Background: Fibromyalgia is a chronic disease characterized by widespread pain and fatigue that may be triggered by reactivation of latent herpes simplex virus type 1 (HSV-1). In a Phase 2a proof of concept trial, IMC-1 (a fixed dose combination of famciclovir and celecoxib) demonstrated greater tolerability and statistically significant reduction in pain compared with placebo, as measured by change from baseline to week 16 in 24-hour recall pain intensity on an 11-point Numerical Rating Scale (NRS) and 7-day recall pain intensity on the 11-point pain item on the Revised Fibromyalgia Impact Questionnaire (FIQ-R).

Objectives: In this post hoc analysis, we evaluated the effects of IMC-1 compared with placebo on other fibromyalgia symptoms, including lack of energy, stiffness, problems with sleep, problems with memory, depression, and anxiety.

Methods: In the double-blind, multi-center, placebo-controlled trial, male or female patients 18–70 years of age who met diagnostic criteria for fibromyalgia and had a 24-hour recall average pain intensity score between 4 and 9 on the McGill pain questionnaire (MPQ-SF), pain visual analogue scale (VAS) and Revised Fibromyalgia Impact Questionnaire (FIQQR). Subjective experience questionnaires collected acceptability data with 7-point Likert scale rating questions (strongly disagree to strongly agree). The simulation sickness questionnaire (SSQ) gained side-effect data (total severity score: 0-236). Categorical data were described using frequencies; and continuous data using mean and standard deviation. Likert-scale data were dichotomised (rating ≤3: disagree, rating ≥5: agree).

Four VR systems representing the spectrum of commercially available technologies were used (seen in Figure 1). These possess different characteristics including screen resolution, processor speed, weight, strap and controller type. The VR experience used with each headset was co-developed alongside industry partners (Orbital Global). Participants are immersed within a naturalistic environment, situated on a wooden boat travelling slowly along a calm river surrounded by trees and hills. The interactive element involves the user shooting targets that appear using handheld controllers.

Results: 13 patients with FMS were included (mean age 41.8±15.6, 92.3% female). Most had severe disease (mean MPQ 25.5±8.8, VAS 6.0±1.7). Most had no previous VR exposure (69.2%). 100% of patients agreed that they would be open to using VR for future pain management (mean 6.5±0.7) and that they would use VR regularly at home (mean 6.5±0.7). VR HMD comfort and enjoyment data are presented in Table 1. Mean ratings of comfort were high across the four HMDs (Gear VR: 4.9±1.7, Oculus Go: 5.4±1.8, Oculus Quest 5.3±1.9, Oculus Rift S: 6.6±0.5). Mean ratings of enjoyment with each HMD were also high (Gear VR: 5.4±1.6, Oculus Go: 5.4±1.8, Oculus Quest 5.6±1.9, Oculus Rift S: 6.6±0.5). Low levels of side effects were described with mean SSQ total scores ranging from 20.1±16.8 (Oculus Rift S) to 36.0±23.9 (Gear VR).

Conclusion: Preliminary results indicate that FMS patients find VR acceptable, describing high ratings of comfort and enjoyment across the VR HMD spectrum. Side-effect frequency was low, with most settling after HMD removal. All participants were open to future use of VR for home-based pain management.

REFERENCES: