ani Pharmaceuticals, Inc.

NEW DAY Clinical Trial Results

July 23, 2025

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Speakers and Agenda

NIKHIL LALWANI
President and Chief Executive Officer

CHRISTOPER MUTZ
Senior Vice President, Head of Rare Disease

MARY PAO, MD, PhD
Chief Medical Officer of Rare Disease

MICHAEL A. SINGER, MD
Medical Center Ophthalmology Associates and University of Texas Health Science Center, San Antonio, TX

1. **Opening Remarks**
2. **ILUVIEN & DME Treatment Background**
3. **NEW DAY Study Overview & Results**
4. **Closing Remarks**

ILUVIEN Overview

ILUVIEN is indicated for the treatment of:

DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure

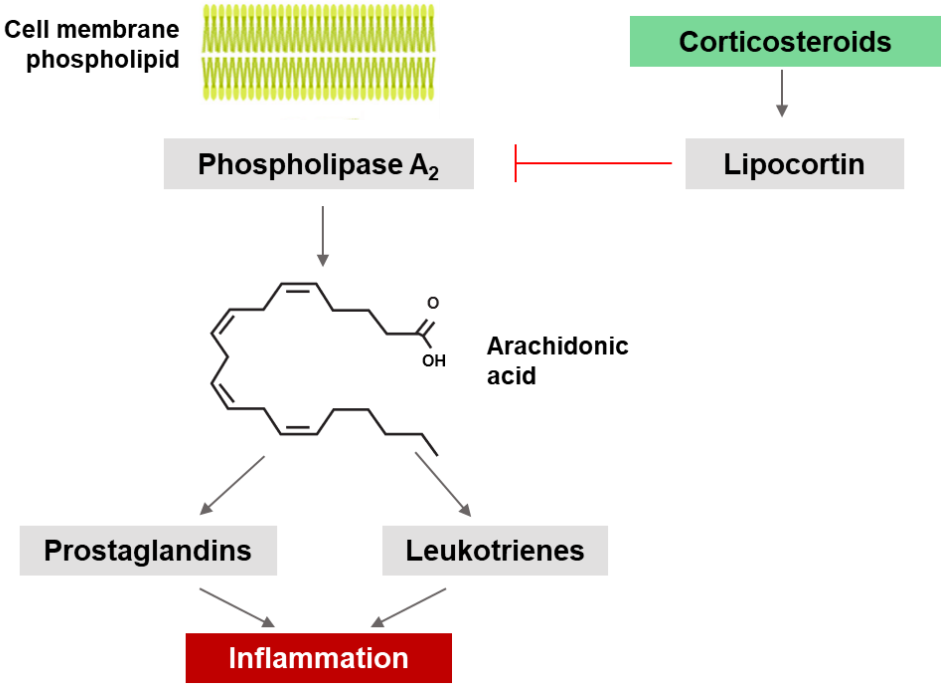
Chronic non-infectious uveitis affecting the posterior segment of the eye

Provides constant and controlled drug release with stable fluocinolone acetonide (FAc) release for up to 36 months

