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SUMMARY OF RESEARCH

Summary of Research: An Anti-OX40 Antibody to Treat Moderate-to-Severe Atopic Dermatitis: A Multicentre, Double-Blind, Placebo-Controlled Phase 2b Study

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ABSTRACT

This is a summary of the original article "An Anti-OX40 Antibody to Treat Moderate-to-Severe Atopic Dermatitis: a Multicentre, Double-blind, Placebo-Controlled Phase 2b Study". Atopic dermatitis (AD) is an inflammatory skin disease caused by a complex interplay of genetic factors, alterations to the skin microenvironment, and immune dysregulation, including T cells that have become uncontrolled. Rocatinlimab is an investigational agent that blocks OX40, a receptor on activated T cells that has an important role in inflammatory conditions such as AD. This summary of research provides an overview of a previously published article on the results of a phase 2b study of patients with moderate-to-severe AD who were treated with different doses of rocatinlimab or placebo and followed for up to 56 weeks. Rocatinlimab significantly improved the symptoms of AD and was well tolerated. The most common adverse events were fever, nasopharyngitis, and chills. This study supports rocatinlimab as a potentially safe and effective treatment for moderate-to-severe AD.

INTRODUCTION

This is a summary of the original article "An Anti-OX40 Antibody to Treat Moderate-to-Severe Atopic Dermatitis: a Multicentre, Double-Blind, Placebo-Controlled Phase 2b Study" [1] (Fig. 1).

