

Drugs For IPF: Nintedanib (Ofev)

Robert Hallowell, M.D.

Assistant Professor of Medicine

Harvard Medical School

Director, Pulmonary Practice, BIDMC

Disclosures

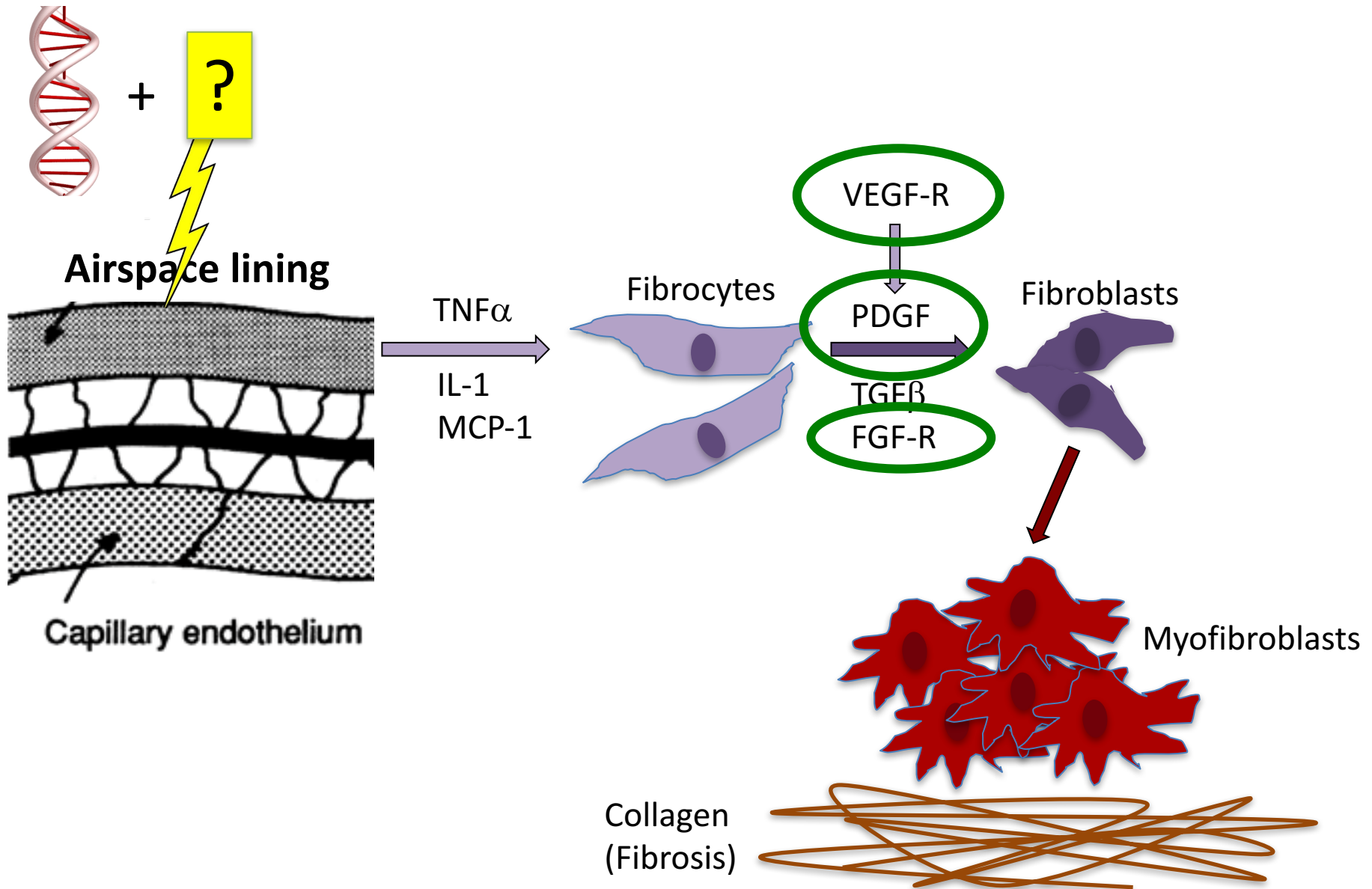
- No financial disclosures

Nintedanib (Ofev)

- FDA approved October 2014
- (BIBF 1120)



Nintedanib



The INPULSIS trials

INPULSIS-1: 513 patients (309 drug; 204 placebo)

FVC decline (52 weeks): -114.7 ml vs -239.9 (p<0.001)

