ASPIRE: patient input for design of a Phase 2b trial in Idiopathic Pulmonary Fibrosis with Buloxibutid

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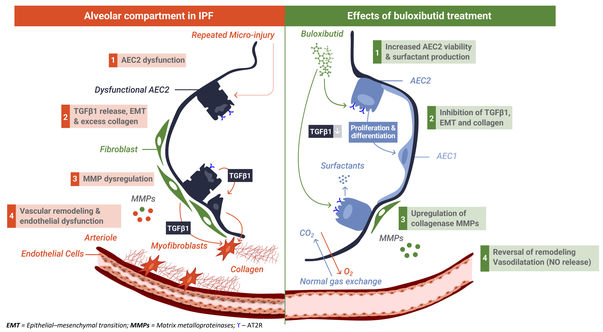
Objectives

Idiopathic pulmonary fibrosis (IPF) is a severe, progressive respiratory illness with a huge remaining medical need despite approved therapies.

Buloxibutid is an oral, angiotensin II type 2 receptor agonist that activates an upstream pathway that drives alveolar repair, resolves fibrosis, and promotes vascular function (Figure 1).



***EMT** = Epithelial–mesenchymal transition; **MMPs** = Matrix metalloproteinases; T – AT2R*

In the Phase 2a AIR trial investigating buloxibutid in IPF, buloxibutid demonstrated stabilization and improvement of lung function over 36 weeks.

Participation in clinical trials is necessary to research new drugs, but many of the practical aspects reduce the willingness to take part and pose a hurdle for many patients (Ref 2). Involving patients and caregivers in designing a clinical trial may help reduce these hurdles and optimize trial design.

Methods

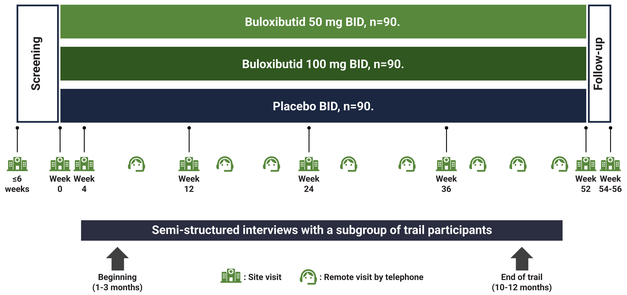
An advisory panel of IPF patients and caregivers was asked for ways to improve patient experience in our planned phase 2b trial. Feedback was given based on the panel's own clinical research experience, and suggestions were received on trial conduct and patient-facing materials.

As a response to the feedback, several design measures were put in place:

- Minimize the number of clinic visits.
- Implement telephone visits to ensure patient safety and keep participants engaged.
- Ensure travel assistance for remote patients.
- Conduct semi-structured interviews for a subgroup of 10-14 participants on 2 occasions during the trial to obtain feedback.

Trial Design

The resulting ASPIRE phase 2b trial of buloxibutid is a patient friendly trial designed and executed with the help of patients and caregivers. It is a randomized, placebo-controlled trial investigating efficacy and safety of two doses of buloxibutid, 50 mg twice a day and 100 mg twice a day, versus placebo, for 52 weeks in patients with IPF. (figure 2)



"To join this trial means to me that there may be something eventually that can help people."
-ASPIRE participant

Conclusions

- Patient and caregiver feedback optimized the ASPIRE trial design. Additionally, patient interviews will provide important insights on patient experiences during the ASPIRE trial. This may optimise a subsequent phase 3 trial, and other future trials in IPF.

Digital poster

See more about the ASPIRE study

[1] Ganslandt C et al. Buloxibutid, a Novel Angiotensin II Type 2 Receptor Agonist, Stabilized and Improved Lung Function in Individuals with Idiopathic Pulmonary Fibrosis in the 36-week Phase 2 AIR Trial. Am J Respir Crit Care Med 2024; 209: A1055.
[2] Desai M. Recruitment and retention of participants in clinical studies: Critical issues and challenges. Perspect Clin Res. 2020 Apr-Jun;11(2):51-53.

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Shull, Garly, and Lindmark are current employees of Vicore Pharma.