Inhalation innovation: An overview of AURA-IPF (AP02-003), a new trial studying inhaled nintedanib in the treatment of idiopathic pulmonary fibrosis

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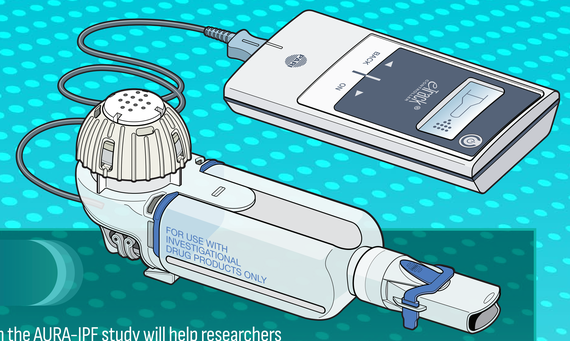


BACKGROUND

Idiopathic Pulmonary Fibrosis (IPF) is a severe, chronic, progressive, fibrosing interstitial lung disease with no cure.[1,2]

THE PROBLEM

- Currently, three drugs are approved to treat IPF (nintedanib, pirfenidone, and nerandomilast).[1-3] All are pills. They slow disease progression, but some patients find them difficult to take because of side effects like diarrhea and other digestive problems.[3-5]
- Avalyn is studying a new inhaled version of nintedanib, called **AP02**. Breathing in the medicine may help it reach the lungs more directly, where it's needed most, while reducing the amount that goes to other parts of the body, meaning potentially fewer side effects.
- AP02 has already been successfully studied in healthy volunteers and patients with IPF, but a larger study is being started to learn even more about its potential to treat IPF.[5,6]

METHODS

- The AURA-IPF study (NCT07194382) is a clinical trial that will enroll **160 patients** with IPF[7]
- Its main goal is to assess AP02's effectiveness and safety in patients with IPF
- The study lasts about **16 weeks**. It includes:
  - Up to 2 weeks of screening
  - 12 weeks of treatment
  - 2 weeks of follow-up
- During the study, participants will use a redesigned nebulizer inhaler **twice a day** to take AP02 or a placebo. A nebulizer is a device that turns liquid medicine into a fine mist that can be inhaled into the lungs
- Patients will need to visit the study site **6 times** during the study
- At study visits, doctors will perform several tests, including:
  - Measuring lung function (forced vital capacity)
  - Taking CT scans
  - Assessing quality of life using the Living with Pulmonary Fibrosis questionnaire
  - Monitoring for any side effects

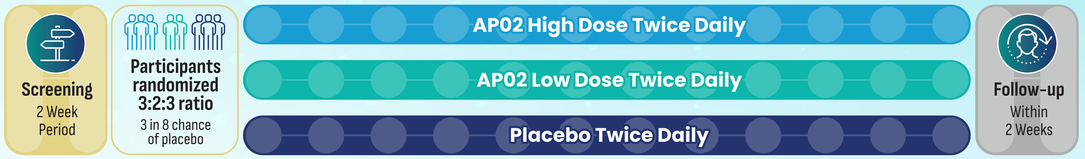
KEY INCLUSION CRITERIA

- Age ≥40 years
- A diagnosis of IPF within 5 years
- Other clinical criteria are met

KEY EXCLUSION CRITERIA

- Had approved IPF treatment within 3 months
- Took any clinical trial drug within 30 days

STUDY GROUPS – 12 WEEKS

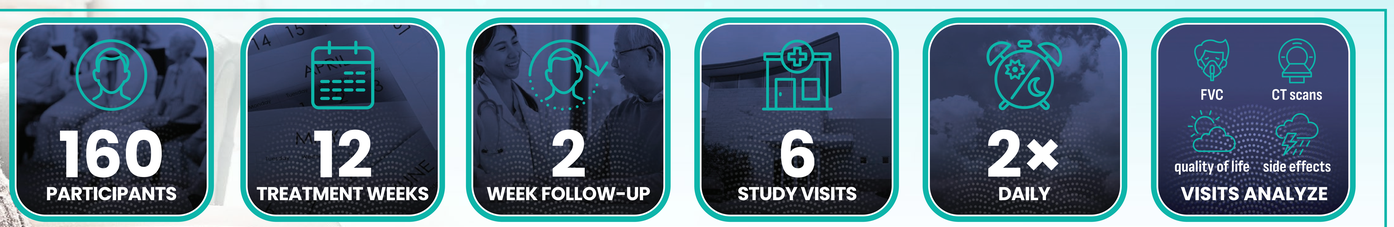


SUMMARY & NEXT STEPS

- Results gathered from the AURA-IPF study will help researchers learn if AP02 has the potential to safely and effectively treat IPF.
- If the results are positive, more studies will be conducted to gather even larger amounts of data and determine whether AP02 can be considered as a new treatment option for patients.

AURA-IPF
AN IPF CLINICAL STUDY

HIGHLIGHTS



REFERENCES & DISCLOSURES

Author Disclosure:

MK has nothing to disclose. **KS** serves as an IPF support group leader and as an advisor on Avalyn's IPF Patient Advisory Council with no financial relationship to Avalyn. **SMK** serves as an advisor on Avalyn's IPF Patient Advisory Council and as a voice of the patient consultant with no financial relationship to Avalyn. **HML, DM, EA, BNJD, AT, MH, and CSC** are employees of and have been granted options to receive equity from Avalyn Pharma. Outside of the submitted work, **JSL** is a recipient of grants from the NIH and Boehringer Ingelheim; an unrestricted research gift from Pliant; and consulting fees from Blade, Boehringer Ingelheim, Astra Zeneca, Elima, Gatehouse Bio, Mannkind, Syndax, Mediar Therapeutics, Abbvie, Avalyn and Eleven P15. **JSL** served as Data and Safety Monitoring Board member for United Therapeutics and Pulmovant; advisor for the Pulmonary Fibrosis Foundation; and section editor for UpToDate and Merck.

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