CLINICAL STUDY RESULTS – PART A

Plain Language Summary: Study of an Anti-TNF Medicine in People Living with Pulmonary Sarcoidosis

About this summary

Results from research studies about investigational drugs are described in a report called a "Clinical Study Report." A Clinical Study Report is for researchers, health professionals and people who approve investigational drugs. This is a summary of that report in plain language.

The summary describes the results of Part A, one part of a two-part study. Other studies of XTMAB-16 may have different results.

CLINICAL STUDY IDENTIFICATION

Study name: A Seamless, Phase 1b/2 Multiple Ascending Dose/Proof of Concept Study of XTMAB-16 in Patients with Pulmonary Sarcoidosis with or without Extrapulmonary Manifestations

Protocol number: XTMAB-16-201

Date of summary: April 2026

CONTACT DETAILS OF SPONSOR

This study was sponsored by Xentria™, Inc.

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1. WHY WAS THIS STUDY DONE?

About Pulmonary Sarcoidosis

Pulmonary sarcoidosis is a disease that causes inflammation in the lungs. This inflammation can lead to small clumps of immune cells called granulomas. Over time, granulomas can affect breathing and cause symptoms such as:

- Shortness of breath
- Cough
- Chest tightness
- Tiredness

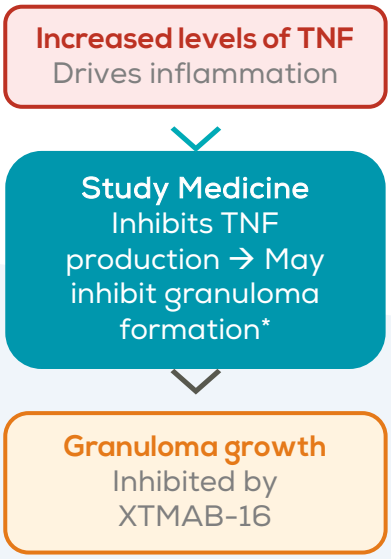
One of the signaling proteins in the body that plays a key role in inflammation is called tumor necrosis factor (TNF).

In people with sarcoidosis, TNF levels may be too high. High TNF levels can help drive inflammation and granuloma formation.

XTMAB-16 is an anti-TNF monoclonal antibody currently under investigation. It is designed to block TNF and as a result, may reduce inflammation. In this document, XTMAB-16 will be referred to as the 'study medicine' or 'medicine.'

***XTMAB-16 has not yet been studied in large, carefully controlled clinical trials in people with pulmonary sarcoidosis, and it is not approved to treat this condition**.

HOW WE THINK XTMAB-16 WORKS



About this study (XTMAB-16-201): This is the first study of XTMAB-16 in patients with pulmonary sarcoidosis. The study is conducted in two parts: Part A and Part B. This summary describes the results of Part A only.

2. WHAT WAS THE GOAL OF THE STUDY?

XTMAB-16-201 is an "early phase" study. The purpose of the study was to better understand the safety of XTMAB-16 and whether it may help improve lung function in people using a small group of patients with pulmonary sarcoidosis.

This study's purpose was to learn:

- Whether XTMAB-16 is safe in people with pulmonary sarcoidosis
- How the body processes XTMAB-16
- Whether XTMAB-16 may improve lung function

Part A: A Dose-Ranging study

Part A was a **dose-ranging study**. In a dose-ranging study, researchers test different amounts (doses) of a medicine to understand how the effects change as the dose changes. A dose-ranging study helps researchers learn:

- How safe different doses are
- Which dose may work best

Part A evaluated **two different doses** of XTMAB-16 given at **two different schedules** (how often the medicine was given), creating four treatment groups (cohorts).

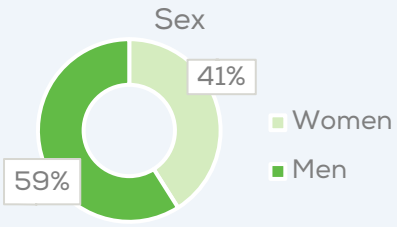
The goals of Part A were to:

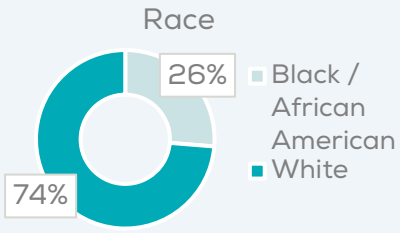
- Evaluate safety
- Understand how the medicine moves through and leaves the body
- Explore whether different doses and schedules may improve lung function

Part A → Part B: The results from Part A will help guide the design of Part B.

3. WHO TOOK PART IN THE STUDY

A total of 39 adults with pulmonary sarcoidosis enrolled in Part A. 38 participants completed the study. About the participants:





Participants' ages ranged between ages 18 and 80 with an average age of 54.

