Peak Pruritus Numerical Rating Scale Response With Abrocitinib in Patients With Moderate-to-Severe Atopic Dermatitis: Results From a Randomized, Phase 3 Clinical Trial

EL Simpson[1], S Ständer[2], G Yosipovitch[3], B Kim[4], M Cameron[5], M DiBonaventura[5], D Williams[6], S Tatulych[7], C Nduaka[8], H Valdez[5]

[1]Oregon Health & Science University, Portland, OR, USA

[2]Center for Chronic Pruritus, University of Münster, Münster, Germany

[3]Miami Itch Center, Miller School of Medicine, University of Miami, Miami, FL, USA

[4]Center for the Study of Itch and Sensory Disorders, Washington University School of Medicine, St. Louis, MO, USA

[5]Pfizer Inc., New York, NY, USA

[6]Syneos Health, Indianapolis, IN, USA

[7]Pfizer Inc., Groton, CT, USA

[8]Pfizer Inc., Collegeville, PA, USA

Background: Pruritus imparts a significant burden to patients suffering with atopic dermatitis (AD). Abrocitinib is an oral Janus kinase 1 (JAK1) selective inhibitor under investigation for the treatment of AD. JAK1 inhibitors may have unique itch-mitigating effects in the setting of AD. This randomized, placebo-controlled phase 3 trial explored the efficacy and safety of abrocitinib in patients with moderate-to-severe AD (JADE MONO-1; NCT03349060).

Objective: To assess Peak Pruritus Numerical Rating Scale (PP-NRS; used with permission of Regeneron Pharmaceuticals, Inc. and Sanofi) responder rates, times to PP-NRS response, and percent change from baseline in PP-NRS overall and by baseline PP-NRS with abrocitinib versus placebo.

Methods: Patients ≥12 years with clinical diagnosis of moderate-to-severe AD and Peak Pruritus Numerical Rating Scale (PP-NRS) ≥4 at baseline were randomly assigned (2:2:1) to once-daily abrocitinib 200 mg, abrocitinib 100 mg, or placebo for 12 weeks. PP-NRS was assessed daily through day 15 and weekly thereafter. Proportions of patients and times to achieving PP-NRS2 or PP-NRS4 response (≥2 point or ≥4-point improvement, respectively) were analyzed, as well as percentage of change from baseline in PP-NRS.

Results: 156, 154, and 77 patients received abrocitinib 100 mg, abrocitinib 200 mg, or placebo, respectively. At week 12, significantly greater proportions achieved weekly average PP-NRS2 or PP-NRS4 response with abrocitinib 200 mg (87% and 57.2%) or 100 mg (66% and 37.7%) versus placebo (20% and 15.3%; $P<0.05$ for all). Times to PP-NRS2 response were significantly shorter for abrocitinib 200 mg (median days, 4.0 [95% CI, 3.0-5.0]) or 100 mg (7.0 [6.0-9.0]) versus placebo (19.0 [8.0-57.0]; $P=0.025$ and $P<0.001$, respectively). Percent reductions in PP-NRS were significantly greater for abrocitinib (both

doses) versus placebo from day 2 through week 12 ($P<0.05$ for all); these effects were generally observed regardless of baseline PP-NRS.

Conclusion: Abrocitinib rapidly (within 1 day) and significantly improved pruritus versus placebo regardless of baseline PP-NRS.

Previously submitted to American Academy of Dermatology 2020 Annual Meeting; March 20-24, 2020; Denver, Colorado.

Supported by Pfizer Inc.