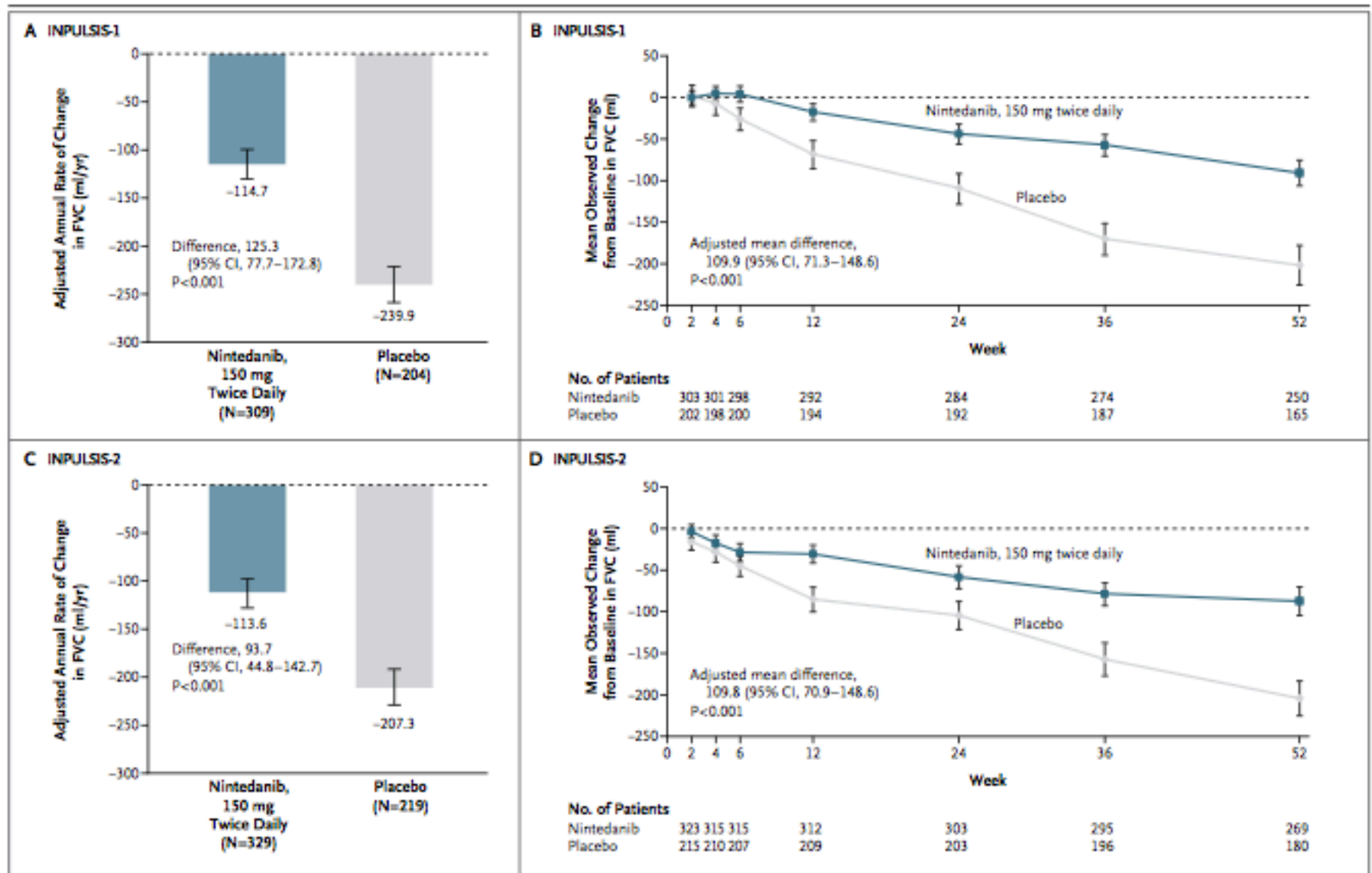
Time to first exacerbation: HR 1.15 (P = 0.67)

INPULSIS-2: 548 patients (329 drug; 219 placebo)

