

Pharmacokinetics, pharmacodynamics, and safety profile of ulviprubart:

Results from a 48-week, open-label, phase 1 study in patients with inclusion body myositis

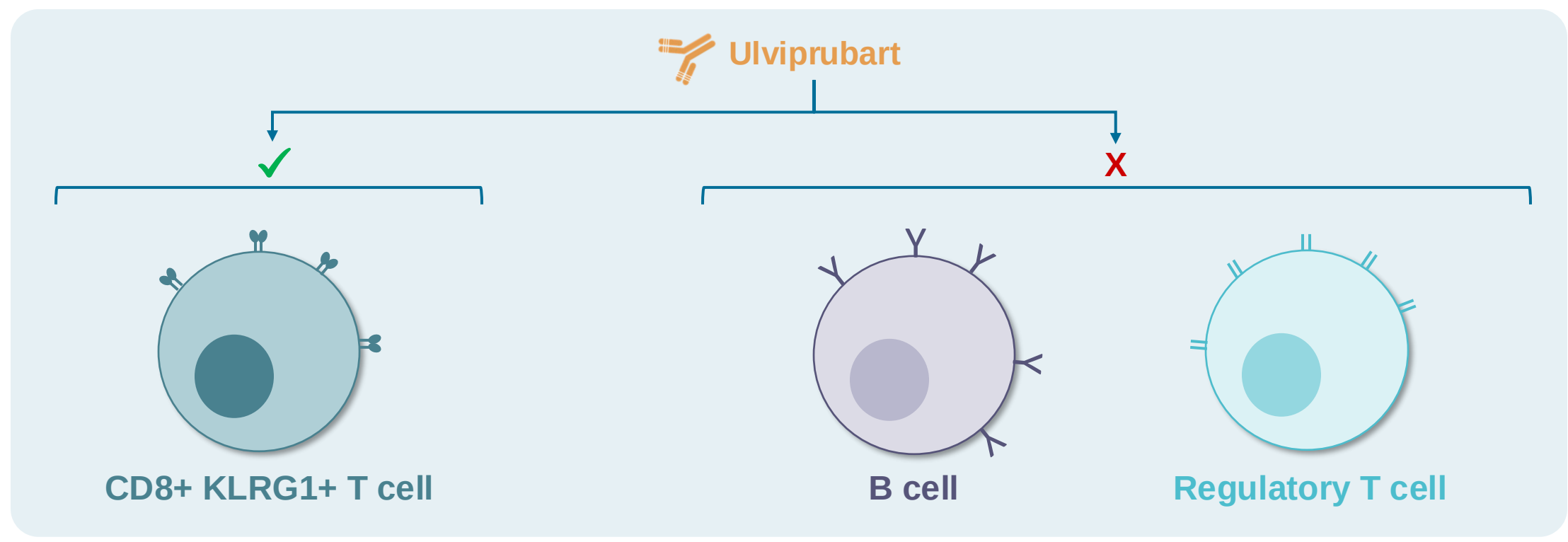
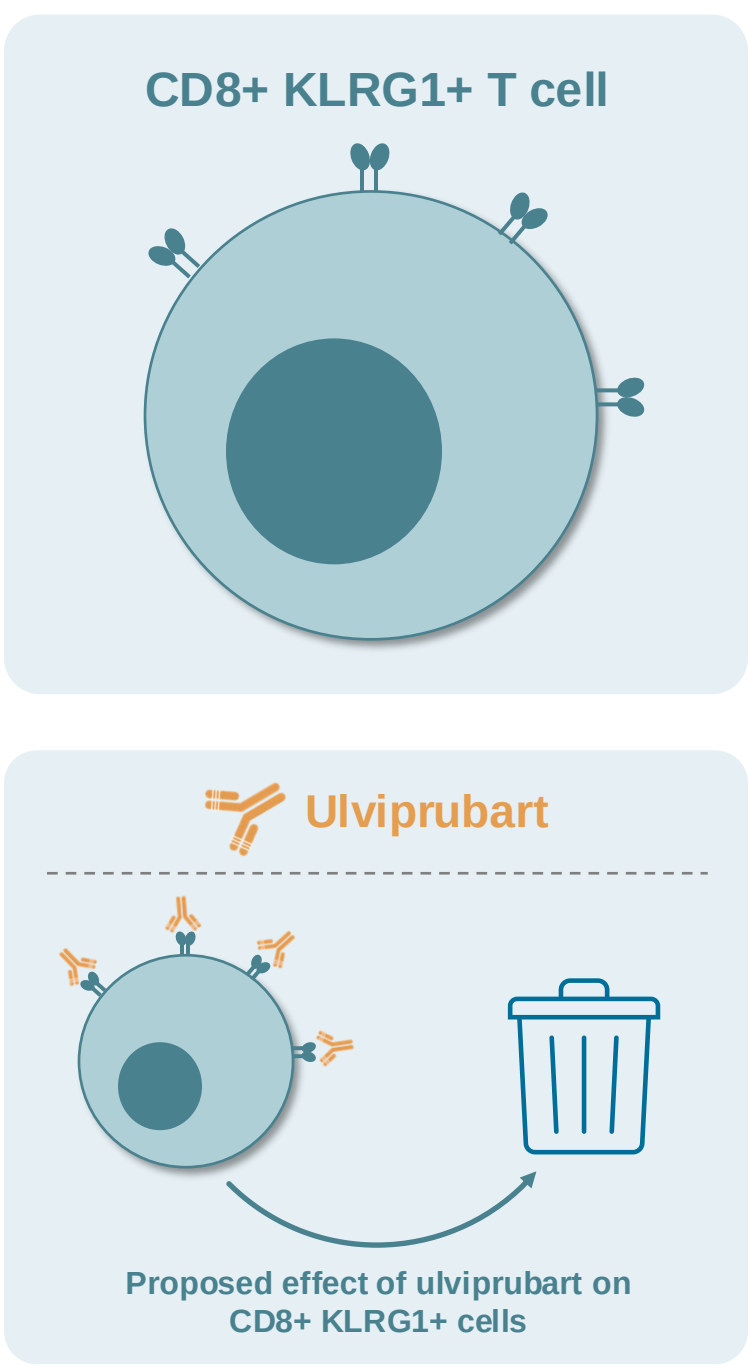
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PLAIN LANGUAGE SUMMARY