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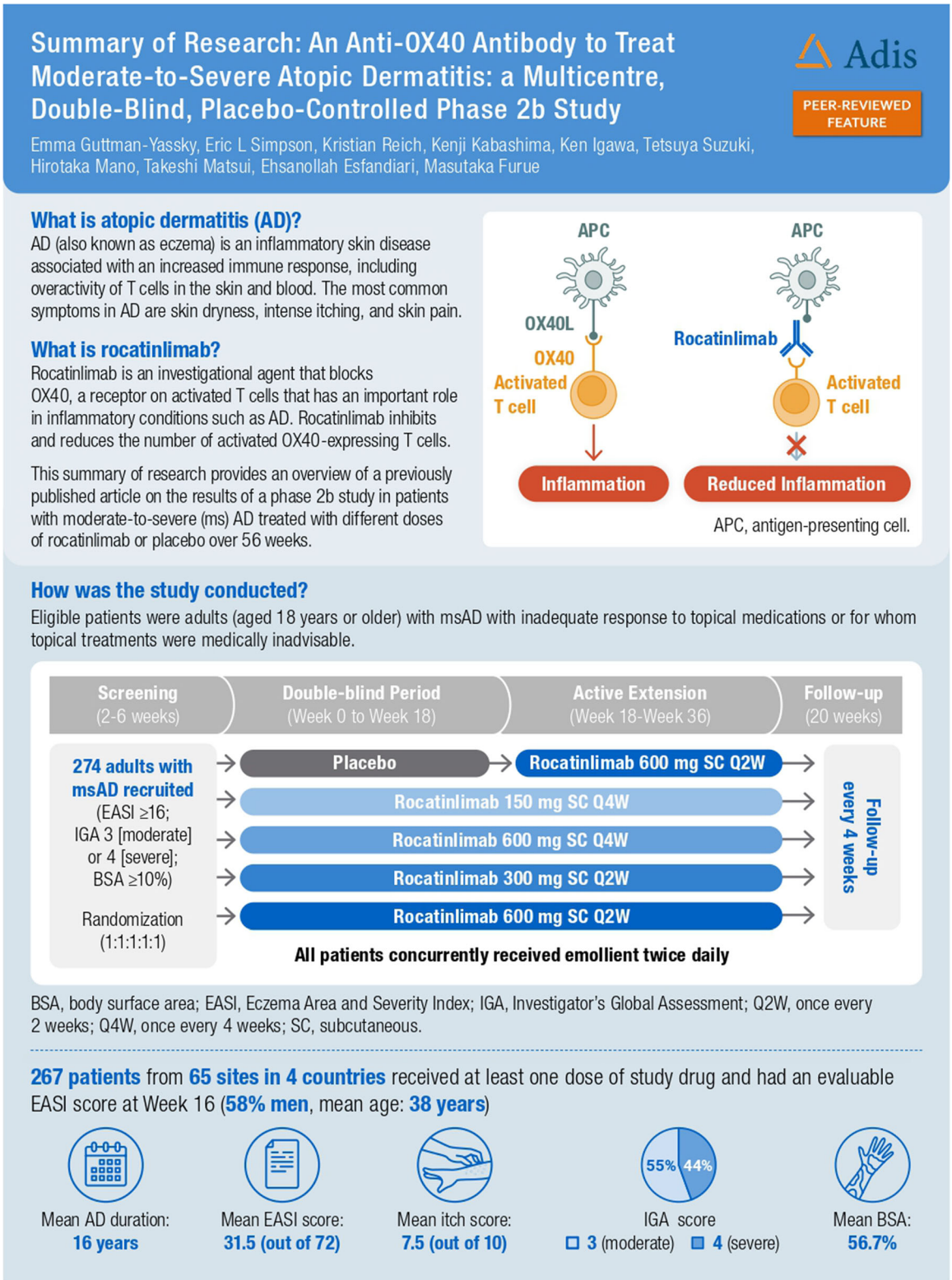
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PEER-REVIEWED FEATURE
Emma Guttman-Yassky, Eric L Simpson, Kristian Reich, Kenji Kabashima, Ken Igawa, Tetsuya Suzuki, Hirotaka Mano, Takeshi Matsui, Ehsanollah Esfandiari, Masutaka Furue
What is atopic dermatitis (AD)?
AD (also known as eczema) is an inflammatory skin disease associated with an increased immune response, including overactivity of T cells in the skin and blood. The most common symptoms in AD are skin dryness, intense itching, and skin pain.
What is rocatinlimab?
Rocatinlimab is an investigational agent that blocks OX40, a receptor on activated T cells that has an important role in inflammatory conditions such as AD. Rocatinlimab inhibits and reduces the number of activated OX40-expressing T cells.
This summary of research provides an overview of a previously published article on the results of a phase 2b study in patients with moderate-to-severe (ms) AD treated with different doses of rocatinlimab or placebo over 56 weeks.
APC
OX40L
OX40
Activated T cell
Inflammation
APC
Rocatinlimab
Activated T cell
Reduced Inflammation
APC, antigen-presenting cell.
How was the study conducted?
Eligible patients were adults (aged 18 years or older) with msAD with inadequate response to topical medications or for whom topical treatments were medically inadvisable.
Screening (2-6 weeks)
Double-blind Period (Week 0 to Week 18)
Active Extension (Week 18-Week 36)
Follow-up (20 weeks)
274 adults with msAD recruited (EASI ≥16; IGA 3 [moderate] or 4 [severe]; BSA ≥10%)
Randomization (1:1:1:1:1)
Placebo
Rocatinlimab 600 mg SC Q2W
Rocatinlimab 150 mg SC Q4W
Rocatinlimab 600 mg SC Q4W
Rocatinlimab 300 mg SC Q2W
Rocatinlimab 600 mg SC Q2W
Follow-up every 4 weeks
All patients concurrently received emollient twice daily
BSA, body surface area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; Q2W, once every 2 weeks; Q4W, once every 4 weeks; SC, subcutaneous.
267 patients from 65 sites in 4 countries received at least one dose of study drug and had an evaluable EASI score at Week 16 (58% men, mean age: 38 years)
Mean AD duration: 16 years
Mean EASI score: 31.5 (out of 72)
Mean itch score: 7.5 (out of 10)
55%
44%
IGA score
3 (moderate)
4 (severe)
Mean BSA: 56.7%

