PF-ILD: Treatment Efficacy Based on Disease Severity and with Progressive Phenotype

Claudia Valenzuala and colleagues present the analysis from the INBUILD trial of nintedanib in patient with progressive fibrosing interstitial lung disease, considering different level of baseline forced vital capacity. This analysis was already done for the INPULSIS trial on IPF. And so the question behind these trial is if there is any difference in the efficacy or the safety of nintedanib at different level of forced vital capacity.

So what is interesting to see is that there was a significant fraction of patients with an FVC below 50% treated at baseline, between 50% and 70% treated at a baseline and over 70% treated at baseline. And it is interesting to see that basically overall the treatment by group by time interaction was not statistically significant. That's meaning that the rate of decline in FVC is similar, irrespective of the degree of FVC impairment at baseline. And the same was also true for the side effects. So this abstract is important in providing further evidence that nintedanib is effective in slowing down disease progression measured as forced vital capacity over 52 weeks, irrespective of the severity of baseline involvement. And also, the safety profile of the drug is similar across the spectrum of different severities. So FVC at baseline is not a determinant of either efficacy or safety of nintedanib. And safety and efficacy of nintedanib in patient with progressive fibrosing ILD is similar across group with different severities.

In this abstract Kevin Flaherty and colleagues presented the results of a further analysis of the INBUILD trial. As you know, the INBUILD trial is a trial, 52 weeks, placebo control assessing the efficacy of nintedanib in patients with progressive fibrosing interstitial lung disease. Now, this trial was composed of a part A and part B. That means that this analysis is providing us with results, which are covering a mean follow-up period of 19 months, so longer than the 52 weeks part A of the trial.

And in particular, Kevin Flaherty is presenting here the results for three important efficacy endpoint: death, acute exacerbation or death and progression of interstitial lung disease, which is a composite of absolute declining FVC of more than 10% predicted or death. In all of these efficacy endpoint, nintedanib showed that reduced the frequency of these events as compared to placebo. In particular, the reduction of death is of 22% with nintedanib compared to placebo. The reduction of acute exacerbation or death is 33%. And the reduction of progression of ILD is 34%. And this is reassuring in terms of telling us that even beyond the 52 weeks period that has been published so far, there is a consistent reduction of clinical important efficacy endpoint with regard to nintedanib as compared to placebo. Reassuringly, also, the side effect profile is not changing in these extended period of observation. So these data lend further support on the efficacy and safety of nintedanib in patient with progressive fibrosing interstitial lung disease.