Background and objectives

- In **inclusion body myositis (“IBM”)**, the loss of muscle and weakness that worsens over time is thought to happen because a subset of the body’s immune cells incorrectly attack and destroy the muscles in the body^{1,2}
- This subset of cells belongs to the group of immune cells called “T cells,” and most of these T cells that are attacking the body’s muscles are marked with proteins called CD8 and KLRG1^{3,4}
 - Such a cell is referred to in shorthand as a **“CD8+ KLRG1+”** T cell
- A new potential medication called **ulviprubart** has been developed that is designed to recognize cells that are marked with KLRG1 and clear them from the body
 - Ulviprubart is a medication that is administered subcutaneously, meaning it is injected underneath the skin
- The researchers of this study hypothesized that if ulviprubart can clear the T cells marked with KLRG1 out from the body, perhaps the attack on the muscles that occurs in IBM can be slowed down
- One of the key goals of this study was to see how ulviprubart affected the muscle-attacking CD8+ KLRG1+ T cells in patients with IBM
- Because the immune system is also important for protecting the body from infections, the researchers wanted to make sure that ulviprubart affected only the cells of interest without disrupting other types of immune cells that are important to fight infections (such as B cells) or cells that keep the immune system in balance (such as regulatory T cells, also known as “T regs”)⁵



Who was included in this analysis?

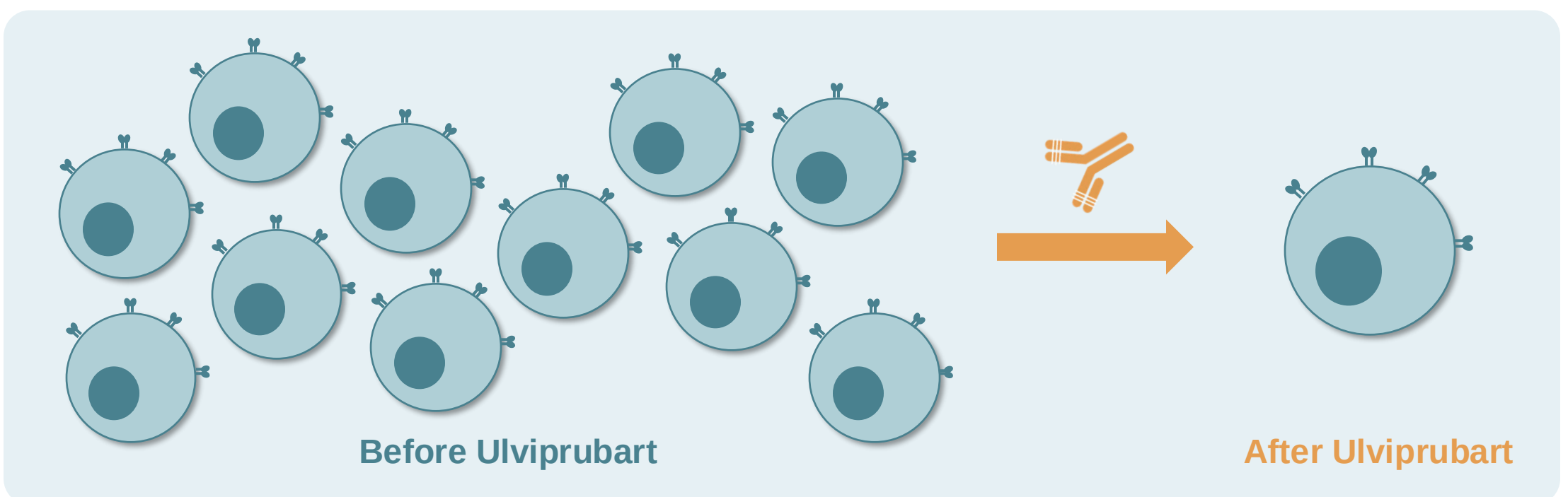
- Nineteen patients participated in this study and received ulviprubart
- 79% male