Fig. 1

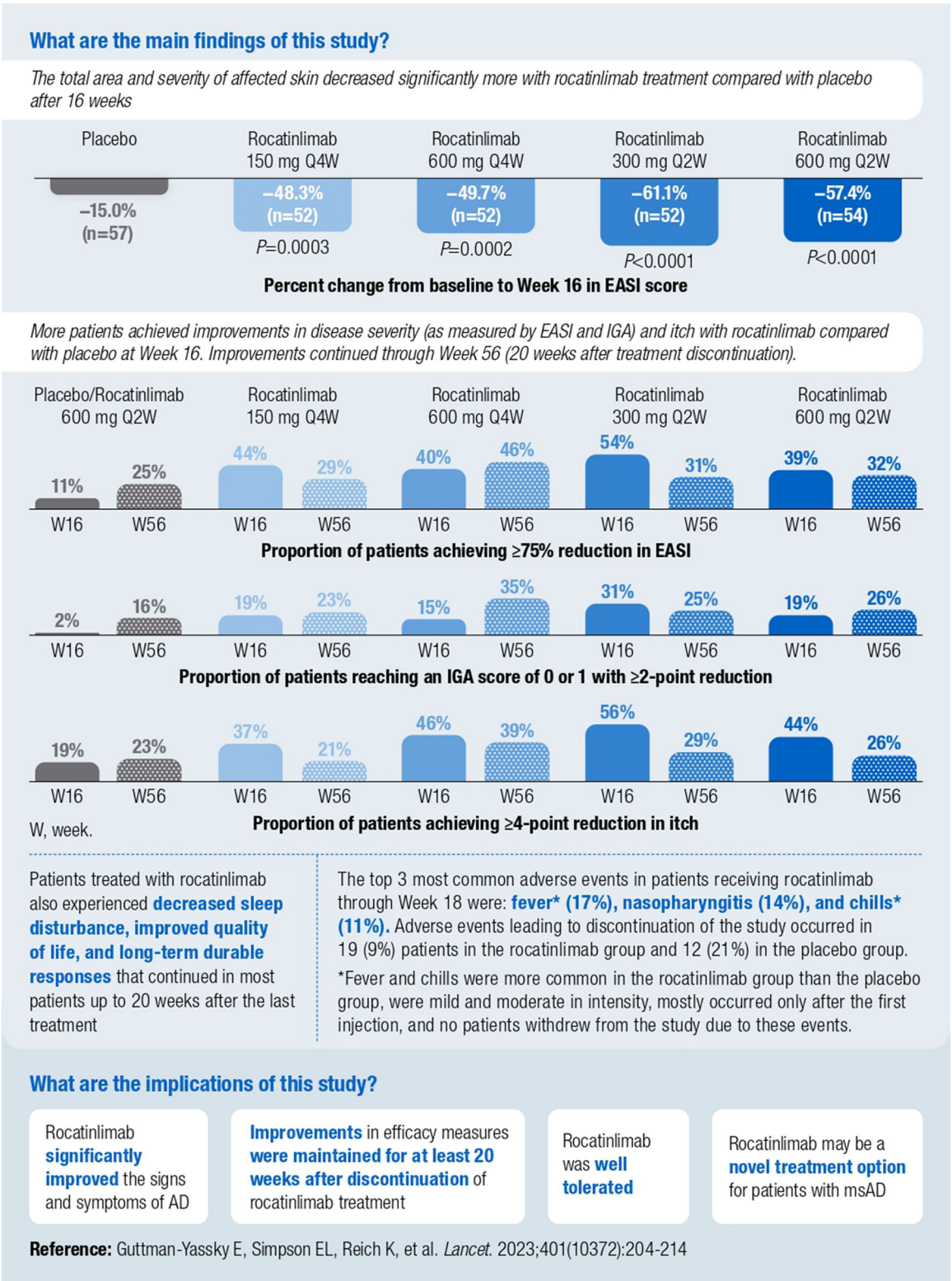

Fig. 1 continued

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Data Availability. Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices), and the study protocol, reporting and analysis plan, dataset specifications, and clinical study report will be available to investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. Data will be available online beginning 3 months and ending 20 years after article publication, marketing approval received in North America, Europe, and Japan, and completion of worldwide development programs.

Declarations

Conflict of Interest. Please see original article for full author disclosures.

Ethical Approval. The study protocol was approved by the Institutional Review Board or Independent Ethics Committee and regulatory health authorities in accordance with local regulations before study commencement. The principal investigator and sub-investigators were responsible for conducting the study in full accordance with the Declaration of Helsinki and the Good Clinical Practice Guidelines. All patients provided written informed consent before participating.

REFERENCE

1. Guttman-Yassky E, Simpson EL, Reich K, Kabashima K, Igawa K, Suzuki T, Mano H, Matsui T, Esfandiari E, Furue M. An anti-OX40 antibody to treat moderate-to-severe atopic dermatitis: a multicentre, double-blind, placebo-controlled phase 2b study. Lancet. 2023;401(10372):204–14. https://doi.org/10.1016/S0140-6736(22)02037-2.