A Phase 2a, Randomized, Double-Blinded, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Rezpegaldesleukin in Adults with Severe to Very-Severe Alopecia Areata (Rezova AA)

David Rosmarin, Neil Sadick, Timothy G. Rodgers, Edward Lain, Lawrence Osman, Stephen Schleicher, Adam Reich, Jacke C Szepietowski, Agnieszka Owczarczyk-Saczonek, Wojciech Ban, Bartlomiej Kwiec, Michal Torz, Jacke Zdyla, Sohail Chaundhry, Zachary Lee, Heng Xu, Li Yu, Brian Lewis, Kate Mellskog, Lucinda M. Elko-Simms, Christine Fanny, Mary Tagliaferi, Jonathan Zalevsky, Charles W. Lynde

Treadwell University School of Medicine, Indianapolis, IN, United States; Department of Dermatology, Woll Cornell Medicine, New York, NY, United States; Sadick Research Group, New York, NY, United States; North Texas Center for Clinical Research, Frisco, TX, United States; Department of Dermatology, New York University, New York, NY, United States; Department of Dermatology, Institute of Medical Sciences, Medical College of Rzeszow University, Rzeszow, Poland; Department of Dermatology, Sexually Transmitted Diseases and Clinical Immunology, University of Wroclaw and Maszow, Ostbym, Poland; Klinika Ambulatoria Dermatologiczna, Lasnicy University, Warsaw, Poland; Dermacium Centrum Badak Krzewno, Wroclaw, Poland; Dermacium Jack Zdylski, Ostrowieckie Szpitali, Poland; Rezova Therapeutics, San Francisco, CA, United States; Division of Dermatology, Department of Medicine, University of Toronto, Toronto, ON, Canada; Lynde Institute for Dermatology, Monash, OR, Canada.

ABSTRACT

Patient, % (NRI)

JAK inhibitors (like baricitinib, ritlecitinib) carry multiple black boxed warnings in North America (Canada, United States)

Corresponding author David Rosmarin: drosmar@iu.edu

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Figure 1: Rezpegaldesleukin (REZPEG): Novel Treatment Approach for Auto-immune Disorders

Why We Need Additional Therapies for Severe Alopecia Areata

• Majority of patients do not achieve adequate disease control with the current standard of care therapies (baricitinib and adalimumab)

• Current available cytokine therapies may be limited by their safety profile

• JAK-inhibitior (baricitinib, ritlecitinib) carry multiple black boxed warnings

• REZPEG is a novel potential therapy for severe AA

Figure 2: Phase 1b Study of REZPEG in Alopecias Dermatitis (AD) Sustained Benefit Observed After 12-Weeks of Therapy

REZPEG preferentially stimulates expansion of regulatory T cells with minimal effects on T-effectors

Figure 3: Central Role of T Regulatory Cells in Immune Homeostasis

Study Design

Figure 4: Phase 2b Study for Patients with Severe Alopecia Areata

REZPEG may be an additional treatment option for inflammatory hair loss such as alopecia areata

Secondary Endpoints

• Proportion of patients achieving improvement in Severity of Alopecia Tool (SALT) score at Week 36

• Safety and tolerability

STUDY DESIGN

• This is a Phase 2b, randomized, double-blind, placebo-controlled, international multicentre study of REZPEG in patients with moderate-to-severe alopecia areata

• Patients will be randomly assigned to A 2:2:2 ratio of 2 different REZPEG dosing regimens vs. placebo, administered subcutaneously, during the 24-week treatment period

• All patients will be followed for 24-weeks, following the treatment period.

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ABSTRACTS

The study included a total of 74 patients across 25 sites in 11 countries. REZPEG was administered subcutaneously 2 mg/kg (12 μg/kg) in a 2:2:2 ratio of 2 different dosing regimens vs. placebo, administered subcutaneously, during the 24-week treatment period.

REFERENCES