Participants in the study had the following characteristics before receiving XTMAB-16. These describe their *existing* condition and are *not caused by* the study medicine:

- They had been diagnosed with pulmonary sarcoidosis at least six months before joining the study.
- They had symptoms such as shortness of breath and reduced lung function based on breathing tests.
- They were taking stable background treatment (for example, corticosteroids and methotrexate).

Participants were enrolled across 17 centers in 4 countries (US, UK, Poland, Czech Republic).

4. WHAT TREATMENT DID PARTICIPANTS RECEIVE?

Participants were assigned to one of four groups (called cohorts). Within each group, some participants received XTMAB-16 and others received **placebo** (a treatment with no active medicine).

Cohort	Dose	Schedule	Ratio (XTMAB-16 : Placebo)
Cohort 1	2 mg/kg	Every 4 weeks (Q4W)	3 XTMAB-16 : 1 Placebo
Cohort 2	4 mg/kg	Every 4 weeks (Q4W)	3 XTMAB-16 : 1 Placebo
Cohort 3	2 mg/kg	Every 2 weeks (Q2W)	3 XTMAB-16 : 1 Placebo
Cohort 4	4 mg/kg	Every 2 weeks (Q2W)	3 XTMAB-16 : 1 Placebo

Randomization

3 : 1

Participants were randomly assigned treatment. For every 4 participants, 3 received XTMAB-16 and 1 received placebo.

Double-Blind Study

This was a **double-blind study** meaning,

- Participants did not know which treatment they received
- Most study staff did not know either

XTMAB-16 was given by intravenous infusion for a total of 12 weeks.

5. WHAT TESTS WERE DONE DURING PART A?

Participants had:

- Lung function tests (including forced vital capacity or FVC)
- Blood tests
- Physical exams
- Questionnaires about symptoms and daily activities
- High-resolution chest imaging
- Screening for infections, including tuberculosis

Participants were screened for tuberculosis before starting treatment because anti-TNF medicines can reactivate inactive (latent) tuberculosis. Because anti-TNF medicines affect part of the immune system, participants were closely monitored for infections throughout the study.

6. WHAT WERE THE RESULTS OF PART A?

Safety Results

Researchers closely monitored **adverse events**, which are unfavorable medical experiences that may or may not be related to the study medication.

In this study, 21 of 28 participants (75%) receiving XTMAB-16 reported adverse events. 11 of 11 participants (100%) receiving placebo also reported adverse events.

The most common adverse events in participants receiving XTMAB-16 were:

- **Increased muscle enzyme levels** (seen in blood tests)
- **Joint pain**
- Headache
- **Upper respiratory infections** (such as colds)

Most adverse events were **mild or moderate**. They were generally similar across all 4 cohorts, with no clear pattern of more adverse events at higher doses or with more frequent dosing.

Because this was a dose-ranging study, safety was evaluated separately in each cohort to see whether adverse events differed by:

- Dose level
- Dosing frequency

Serious Adverse Events

An adverse event is considered serious if it results in outcomes such as hospitalization, life-threatening conditions or lasting health problems.

Anti-TNF medicines can increase the risk of serious infections because they reduce part of the immune response.

One participant in the 2mg/kg every 4 weeks (Q4W) group experienced two serious adverse events: a post-surgical wound infection and narrowing of an artery. These events were ***not considered related*** to the study drug because they occurred after surgery or were consistent with known underlying health conditions, and there was no clear evidence linking them to the study medicine.

There were no serious adverse events related to the study treatment, no deaths, and no treatment discontinuations or dose changes due to side effects.

Overall, XTMAB-16 was generally safe and well tolerated at all doses studied. The safety findings from Part A were:

- Consistent with what is known about anti-TNF medicines, such as reactions at or around the time the medicine was given[1]
- Mild to moderate and generally consistent across all dose groups

[1] Gerriets et al., 2023; StatPearls

Did XTMAB-16 improve lung function?

Lung function was measured using **forced vital capacity (FVC)**, a test that doctors use to determine lung capacity.

