

Nintedanib (Ofev) for Idiopathic Pulmonary Fibrosis

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Nintedanib

Mechanism of action

Evidence supporting its use – impact upon lung function and symptoms

Tolerability

Management of side effects

Nintedanib

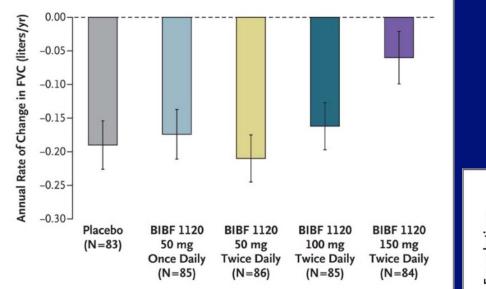
capsule, usually 150mg taken twice daily, though available at 100mg strength

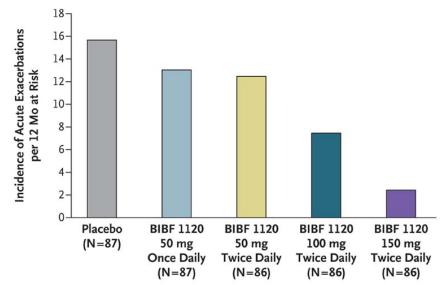
Tyrosine kinase inhibitor
There are a number of important proteins and lipids that play a role in the fibrosis process
These include the PDGF, FGF and VEGF families
nintedanib blocks the action of these proteins, slowing the development of further fibrosis

First investigated nearly 10 years ago as a potential cancer treatment – still being studied as therapy for lung, colon, breast and other cancers Approved in Europe for treatment of lung cancer

Nintedanib (BIBF 1120) – phase II trial published 4 years ago

Slowed the loss of lung function and decreased the likelihood of developing an IPF exacerbation



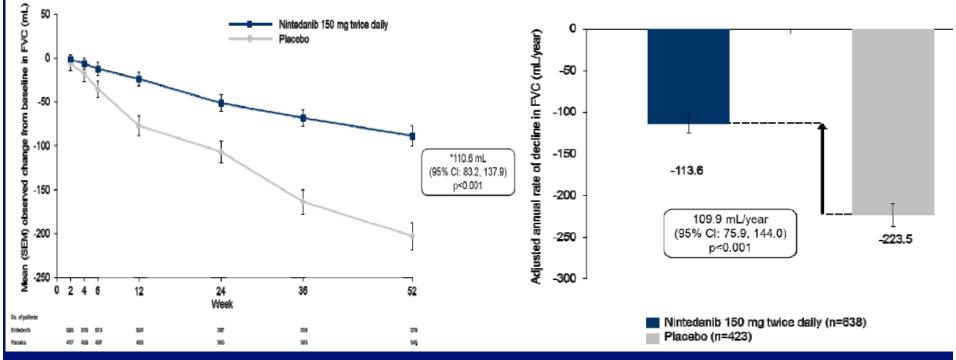


Richeldi L et al. N Engl J Med 2011;365:1079-1087

IMPULSIS Vital Capacity Results

Change from baseline

Annual decline



49% relative reduction

Major finding was that nintedanib slowed the loss of lung function due to IPF over the course of a year

IMPULSIS, NEJM 370:2071-2082, May 29, 2014

Did that translate into an improved health related quality of life?

St. George's Respiratory Questionnaire : 0-100 scale, measures symptoms, exercise limitations and the social and psychological impact of illness (the lower the better)

Both the nintedanib and the placebo group experienced an increase in their SGRQ score, the nintedanib group increased to a lesser extent, however the difference between the 2 groups was not statistically significant

Tolerability

IMPULSIS: treatment stopped because of adverse events (not including respiratory events) nintedanib 16.1% placebo 6.4%

	<u>nintedanib</u>	placebo
Diarrhea	62%	18%
Nausea	25%	7%
Liver test abnormalities	14%	3%
Vomiting	12%	3%
Decreased appetite	10%	6%
Weight loss	10%	3%

Important to follow liver function tests (LFTs)

Strategies for dealing with side effects

Diarrhea - will often resolve over a handful of weeks

- review your other medications, make sure no other culprits
- loperamide (Imodium)
- BRAT diet
- consider reducing dose
- keep yourself hydrated

Nausea

- small, frequent meals, familiar foods
- keep yourself hydrated
- avoid strong, unpleasant smells
- anti-nausea medications are available



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