HAIR DISORDERS

RESULTS FROM THE ALOPECIA AREATA SYMPTOM IMPACT SCALE AND CORRELATION WITH THE SEVERITY OF ALOPECIA TOOL AT 24 WEEKS IN A PHASE 2A STUDY OF TWO ORAL JANUS KINASE INHIBITORS IN ALOPECIA AREATA

R Winnette [1] - A Banerjee [2] - L Chen [3] - V Sikirica [4] - J Xenakis [4] - E Peeva [5]

Pfizer, Patient Centered Outcomes Assessments, Patient & Health Impact, New York, United States [1] - Pfizer, Department Of Statistics, Early Clinical Development, Cambridge, United States [2] - Health Economics And Outcomes Research, Consultant, New York, United States [3] - Pfizer, Health Economics And Outcomes Research, Patient & Health Impact, Inflammation And Immunology, New York, United States [4] - Pfizer, Inflammation And Immunology, Cambridge, United States [5]

Introduction: A study reported efficacy and safety of PF-06651600 (oral JAK3 inhibitor) and PF-06700841 (oral TYK2/JAK1 inhibitor) in patients with moderate-severe alopecia areata (AA). To understand patients' treatment experience, measuring patient priority concepts via patient-reported outcomes (PRO) tools is important. We report results with the Alopecia Areata Symptom Impact Scale (AASIS), a PRO measure of symptoms, interference with daily life, and impact on health-related quality-of-life.

Objective: To report results from the AASIS and its correlation with the Severity of Alopecia Tool (SALT) in a clinical trial of patients with AA.

Materials & Methods: In this randomized, double-blind, multicenter study (NCT02974868), patients aged 18–75 with chronic, moderate-severe AA were randomized 1:1:1 to PF-06651600 (200mg daily x4wks, then 50mg daily x20wks), or PF-06700841 (60mg daily x4wks, then 30mg daily x4wks), or placebo. Patients completed the AASIS and investigators assessed the primary efficacy measure (SALT), throughout the study, including baseline and Wk24 (primary efficacy timepoint).

Results: The study enrolled 142 patients: PF-06651600, n=48; PF-06700841, n=47; placebo, n=47. By Wk24, both treatments demonstrated significant placebo-adjusted mean change from baseline in SALT score and least-squares mean difference (90% CI) from placebo in AASIS: Total score (PF-06651600: −14.3[−21.4, −7.3], P<0.001; PF-06700841: −20.2[−27.4, −13.0], P<0.001), Disease severity sub-score: (PF-06651600: −9.2[−13.3,

–5.1], P<0.001; PF-06700841: –12.0[–16.2, –7.8], P<0.001), Disease impact sub-score: (PF-06651600: –5.1[–9.3, –0.9], P=0.024; PF-06700841: –7.7[–12.0, –3.5], P=0.002). At Wk24, most AASIS items had moderate correlation with SALT (e.g., R2 scalp hair loss: 0.57; interaction with others: 0.45; feeling anxious/worry: 0.39), while several symptom items were low (e.g., R2 itch/pain: 0.1).

Conclusions: Both oral JAK inhibitors differentiated from placebo with respect to AASIS by Wk24. The SALT is an accepted clinician reported outcome efficacy measure; however, correlation between AASIS items and SALT suggest that additional research is needed to understand how these patient-reported concepts relate to hair loss/growth.