



Johnson & Johnson Vision's Investigational Antihistamine-Releasing Contact Lens Demonstrates Positive Phase 3 Results

Two placebo-controlled studies published in Cornea show potential for contact lenses to correct vision and reduce occurrence of eye itch from allergies

JACKSONVILLE, Fla. (March, 26, 2019) – Johnson & Johnson Vision today announced that results from two Phase 3 clinical studies evaluating the company's investigational antihistamine-releasing contact lens (etafilcon A with 0.019 mg ketotifen) were published in the journal *Cornea*. The results demonstrated that patients wearing the investigational contact lens had lower mean itching scores after their eyes were exposed to allergens compared to those wearing non-medicated control lenses, indicating that in these studies, the lenses reduced symptoms of eye itch.

[Click to Tweet:](#) @JNJVision announces Phase 3 data published on its investigational antihistamine-releasing contact lens in patients with #allergy eyes <https://bit.ly/2HIXDzY>

"These Phase 3 study results are important on multiple fronts. Contact lens wearers who historically suffer from itchy, allergy eyes had meaningful reductions in itching across two randomized, well-controlled studies," said Brian Pall, OD, MS, FAAO, Director, Clinical Science, Johnson & Johnson Vision Care, Inc. and lead author of the manuscript. "There was both a clinically and statistically significant reduction in ocular itching that occurred 15 minutes after lens insertion and lasted for the 12-hour study evaluation period. This marks the first time that contact lens technology has shown potential in a large-scale study to address itch stemming from ocular allergies."

According to the *Cornea* publication, more than 20 percent of the U.S. population experience ocular allergy, or itchy eyes, when exposed to allergens such as tree or grass pollen, pet dander or dust. The condition has a similar prevalence worldwide and can have a significant impact on productivity and quality of life.^{1,2,3,4,5,6}

"At Johnson & Johnson Vision, we are committed to pioneering new technologies that both correct people's vision and also have potential to address other lifestyle or medical needs they may have," said Xiao-Yu Song, PhD, MD, Global Head of Research and Development, Johnson & Johnson Vision Care, Inc. "It is encouraging to see this large-scale assessment that indicates the potential of a contact lens-based drug delivery system which, in the future, could represent an entirely new category of contact lenses. We will continue development of this contact lens technology and are committed to making regulatory submissions for this antihistamine-releasing contact lens as we move forward."

Study Design and Results

The antihistamine-releasing contact lenses worn in the studies are daily disposable lenses containing ketotifen, a drug that inhibits certain substances in the body that are known to cause allergic reactions and inflammation. They were tested in two multicenter, double-masked, randomized, placebo-controlled trials that included 244 patients and used the conjunctival allergen challenge model (Ora-CAC[®]) to measure efficacy.

After the initial screening visits, patients were randomized by eye to receive either the antihistamine-releasing lens or the placebo control lens. The lenses were then worn for either 15 minutes or 12 hours depending on the study visit. After the prescribed wearing time, allergens were dosed into the eyes wearing the contact lenses and the patients reported the severity of their itching symptoms using a 0-4 scale (where 0 equals no itch and 4 equals an incapacitating itch with an irresistible urge to rub).

The primary study endpoint was comparisons of reported itching scores between the two lens types. Across both studies, the patients who wore the antihistamine-releasing contact lenses experienced both a

clinically and statistically significant ($p < 0.001$) reduction in the average eye itch symptom at both time point evaluations (15 minutes and 12 hours) as compared to those receiving control lenses in the study.

Secondary endpoints in the trials evaluated the reduction in eye redness (ciliary, conjunctival and episcleral vessel beds) while wearing the antihistamine-releasing lens. The antihistamine-releasing lenses did not demonstrate a clinically significant reduction in eye redness.

In the studies, both the antihistamine-releasing contact lenses and control lenses demonstrated a low rate of ocular adverse events (4.9% overall) with the majority being mild and not considered study related. The most commonly reported adverse events associated with the antihistamine-releasing lenses were stinging upon insertion (1.7%) and temporary pupil enlargement (2.1%). The stinging upon insertion was generally classified as mild and there were no discontinuations from study treatment based on these or any other ocular adverse events.

Johnson & Johnson Vision

At Johnson & Johnson Vision, part of Johnson & Johnson Medical Devices Companies*, we have a bold ambition: to change the trajectory of eye health around the world. Through our operating companies, we deliver innovation that enables eye care professionals to create better outcomes for patients throughout their lives, with products and technologies that address unmet needs including refractive error, cataracts and dry eye. In communities with greatest need, we work in collaboration to expand access to quality eye care, and we are committed to helping people see better, connect better and live better. Visit us at www.jjvision.com. Follow [@JNJVision](https://twitter.com/JNJVision) on Twitter and Johnson & Johnson Vision on [LinkedIn](https://www.linkedin.com/company/jnjvision).

About Johnson & Johnson Medical Devices Companies

As the world's most comprehensive medical devices business, we are building on a century of experience, merging science and technology, to shape the future of health and benefit even more people around the world. With our unparalleled breadth, depth and reach across surgery, orthopaedics, vision and interventional solutions, we're working to profoundly change the way care is delivered. We are in this for life.

**Comprising the surgery, orthopaedics, vision and interventional businesses within the Johnson & Johnson's Medical Devices segment*

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding data on an investigational antihistamine-releasing contact lens. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson Vision Care, Inc., any of the other Johnson & Johnson Medical Devices Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of regulatory approvals; uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of Johnson & Johnson Vision Care, Inc., the Johnson & Johnson Medical Devices Companies, or Johnson & Johnson

undertakes to update any forward-looking statement as a result of new information or future events or developments.

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⁵ Smith AF, Pitt AD, Rodriguez AE, et al. The economic and quality of life impact of seasonal allergic conjunctivitis in a Spanish setting. *Ophthalmic Epidemiol*. 2005; 12: 233-42.
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