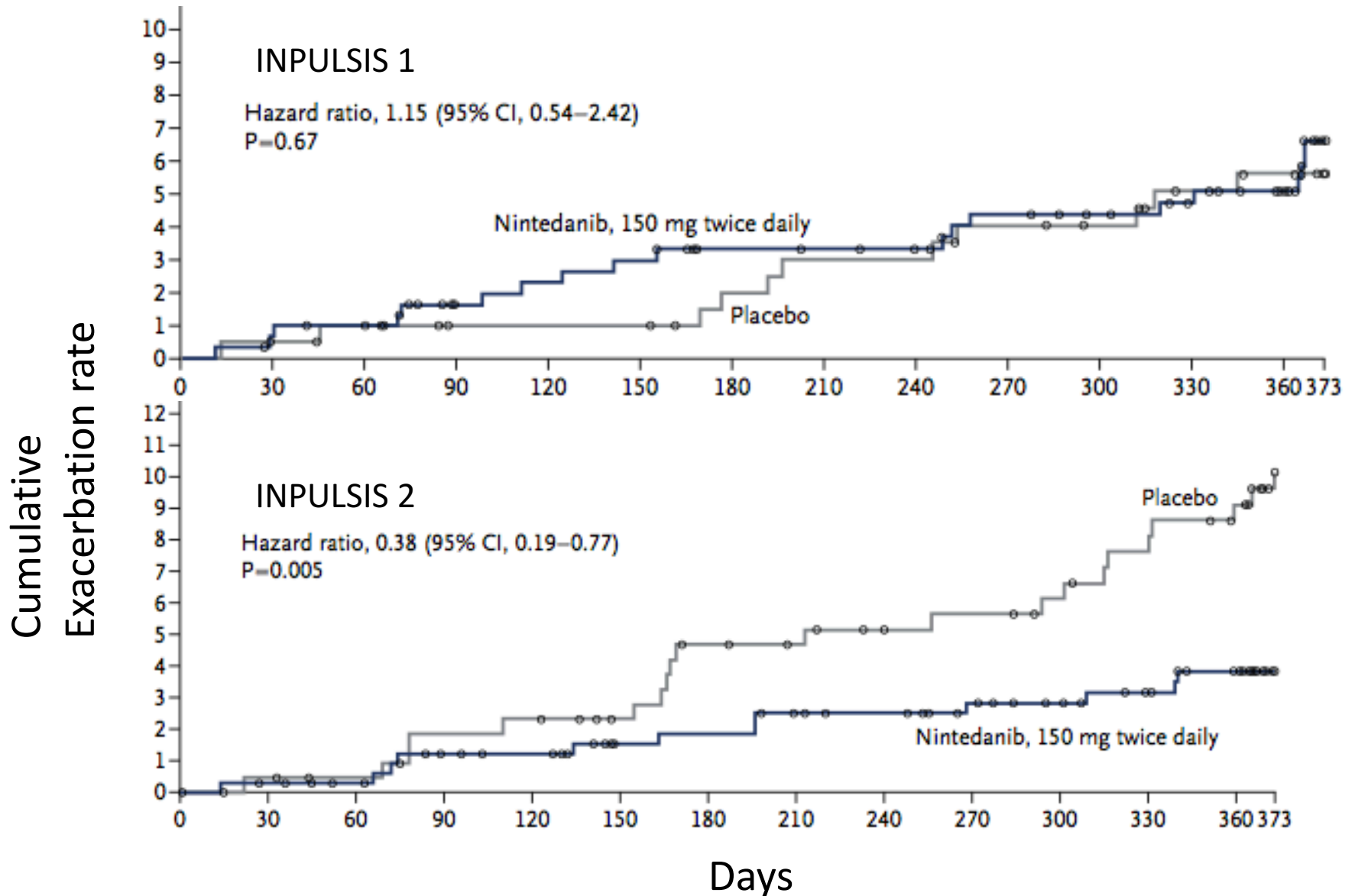
FVC decline (52 weeks): -113.6 ml vs -207.3 (p<0.001)

Time to first exacerbation: HR 0.38 (P = 0.005)

