



ANI Pharmaceuticals Announces New Fluocinolone Acetonide Intravitreal Implant Data to be Presented at the American Academy of Ophthalmology 2026 Annual Meeting

September 30, 2026

Data from Phase 4 Open-Label, Single-Arm SYNCHRONICITY Trial will be presented in a late-breaking oral presentation during Uveitis Subspecialty Day 2026

Post-hoc analyses of baseline characteristics and efficacy outcomes in rescued and non-rescued patients from the Phase 4 NEW DAY trial will be presented in an on-demand ePoster

PRINCETON, N.J., Sept. 30, 2026 (GLOBE NEWSWIRE) -- ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) (ANI or the Company) today announced that data from SYNCHRONICITY, its Phase 4, open-label, single-arm clinical trial of Fluocinolone Acetonide Intravitreal Implant in patients with chronic non-infectious uveitis affecting the posterior segment of the eye (chronic NIU-PS) will be presented in a late-breaking oral presentation during Uveitis Subspecialty Day 2026, being held October 9, 2026 at the American Academy of Ophthalmology (AAO) 2026 Meeting in New Orleans. This follows the Company's [announcement](#) of six-month topline results from the SYNCHRONICITY trial in July 2026. Additionally, the Company plans to present post-hoc analyses from the Phase 4 NEW DAY clinical trial of Fluocinolone Acetonide Intravitreal Implant in Diabetic Macular Edema (DME) as an on-demand ePoster.

The AAO 2026 presentation details are as follows:

The Use of Fluocinolone Acetonide Implant in the Treatment of Chronic Noninfectious Posterior Segment Uveitis: Results of the Phase 4 SYNCHRONICITY Trial

- **Date/Time:** Uveitis Subspecialty Day, October 9, 4:50 p.m. ET
- **Session:** Section VIII: A Uveitis Lagniappe: Late Breaking Topics
- **Presenter:** David Almeida, MD, PhD, MBA, President and CEO of Erie Retina Research, and Principal Investigator in SYNCHRONICITY

Baseline Characteristics and Efficacy Outcomes in Rescued vs. Non-Rescued Patients After Fluocinolone Acetonide Implant in the Phase 4 NEW DAY Trial for DME

- **Date/Time:** Scientific poster available on demand
- **Session:** PO631
- **Presenter:** Christina Y Weng, MD, MBA, Professor and Alice R. McPherson Retina Research Foundation Chair in Ophthalmology, Baylor College of Medicine

The Company also plans to share an encore presentation of the Phase 4 SYNCHRONICITY results during a podium presentation by Victor Gonzalez, MD, on January 21, 2027, at the Hawaiian Eye & Retina 2027 Meeting.

INDICATIONS FOR ILUVIEN® (fluocinolone acetonide intravitreal implant)

ILUVIEN is a corticosteroid indicated for:

- the treatment of diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.
- the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

IMPORTANT SAFETY INFORMATION FOR ILUVIEN CONTRAINDICATIONS

- ILUVIEN is contraindicated in patients with active or suspected ocular or periocular infections including most viral disease of the cornea and conjunctiva including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections and fungal diseases.
- ILUVIEN is contraindicated in patients with glaucoma who have cup to disc ratios of greater than 0.8.
- ILUVIEN is contraindicated in patients with known hypersensitivity to any components of this product.

WARNINGS AND PRECAUTIONS

- **Intravitreal Injection-related Effects:** Intravitreal injections, including those with ILUVIEN, have been associated with endophthalmitis, eye inflammation, increased or decreased intraocular pressure, and choroidal or retinal detachments. For patients with non-infectious uveitis affecting the posterior segment, hypotony has been observed within 24 hours of injection and has resolved within 2 weeks. Patients should be monitored following the intravitreal injection. Patients may

experience temporary blurred vision after injection of the implant.

- **Intraocular Pressure (IOP) Increase:** Prolonged use of corticosteroids may result in the development of glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be routinely monitored during the course of the treatment.
- **Cataracts:** The use of corticosteroids may result in posterior subcapsular cataract formation.
- **Delayed Corneal Wound Healing:** The use of corticosteroids after cataract surgery may delay healing and increase the incidence of bleb formation.
- **Corneal and Scleral Melting:** Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of ophthalmic corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation of the globe.
- **Bacterial Infections:** Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. Acute purulent or parasitic infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated.
- **Viral Infections:** Use of ocular corticosteroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.
- **Fungal Infections:** Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid application. Fungus invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.
- **Risk of Implant Migration:** Patients in whom the posterior capsule of the lens is absent or has a tear are at risk of implant migration into the anterior chamber.

ADVERSE REACTIONS

Diabetic Macular Edema

Ocular adverse reactions reported by greater than or equal to 1% of patients in the two combined 3-year clinical trials following injection of ILUVIEN for diabetic macular edema include: cataract (82%), myodesopsia (21%), eye pain (15%), conjunctival hemorrhage (13%), posterior capsule opacification (9%), eye irritation (8%), vitreous detachment (7%), conjunctivitis (4%), corneal oedema (4%), foreign body sensation in eyes (3%), eye pruritus (3%), ocular hyperaemia (3%), optic atrophy (2%), ocular discomfort (2%), photophobia (2%), retinal exudates (2%), anterior chamber cell (2%), and eye discharge (2%). Non-ocular adverse reactions reported by greater than or equal to 5% of patients include: anemia (11%), headache (9%), renal failure (9%), and pneumonia (7%).

Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 34% of ILUVIEN patients versus 10% of sham patients. IOP elevation greater than or equal to 30 mm Hg was seen in 20% of ILUVIEN patients versus 4% of sham patients. 38% of the patients who received ILUVIEN were subsequently treated with IOP-lowering medications during the study versus 14% of sham patients. 5% of the patients who received ILUVIEN needed surgical intervention for elevated IOP versus 1% of sham patients.