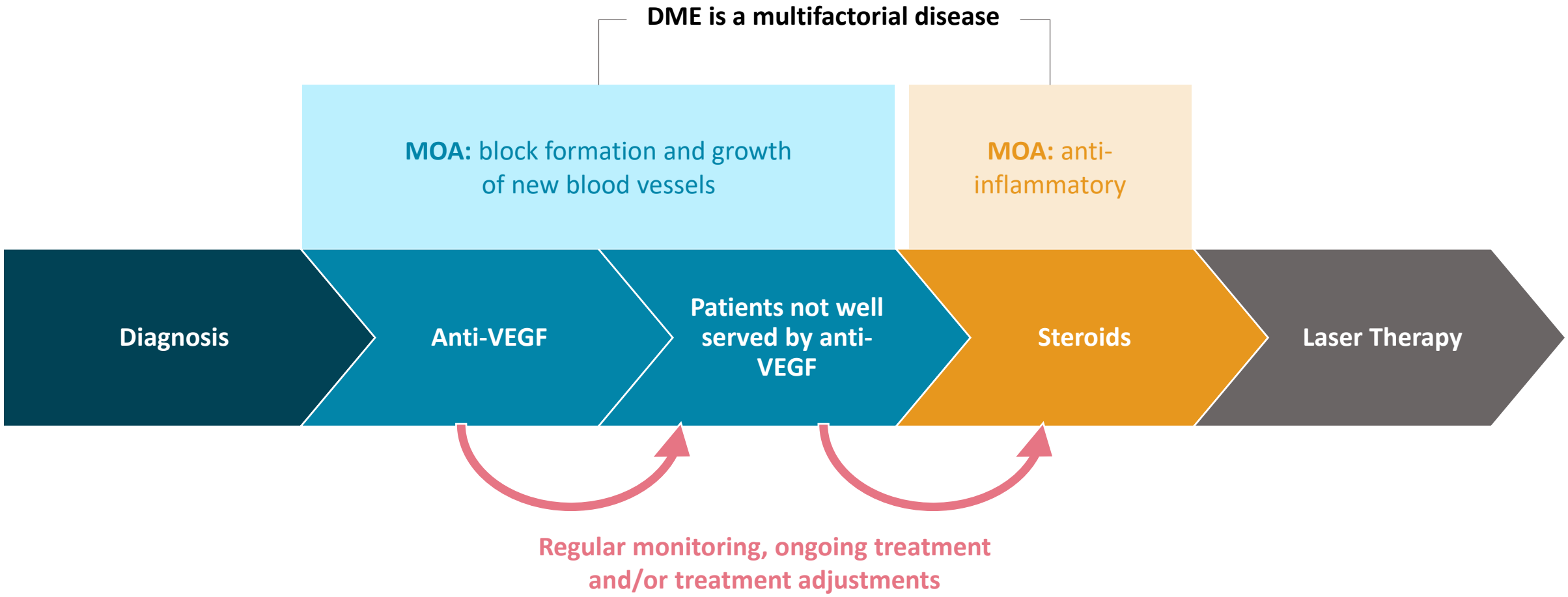
ILUVIEN mechanism of action – inhibiting inflammatory response:

Corticosteroids inhibit inflammatory responses to a variety of inciting agents including multiple inflammatory cytokines

Corticosteroids are thought to act by inhibition of phospholipase A2 via induction of inhibitory proteins collectively called lipocortins



The Most Commonly Used Pharmacologic Treatments for DME Include Anti-VEGF Agents and Corticosteroids



Steroids are the Treatment of Choice for DME Patients Not Well Served by Anti-VEGF Therapy

NEW DAY STUDY

Incomplete Response or Resistance to Anti-VEGF Therapy Can Be Attributed to Multiple Causes

- **Burden of Frequent Injections**[1,2]
- **Underlying Pathophysiology**[3,4]
- **Differential Expression of VEGF**[3]
- **Metabolic Factors**[4,5]
- **Socioeconomic Disparities**[1,6,7]

Inflammation and angiogenesis act interdependently, contributing to the breakdown of the blood-retina barrier during the development of DME

Positive Correlation Between DME Severity and Concentration of Inflammatory Cytokines[7]

A statistically significant positive correlation between aqueous humor levels of inflammatory cytokines and diabetic retinopathy severity was observed