The INPULSIS trials



Exacerbation Rate

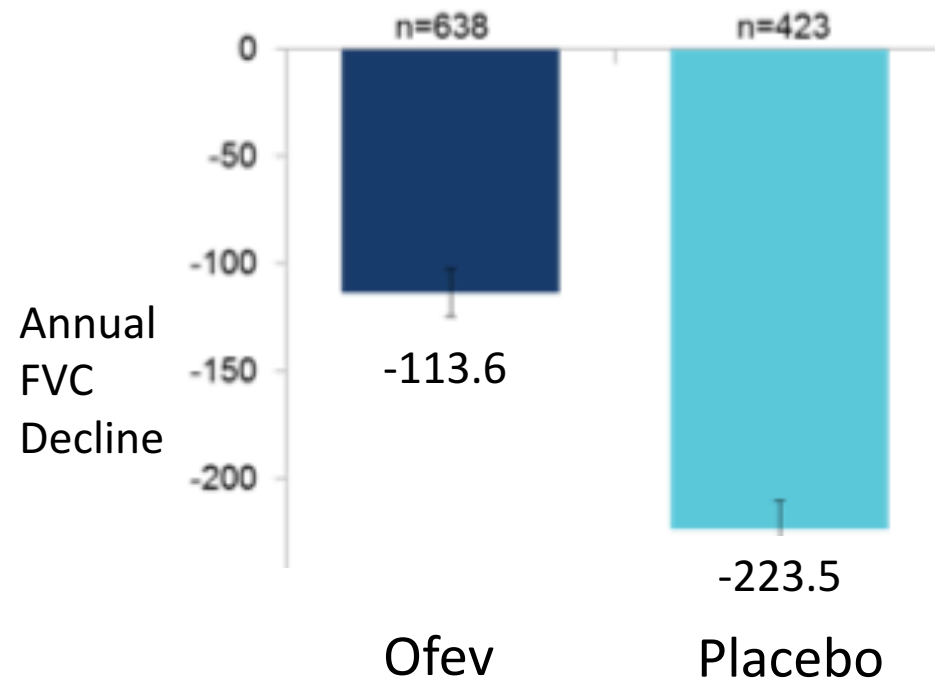


INPULSIS-ON

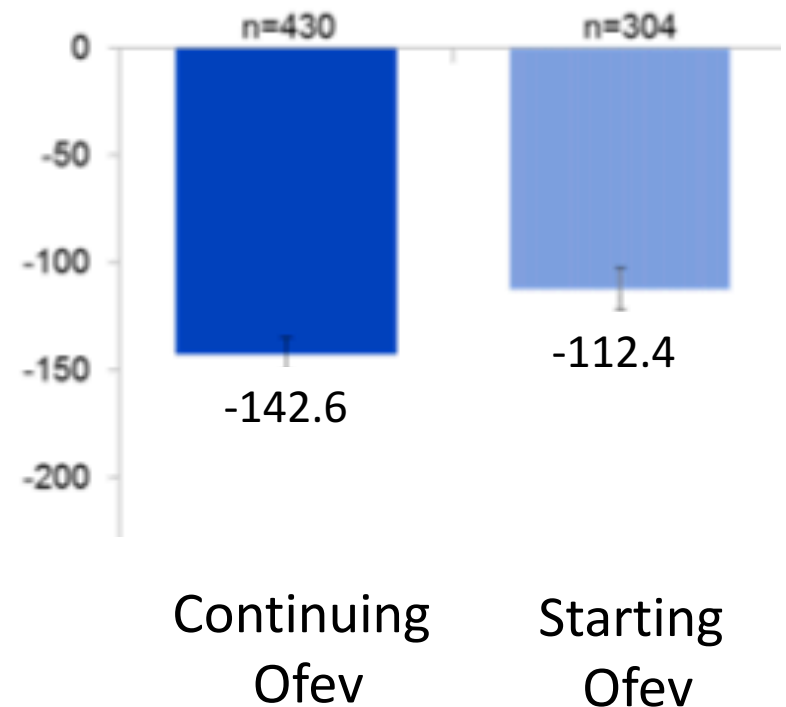
- Patients from INPULSIS were eligible to continue treatment with OFEV (open-label)
- 734/1061 original patients enrolled
- 430 continuing Ofev; 304 had been on placebo
- Still ongoing

The protective effects of Ofev persist beyond 52 weeks

INPULSIS (52 WEEKS)



INPULSIS-ON (144 WEEKS)



Ofev reduces acute exacerbations

	INPULSIS*		INPULSIS-ON	
	OFEV (n=638)	Placebo (n=423)	Continuing OFEV (n=430)	Initiating OFEV (n=304)
Patients with ≥ 1 acute exacerbation, n (%)	31 (4.9)	32 (7.6)	54 (12.6)	35 (11.5)
Total years at risk	601	401	1026	673
Adjusted incidence of acute exacerbation	5.2	8.0	5.3	5.2

~ 80% relative risk reduction in exacerbation
(INPULSIS 2 + INPULSIS-ON)

Common Side Effects

Diarrhea (62%)

Nausea (24%)

Abdominal pain (15%)

Vomiting (12%)

Decreased appetite (11%)

Only 4% stopped Ofev due to diarrhea (INPULSIS)

Dealing with side effects



Dealing with side effects

Take each dose with a meal large enough to feel **full**

Space each dose by a full 12 hours
(Skip a dose if you are more than 1h late)

Take Imodium at the first sign of diarrhea
(Can get up to three free boxes)

Nurse support over the phone 24/7

Assistance to find local social support

An educational class with a Clinical Educator

Combination therapy?

IPF involves dysregulation of multiple, complex pathways.

Barriers:

Cost

More GI side effects

Hard to show efficacy

Pirfenidone decreases nintedanib levels

Special Thanks

- Elaine Triano-Kim
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- Mary Leroy-Sullivan



Questions?