IMPALA-2 TRIAL
DATA RESULTS SUMMARY

What was the IMPALA-2 trial about?

The IMPALA-2 trial studied the investigational drug molgramostim inhalation solution (molgramostim) in adults living with autoimmune pulmonary alveolar proteinosis (aPAP).

In aPAP, a material called surfactant builds up in the lungs and makes it hard to breathe. Researchers believe that molgramostim activates the cells that help clear surfactant from the lungs. This improves oxygen flow from the lungs to the bloodstream. Currently, there are no approved medications for aPAP in the United States. However, the symptoms of aPAP can be treated with whole lung lavage. Whole lung lavage is an invasive procedure, performed under general anesthesia, that temporarily removes surfactant.

What was the goal of the IMPALA-2 trial?

The goal of the trial was to find out if molgramostim is safe to take and if it can help improve the lung function and quality of life of adults living with aPAP.

What happened in the IMPALA-2 trial?

164 People living with aPAP aged 18 and older from Asia Pacific, Europe, Turkey, and North America took part.

Trial participants were randomly assigned to take either a placebo (no active pharmaceutical ingredients) or molgramostim through a nebulizer daily.

After the first 48 weeks of the trial, all participants had the option to move to the open-label portion of the trial where everyone received daily molgramostim.

How was the impact of molgramostim measured?

Lung function: Diffusing capacity of the lungs for carbon monoxide (DLCO). This measures how well lungs move gas, like oxygen, from inhaled air to the bloodstream.

Quality of life: St. George's Respiratory Questionnaire (SGRQ). This is a survey specifically for people with a pulmonary disorder. It asks participants questions about their quality of life and daily physical activity.

Physical function: Exercise Treadmill Test. This calculates the amount of physical exertion a person can sustain.

And more: Researchers also tracked if participants underwent a whole lung lavage or experienced adverse events (AEs). AEs are side effects or negative medical outcomes that may or may not have been caused by the trial drug.

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What were the results of the IMPALA-2 trial and what did we learn?

Lung function: Trial participants who took molgramostim had greater improvements in lung function compared to participants who took placebo. Lung function was measured using diffusing capacity of the lungs for carbon monoxide (DLCO).

Quality of life: Trial participants who took molgramostim had more quality of life and daily physical activity improvements than participants who took placebo. This was measured using the St. George's Respiratory Questionnaire (SGRQ).

Physical function: Some improvement compared to placebo was seen in physical capacity. This was measured using the Exercise Treadmill Test.

And more:

- Fewer participants taking molgramostim had one or more whole lung lavage procedures than participants who took placebo.
- Molgramostim was well tolerated. Tolerance is measured by the number and severity of adverse events participants experience.
- Participants on placebo and participants who took molgramostim had generally similar adverse events. The most common adverse events for participants who took molgramostim were cough and fever.

Will there be more research on molgramostim?

Participants who completed the first 48 weeks of the IMPALA-2 clinical trial were able to join an open-label extension of the trial. The extension lasts an additional 96 weeks, and all participants receive molgramostim. Researchers continue to learn about molgramostim during the open-label extension portion of the trial.

Where can I learn more about the IMPALA-2 trial?

IMPALA-2 is a global Phase 3 clinical trial. The full name of the trial is: Clinical Trial of Inhaled Molgramostim Nebulizer Solution in Autoimmune Pulmonary Alveolar Proteinosis (aPAP). More details are available on www.ClinicalTrials.gov; search NCT04544293.

This summary includes the results of a single trial, IMPALA-2. The next step is for Savara, the trial sponsor, to submit data from IMPALA-2 and previous studies of molgramostim to the U.S. Food and Drug Administration (FDA) for review. Savara expects to complete this submission in the first half of 2025.

To learn more about molgramostim or Savara, visit www.SavaraPharma.com.

People living with aPAP should consult their physicians with questions about their individual care and should not make changes in their treatments based on the results of this trial.

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