Clinical Trial Results Summary

NOVARTIS

The effects and safety of LYS228 in people with complicated intra-abdominal infection

Thank you!

Thank you to the participants who took part in the clinical trial for the trial drug **LYS228**. If you participated in the trial and have questions, please speak with your trial doctors or staff.

What was the main purpose of this trial?

The main purpose of this trial was to learn more about the effects and safety of LYS228 for people with cIAI, which stands for complicated intra-abdominal infection.

- **Complicated intra-abdominal infection (cIAI)** is a type of infection caused by bacteria. cIAI starts in the stomach area and spreads to other body parts.
- **LYS228** is an antibiotic trial drug designed to kill bacteria that cause certain infections.

The main questions this trial was designed to answer:

- How much and how quickly did LYS228 get into the blood?
- Did LYS228 reduce signs and symptoms of cIAI?
- What medical problems did the participants have during the trial?

Keeping track of the medical problems helped to learn about the safety of LYS228.

How long was this trial?

The trial began in May 2018 and ended in September 2018. The trial was planned to last about 1 month for each participant.

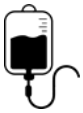
The sponsor ended this trial early because LYS228 was sold to a different company that will continue studying LYS228.

Trial number: CLYS228X2202

Who was in this trial?

This trial planned for 60 participants with cIAI in the United States. Because the trial ended early, only 3 participants were in this trial. The participants were all men 63 to 64 years old.

What trial treatments did the participants take?



A computer program was used to randomly assign each participant to one of the following:

- **LYS228** – directly into the blood through an intravenous infusion every 6 hours for up to 14 days. They also received two other antibiotics along with LYS228.
- **Standard Therapy** – the usual antibiotics prescribed for cIAI. The doctor at the clinical trial site decided the standard therapy.

Including a standard therapy helps doctors make sure that all patients in the trial get a form of treatment for cIAI. It also helps to better understand the effects of the trial drug.

2 participants received LYS228 and 1 received the standard of care.

What were the main results of this trial?

This is a summary of the overall results of this trial. Individual results from each participant may be different and are not included in this summary.

Researchers need many trials to learn if a drug or other treatment is safe and works well. Other trials may provide new information or different results. Always talk to a doctor before making any changes to your health care.

What results were learned?

Because the trial ended early, there were too few participants to conclude:

1. How much and how quickly LYS228 got into the blood
2. If LYS228 could reduce signs and symptoms of cIAI compared to those who received the standard therapy

What medical problems did the participants have during this trial?

Medical problems that happen during trials are called “adverse events”. Trial doctors looked for any adverse events during the visits to the trial site. The participants also reported adverse events.

Many trials are needed to know if a drug or treatment causes an adverse event. Trial doctors keep track of all adverse events that happen in trials, even if they think the adverse events are not related to the trial treatments.

An adverse event is:

- Any **unwanted sign or symptom** that the participants have during a trial
- Considered “**serious**” when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may or may not be caused** by treatments in the trial.

3 serious adverse events occurred in the standard therapy group. All participants reported at least one adverse event.

Please go to the **novctrd.com** to find out more information about other adverse events. See instructions below.

What was learned from this trial?

In this trial, LYS228 seemed to have no safety concerns. However, there were not enough trial participants for researchers to find out the effects and safety of LYS228.

LYS228 is no longer being studied by Novartis.

Where can I learn more about this trial?

For more information about this trial, search for **CLYS228X2202** at any of these websites:

- **novctrd.com** Novartis clinical trial results
- **clinicaltrials.gov** ClinicalTrials.gov

Full trial title: A randomized, controlled, evaluator-blinded, multi-center study to evaluate LYS228 pharmacokinetics, clinical response, safety, and tolerability in patients with complicated intra-abdominal infection

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