Cataracts and Cataract Surgery: The incidence of cataract development in patients who had a phakic study eye was higher in the ILUVIEN group (82%) compared with sham (50%). The median time of cataract being reported as an adverse event was approximately 12 months in the ILUVIEN group and 19 months in the sham group. Among these patients, 80% of ILUVIEN subjects versus 27% of sham-controlled subjects underwent cataract surgery, generally within the first 18 months (median month 15 for both ILUVIEN group and for sham) of the studies.

Chronic Non-Infectious Uveitis Affecting the Posterior Segment of the Eye

Ocular adverse reactions reported by greater than or equal to 1% of patients in the three combined clinical trials through 12 months following injection of fluocinolone acetonide intravitreal implant: cataract (56%), visual acuity reduced (15%), macular edema (11%), uveitis (10%), conjunctival hemorrhage (8%), eye pain (8%), hypotony of eye (7%), anterior chamber inflammation (5%), dry eye (4%), vitreous opacities (4%), conjunctivitis (4%), posterior capsule opacification (4%), ocular hyperemia (4%), vitreous haze (3%), foreign body sensation in eyes (3%), vitritis (3%), vitreous floaters (3%), eye pruritus (3%), conjunctival hyperemia (2%), ocular discomfort (2%), macular fibrosis (2%), glaucoma (2%), photopsia (2%), vitreous hemorrhage (2%), iridocyclitis (1%), eye inflammation (1%), choroiditis (1%), eye irritation (1%), visual field defect (1%), and lacrimation increased (1%). Non-ocular adverse reactions reported by greater than or equal to 2% of patients include: nasopharyngitis (5%), hypertension (3%), and arthralgia (2%).

Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 22% of fluocinolone acetonide patients versus 12% of sham patients. IOP elevation greater than or equal to 30 mm Hg was seen in 12% of fluocinolone acetonide patients versus 3% of sham patients. 43% of the patients who received fluocinolone acetonide were subsequently treated with IOP-lowering medications during the study versus 41% of sham patients. 2% of the patients who received fluocinolone acetonide needed surgical intervention for elevated IOP versus 2% of sham patients.

Please see full [Prescribing Information](#) for ILUVIEN.

About ANI Pharmaceuticals, Inc.

ANI Pharmaceuticals, Inc. (Nasdaq: ANIP) is a diversified biopharmaceutical company committed to its mission of "Serving Patients, Improving Lives" by developing, manufacturing, and commercializing innovative and high-quality therapeutics. The Company is focused on delivering sustainable growth through its Rare Disease business, which markets novel products in the areas of ophthalmology, rheumatology, nephrology, neurology, and pulmonology; its Generics business, which leverages R&D expertise, operational excellence, and U.S.-based manufacturing; and its Brands business. For more information, visit <https://www.anipharma.com>.

Forward-Looking Statements

To the extent any statements made in this release deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements regarding the Company's strategy; its expectations regarding its future operations, financial position or revenues, including its 2026 financial guidance; its expectations regarding its share repurchase program; the results and timing of the Company's preclinical studies, clinical trials, regulatory submissions and regulatory approvals; the commercialization and anticipated sales of the Company's products, including current and planned product launches and any additional product launches from the Company's generic pipeline; the Company's estimates of the market opportunity and addressable patient populations for its products; the expansion and execution capabilities of the Company's sales force for acute gouty arthritis for Cortrophin Gel; the Company's anticipated growth opportunities, including for Cortrophin Gel and ILUVIEN; the Company's positioning for continued shareholder value creation; anticipated R&D developments and clinical trial advances; and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," the negatives thereof, or other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to: the ability of the Company's approved products, including Cortrophin Gel and ILUVIEN, to achieve commercialization at levels of market acceptance that will allow the Company to maintain profitability; the Company's ability to complete or achieve any or all of the intended benefits of acquisitions and investments, in a timely manner or at all; delays and disruptions in the production of the Company's approved products; increased costs and potential loss of revenues if the Company needs to change suppliers due to the limited number of suppliers for its raw materials, active pharmaceutical ingredients, excipients, and other materials; delays and disruptions in the production of the Company's approved products as a result of its reliance on single source third party contract manufacturing supply for certain of its key products, including Cortrophin Gel and ILUVIEN; delays or failure to obtain or maintain approvals by the FDA of the Company's products; changes in policy or actions that may be taken by the FDA, United States Drug Enforcement Administration and other regulatory agencies; risks that the Company may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of the Company's products from both domestic and overseas sources due to supply chain disruptions or for any other reason, including increased costs due to tariffs or macroeconomic disruptions; the ability of the Company's manufacturing partners to meet its product demands and timelines; the impact of changes or fluctuations in exchange rates; the Company's ability to develop, license or acquire, and commercialize new products; the Company's obligations in agreements under which it licenses, develops or commercializes rights to products or technology from third parties and its ability to maintain such licenses; the level of competition the Company faces and the legal, regulatory and/or legislative strategies employed by its competitors to prevent or delay competition from generic alternatives to branded products; the Company's ability to protect its intellectual property rights; the impact of legislative or regulatory reform on the pricing for pharmaceutical products; the impact of any litigation to which the Company is, or may become, a party; the Company's ability, and that of its suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries; the Company's ability to maintain the services of its key executives and other personnel; and general business and economic conditions, such as inflationary pressures, geopolitical conditions.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission (SEC), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, and other periodic reports, as well as other filings with the SEC. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Investor Relations:

Irina Koffler, Vice President, Investor Relations

T: 917-734-7387

E: Irina.koffler@anipharma.com

Media Relations:

Argot Partners

T: 212-600-1494

E: ani@argotpartners.com

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