The Use of Digital Health Technology to Measure Nocturnal Scratch and Sleep in Atopic Dermatitis: Response to Abrocitinib

Yao Zhang[1], Junrui Di[1], Yiorgos Christakis[2], Nikhil Mahadevan[3], Jonathan Bruno[2], and Carrie A. Northcott[2]

[1] Biostatistics, Early Clinical Development (ECD), Pfizer, Cambridge, MA;
[2] Digital Medicine and Translational Imaging (DMTI), ECD, Pfizer, Cambridge, MA;
[3] University of Texas at Austin.

Atopic Dermatits (AD) is often accompanied by nocturnal scratching and disrupted sleep. Scratching can lead to lesion formation, infection, and worsening sleep disruptions, thereby perpetuating the AD and reducing the patient's quality of life (QoL). Quantitatively measuring nocturnal scratch and sleep is challenging. Currently, studies utilize patient reported outcomes (PROs) to evaluate the patient's perceptions of the feeling of itch and the patients' impression of their sleep. While it is valuable to understand the patient's perspective of these symptoms, these do not objectively or quantitively measure the actions occurring. Objective and quantitative measurements of sleep quantity and nocturnal scratching can assess the efficacy of an intervention on important aspects of AD in a home environment over time. Using wrist-worn accelerometers as the chosen digital health technology (DHT), measures of nocturnal scratch and sleep were added as exploratory and optional endpoints to a Phase 3 randomized, double-blind, double-dummy, placebo-controlled, parallel-group, multicenter study to assess efficacy and safety of Abrocitinib (PF-04965842; 100 or 200 mg OD) and dupilumab (per label) in adults on background topical therapy, with moderate to severe AD (NCT03720470). In selected countries, the amount and duration of nocturnal scratching and the sleep duration and arousals from the total sleep opportunity (TSO) were assessed using accelerometry. Subjects wore watch-like accelerometry devices on each wrist to continuously monitor nocturnal scratching and sleep quantity for up to 1 week prior to the Day 1 visit and 2 weeks following the Day 1 visit (through Day 14). Due to the limited number of participants (N=11 evaluable in endpoint analyses), descriptive analyses were performed. Change from baseline (defined as the average of available measures during Day -3 to Day -1) were calculated for all post-dose measurements. As anticipated, during the two-week treatment and measurement period, placebo resulted in variable responses with regard to sleep and nocturnal scratch; whereas treatment with abrocitinib (PF04955842) generally showed an increase in sleep efficiency and decrease in scratch duration and events, even with the limited number of participants. Additional clinical studies will allow for further clinical validation to extend our knowledge about the characteristics of the proposed digital endpoints such as minimally clinically importance difference (MCID). Wrist worn accelerometers and associated digital endpoints could provide quantitative knowledge regarding pharmacotherapies on the action of scratching and sleep quantity in a symptomatic AD population. In addition, these novel digital endpoints will enhance our understanding of AD, and provide future opportunities to refine and improve therapies for other conditions.