablet at night

Potential Side Effects of Nintedanib


Abnormal Liver function tests (LFTS)



- ▶ Regular monitoring of LFTS (hand held blood monitoring booklet given to patient)
- ▶ LFTS monthly for the first 6 months of treatment then 3 monthly
- ▶ Nintedanib shared care guidelines sent to general practitioner
- ▶ Consider reducing dose if LFTs mildly elevated on treatment
- ▶ If LFTS $3\times$ upper limit of normal – reduce or stop treatment


Potential Side Effects of Nintedanib

Nausea


- ▶ Anti-emetics
 - ▶ Review diet – avoid foods that may provoke nausea, smaller lighter meals
 - ▶ Peppermint water/tea
 - ▶ Cool drinks, lighter, dryer, more bland foods
 - ▶ Consider reducing dosage to 100 mgs BD
 - ▶ Discontinue if severe
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Potential Side Effects of Nintedanib

Diarrhoea and abdominal discomfort

- ▶ Loperamide to control diarrhoea symptoms – given at start of treatment for use if required
 - ▶ Dietary advice – avoid foods that may be provoking symptoms (excessive dairy, hot spicy foods)
 - ▶ Peppermint water/tea
 - ▶ Hydration
 - ▶ Reduce dosage if required to 100 mgs BD
 - ▶ Discontinue if severe
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Cautions

- ▶ Haemorrhage (GI, CVA, surgery last 3 months) or thrombotic events
 - ▶ To be used with caution if on anticoagulation
 - ▶ Abnormal liver function (raised)
 - ▶ Gastrointestinal disorders (colitis, crohn's, diverticulitis)
 - ▶ Effect on QT interval (prolongation).
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Contra indications

- ▶ Hypersensitivity to nintedanib,
- ▶ Peanut
- ▶ Soya

Interactions

- ▶ Ketoconazole
- ▶ Erythromycin
- ▶ Cyclosporine
- ▶ Rifampicin
- ▶ Carbamazepine, phenytoin
- ▶ St Johns Wart

Any Questions