NIHR | Innovation Observatory

Newcastle University

Health Technology Briefing
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NVK-002 for myopia in children

Company/Developer	Thea Pharmaceuticals Ltd

☒ New Active Substance ☐ Significant Licence Extension (SLE)

NIHRIO ID: 20478	NICE TSID: Not available	UKPS ID: 666625

Licensing and Market Availability Plans

NVK-002 is currently in Phase III clinical trials.

Summary

NVK-002 is currently in clinical development for the treatment of myopia in children. Myopia, also known as short-sightedness, is an eye condition that means a person is unable to see objects that are far away very clearly due to changes in the shape of the eye structure. The condition usually starts in children aged between 6 and 13 years, with signs of the condition including an inability to read words from a distance, sitting close to screens such as televisions or mobile phones, getting headaches and rubbing the eyes a lot. If children do not receive treatment for myopia, they may develop other eye conditions such as a squint (where the eyes point in different directions) or a lazy eye (where the sight in one eye does not develop properly). It is a condition that can continue getting worse until the eye stops growing at around age 20. Currently, there are few treatment options available to help children treat myopia, and no pharmacological therapies to treat myopia progression in children.

NVK-002 is a low dose of atropine, which is a type of medication called an anticholinergic that is taken as an eye drop at night. It can help to manage changes in the eye shape or components that are associated with the progression of myopia. If it is licensed, NVK-002 may help to offer another alternative treatment option for children with myopia.

Proposed Indication

Treatment of children aged three to 17 with myopia.[1]

Technology

Description

NVK-002 (atropine) is an investigational, preservative-free low-dose atropine eye drop administered nightly.[2] Atropine is an anticholinergic medicine that acts by blocking the cholinergic receptors in the sphincter of the pupil and the ciliary muscle.[3] It addresses anatomic changes (such as longer ocular axial length) that can be associated with the progression of myopia.[4]

NVK-002 is currently in phase III clinical trial assessing the effectiveness of low doses of atropine (0.01% and 0.02%) in treating children with myopia (CHAMP; NCT03350620).[1,5]

Key Innovation

No pharmacologic therapies are approved for treating childhood myopia progression.[5] The National Health Service (NHS) note that children with the condition can generally be treated by using glasses and, for some children, contact lenses.[6] However, contact lenses are also associated with side-effects such as microbial keratitis, inflammation and abrasions.[7] Additionally, while spectacles are associated with fewer side-effects, they have generally lower efficacy.[7] Vision correction with glasses or lenses does not treat myopia progression in children, thus there is a clear unmet need.[2]

NVK-002 helps address the urgent need for pharmacological control of myopia. In the phase III clinical trial (CHAMP; NCT03350620), preliminary results demonstrated that NVK-002 at a dose of 0.01% atropine achieved statistically significant and clinically meaningful differences from placebo in every key outcome measure.[2] If licensed, NVK-002 would provide a novel treatment option for the treatment of myopia progression in children.

Regulatory & Development Status

NVK-002 at a dose of 1% as an eye drop currently has marketing authorisation in the UK for treating iritis, uveitis, induction of mydriasis and/or cycloplegia in adults and for cycloplegic refraction in children.[3]

NVK-002 is not currently in phase II or III clinical trials for any other indication.[8]

Patient Group

Disease Area and Clinical Need

Myopia (also known as short-sightedness) is an eye condition where objects that are far away are unclear. The condition usually starts in children aged between 6 and 13.[6] It is a 'refractive error' that happens when the eyeball elongates too long from front to back, or when there are problems with the shape of the cornea or lens, which makes light focus in front of the retina instead of on it.[9] Signs of myopia in children include: difficulty in reading words from a distance; sitting close to televisions or computers; holding mobile phones or tablets close to the face; headaches; and rubbing the eyes frequently. The condition often runs in families and can get worse until the eyes stop growing at around the age of 20. Young children with myopia are also more likely to develop other eye conditions, including a squint or a lazy eye.[6]

Research has suggested that the number of children between the ages of 10 and 16 with myopia has doubled in the past 50 years, and it is developing at younger ages.[10] In England (2022-23), there were 210 finished consultant episodes (FCE) for myopia (H521), leading to 209 admissions, 196 day cases and 12 FCE bed days. Of these admissions, 11 were in children between one and four years old and 34 were between 5 and 17 years old.[11]

Recommended Treatment Options

There are currently no guidelines covering the treatment or management of myopia in children from the National Institute for Health and Care Excellence (NICE).[12] However, the NHS notes that myopia in children can usually be treated by using glasses and, for some children, contact lenses. The NHS also states that spending more time outdoors may also help to prevent myopia becoming worse, as well as wearing bi-focal or multi-focal contact lenses, or in some cases, wearing a special lens overnight (orthokeratology).[6]

Clinical Trial Information

Trial	**CHAMP; NCT03350620, EudraCT 2018-001077-24**; A 3-Arm Randomized, Double-Masked, Placebo-Controlled, Phase 3 Study of NVK-002 in Children With Myopia **Phase III** – active, not recruiting **Location(s):** 4 countries in the EU, UK and USA **Primary completion date**: 7 August 2023
Trial Design	Randomised, cross-over assignment, double-blinded, placebo-controlled
Population	N = 576 (actual); children aged 3 to ≤ 17 years with myopia spherical equivalent refraction (SER) of at least -0.50 D and no greater than -6.00 D in each eye as measured by cycloplegic autorefraction.
Intervention(s)	Stage one: • NVK-002 0.01%, once daily[5] • NVK-002 0.02%, once daily[5] Stage two: participants are re-randomised to one of the three arms (including vehicle).
Comparator(s)	Stage one: vehicle (placebo) once daily Stage two: participants are re-randomised to one of the two experimental arms
Outcome(s)	**Primary outcome measure:** • Overall between-group difference in proportion of subjects who show < -0.50 D myopia progression (SER) at the 36-month visit. [time frame: 36 months] See trial record for full list of other outcomes.
Results (efficacy)	At 36 months, a dose of 0.01% low-dose atropine achieved statistically and clinically meaningful differences from placebo in all key outcome measures, including responder proportion (OR 4.54, 95% CI 1.15 to 17.97; P = 0.03), slowing of change in SER (least mean squares (LSM) difference 0.24 D, 95% CI

	0.11 to 0.37 D, P < 0.001), and slowing of axial elongation (LSM difference -0.13 mm, 95% CI -0.19 to -0.07 mm, P < 0.001).[5]
Results (safety)	There were no serious ocular adverse events and few serious non-ocular adverse events. None of the adverse events were judged to be associated with atropine.[5]

Estimated Cost

The cost of NVK-002 was confidential at the time of producing this briefing.

Relevant Guidance

NICE Guidance

No relevance guidance identified.

NHS England (Policy/Commissioning) Guidance

- NHS England. 2013/14 Standard Contract for Specialised Ophthalmology (Paediatrics). D12/S/b.

Other Guidance

- The College of Optometrists. Childhood-onset myopia management: Guidance for optometrists. 2022.[13]
- Németh J, Tapasztó B, Aclimandos WA, Kestelyn P, Jonas JB, De Faber JT, et al. Update and guidance on management of myopia. European Society of Ophthalmology in cooperation with International Myopia Institute. European Journal of Ophthalmology. 2021.[14]
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Additional Information

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