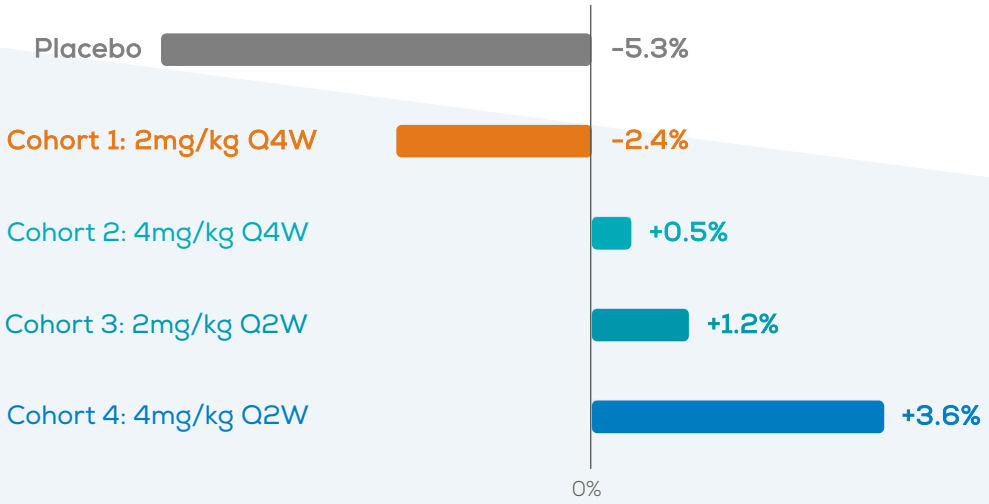
Researchers compared results across the 4 cohorts to explore:

- Whether higher doses led to greater improvement
- Whether more frequent dosing made a difference

After 12 weeks, changes in lung function differed across treatment groups, with some groups showing small increases and others showing decreases in FVC. These changes varied in size, and their **clinical importance** (how much they affect how patients feel or breathe) is still being evaluated.

FVC Change After 12 Weeks

+ Increase = better lung function **- Decrease = worse lung function**



Because Part A included a limited number of participants (39 people) and was designed to explore dosing, the results are considered **preliminary**. More research is needed to confirm the long-term safety and efficacy of XTMAB-16.

Other Findings

Researchers also looked at:

- Cough and breathlessness
- Quality of life measures through Patient-Reported Outcomes
- Inflammatory markers in blood
- Changes in chest imaging

At Week 12, participants receiving XTMAB-16 showed improvements in cough, quality of life and blood markers of inflammation compared to the placebo group. Chest imaging was also stable and improved in most XTMAB-16 treated patients, while all placebo participants showed no change or worsening chest imaging.

7. WHAT ARE THE POSSIBLE RISKS OF XTMAB-16?

Because XTMAB-16 blocks TNF, it lowers part of the immune system.

Possible risks include:

- **Increased risk of infections**
- **Reactivation of tuberculosis**
- **Fungal infections**
- **Rarely, certain cancers** (based on long-term data from other anti-TNF medicines)[1]

Participants were carefully monitored to reduce these risks.

Safety, including long-term safety in pulmonary sarcoidosis is still being studied.

8. WHAT ARE THE LIMITATIONS OF THIS STUDY?

- This was an early-phase study and was not designed to give final answers about how well the medicine works.
- The number of participants was relatively small (39 people).
- The study lasted for a limited time with participants receiving the study medicine for only 12 weeks.
- The study was designed to explore dosing, not to provide final proof of effectiveness.

Longer studies and U.S. Food and Drug Administration (FDA) review and approval are needed to understand long-term safety and effectiveness.

9. WHAT HAPPENS NEXT?

Part B of this study is slated to begin in 2026. The results from Part A helped researchers decide:

- Which dose to study further
  - The chosen dose was 4mg/kg
- How often the medicine should be given
  - The medicine will be given every 4 weeks
- Whether a larger study should be conducted to understand long-term safety and efficacy
  - The safety and efficacy will be evaluated in a future trial

XTMAB-16 is still being studied and is **not approved for pulmonary sarcoidosis.** The safety and effectiveness have not been confirmed. The medicine is still being studied and has not been approved by the FDA.

[1] Gerriets et al., 2023; StatPearls

10. WHERE CAN I LEARN MORE?

ClinicalTrials.gov: NCT05890729

EU Clinical Trials Register: NCT06169397

Contact: info@xentria.com

If you took part in this study and have questions, please contact your study doctor.

What Does This Mean for Patients? This early study suggests that inhibiting TNF may help reduce lung inflammation or prevent inflammation from worsening in some people with pulmonary sarcoidosis. However, more research is needed to confirm how well it works and how safe it is over longer periods of time. The medicine must also be reviewed and approved by the U.S. FDA.

Glossary

Adverse Events: Unfavorable medical experiences that may or may not be related to the study medication.

Anti-TNF medicine: A drug that blocks TNF to reduce inflammation.

Clinical Importance: How meaningful a change is for patients, such as how they feel or breathe

Cohort: A treatment group.

Dosing Schedule: How often the study medicine is given.

FVC (Forced Vital Capacity): A breathing test that measures how much air you can forcefully breathe out.

Granuloma: A small clump of immune cells caused by inflammation.

Placebo: A treatment that looks like the study medicine but has no active medicine.

TNF (Tumor Necrosis Factor): A signaling protein in the body that helps cause inflammation.