

NCC 'FUTURE GENERATION 2024' POSTER Abstracts
SCIENTIFIC SESSION IN COOPERATION WITH THE BCLA

NCC 'Future generation 2024'

Organization Section: NCC/ BCLA

POSTER Abstracts

Sunday, March 10 2024

Netherlands, Veldhoven,

NH De Koningshof, Baroniezaal

Safety and Effectiveness of Hydroxypropyl Guar-Hyaluronic Acid Dual Polymer Lubricating Eye Drops in Indian Subjects with Dry Eye: A Phase IV Study

Deborah Awisi-Gyau, Neha Kapur, Rajesh Parekh, Umesh Yeddula, Shreesha Kumar Kodavoor

Purpose: Hydroxypropyl guar-hyaluronic acid (HPG-HA) dual polymer lubricating eye drops are indicated for temporary relief from burning and irritation associated with dry eye disease (DED). We aimed to evaluate the safety and efficacy of HPG-HA lubricating eye drops in Indian subjects with DED.

Method: A prospective, open-label, single-arm, post-marketing Phase IV study was conducted in India from June 2022 to March 2023. Subjects aged 18-65 years with tear break-up time ≤ 10 seconds in both eyes; best-corrected visual acuity of $\geq 20/40$ in each eye; dry eye questionnaire (DEQ-5) score ≥ 6 ; and average total ocular surface staining score ≥ 4 were included. The study consisted of in-clinic visits (Days 1 and 90 ± 5) and telephonic follow-ups (Days 30 ± 5 and 75 ± 5). Subjects received first dose of HPG-HA dual polymer lubricant eye drops on Day 1, and required to self-administer 1-2 drops in each eye four times/day for 90 ± 5 days. Primary endpoint: frequency and characteristics of treatment-emergent adverse events (TEAEs) reported throughout study period. Secondary endpoint: dry eye symptom score assessed using DEQ-5 questionnaire (5-point scale, symptom frequency: 0=never

to 4=constantly; 6-point scale, symptom severity: 0=never have it to 5=very intense) at Days 1 and 90.

Results: Among 175 subjects (mean \pm SD age: 37.9 ± 13.3 years), 36 (20.6%) reported ≥ 1 TEAEs and 27 (15.4%) had ≥ 1 mild drug-related TEAEs (eye irritation [n=9], eye pruritus [n=8], blurred vision [n=6], increased lacrimation [n=4], ocular hyperaemia [n=3], and ocular discomfort [n=1]). There was one discontinuation due to TEAEs; no TEAEs resulted in drug interruptions. No serious adverse events were observed throughout study. The DEQ-5 score for dry eye symptoms was reduced from Day 1 (11.50 ± 2.27) to Day 90 (5.50 ± 2.50).

Conclusions: The use of HPG-HA dual polymer lubricant eye drops was safe and effective in reducing dry eye symptom score in Indian subjects with DED, over 90 days.

Research funding received: This study was funded by Alcon.