Average age

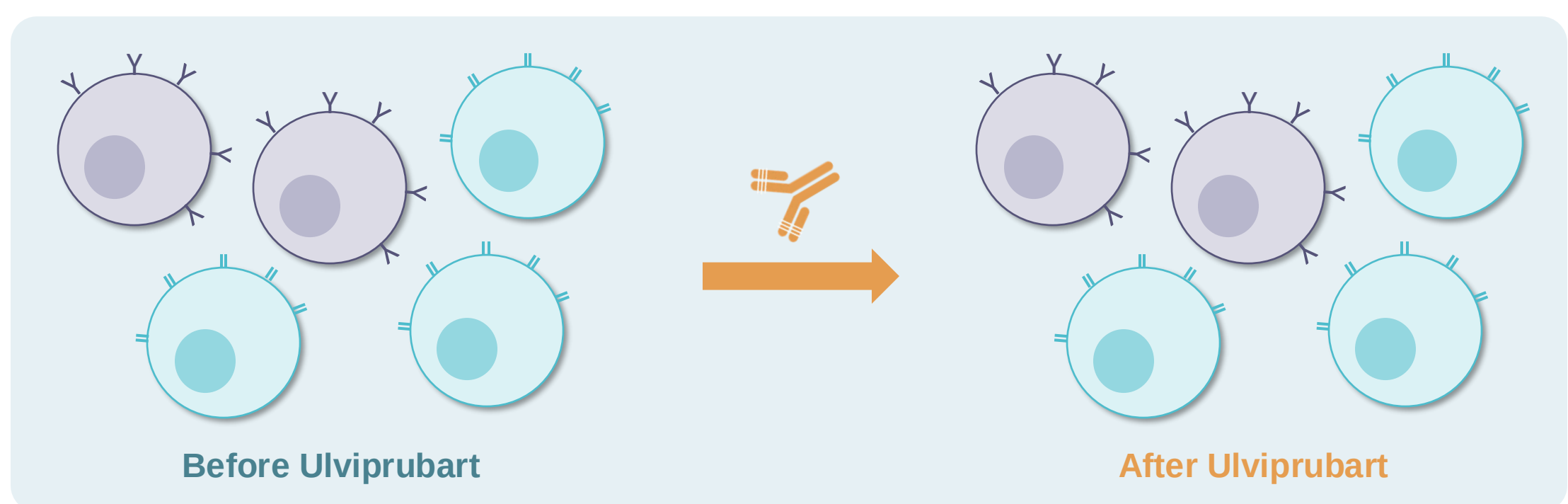
66 years

What were the results?

When patients in the study were treated with ulviprubart, most CD8+ KLRG1+ T cells were eliminated, and this effect was consistent for up to 48 weeks



- Importantly, the levels of other immune cells, like B cells and T regs, stayed fairly constant throughout the study



- No patients stopped the study because of safety issues
- The most common side effect that was related to ulviprubart treatment was injection-related reaction; about one-third of patients (6 of 19) had this side effect

What did the researchers conclude?

- In this study of ulviprubart in patients with IBM, CD8+ KLRG1+ T cells were depleted after dosing, but other key immune cells were relatively undisturbed
- Ulviprubart also had good tolerability
- These results help support the continued development of ulviprubart, and researchers plan to study this medication further as a potential treatment option for patients with this disorder

References

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