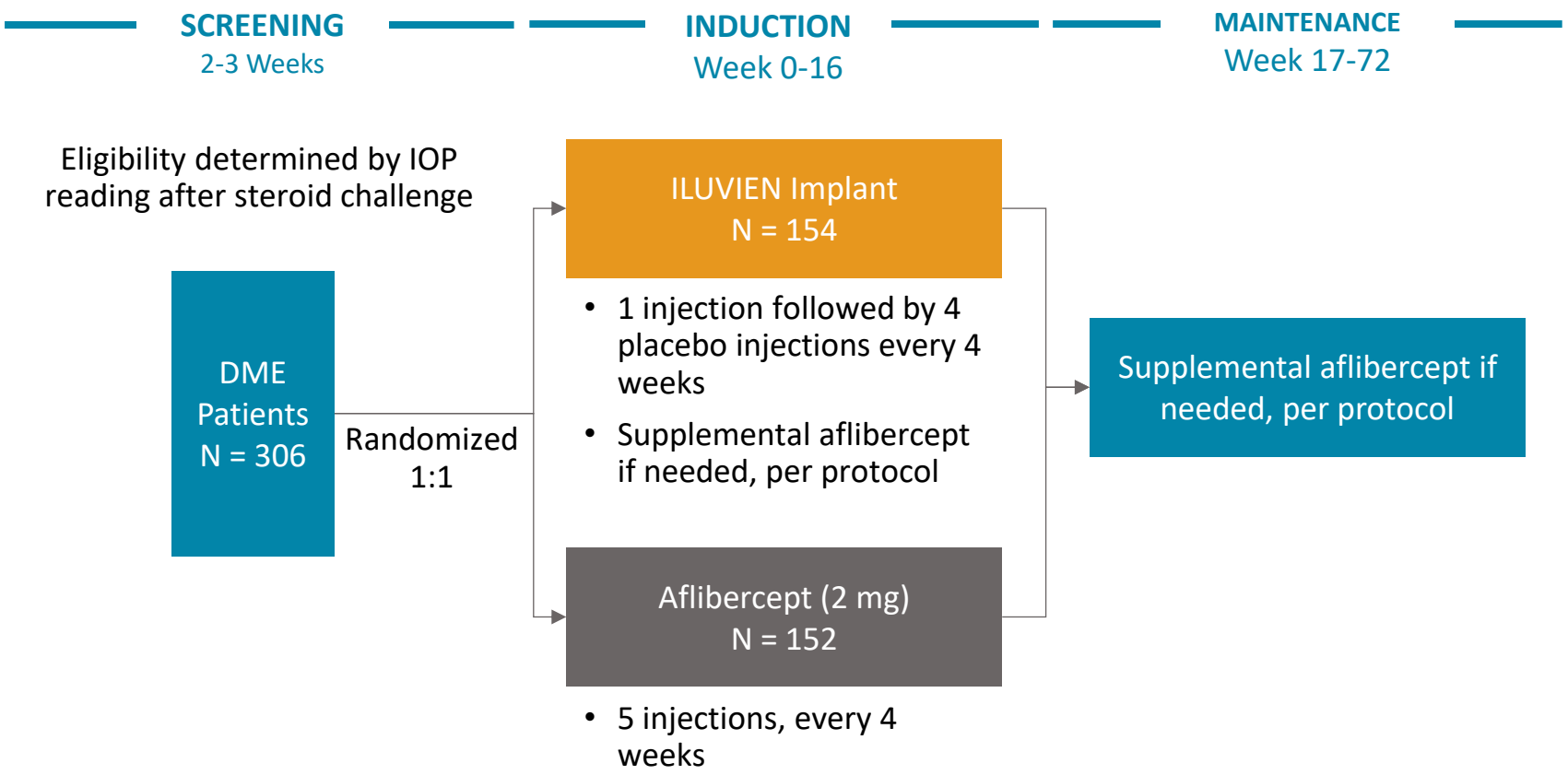
- IL-1β ($p = 0.003$)
- IL-6 ($p < 0.001$)
  IL-8 ($p = 0.001$)
- MCP-1 ($p < 0.001$)
- IP-10 ($p < 0.001$)

No significant correlation between VEGF levels and diabetic retinopathy severity was observed ($p = 0.733$)

1. Ciulla TA, et al. Br J Ophthalmol. 2021;105(2):216-221. 2. Nakao S, et al. Graefes Arch Clin Exp Ophthalmol. 2024;262(12):3749-3759.3. Sorour OA, et al. Surv Ophthalmol. 2023;68(2):147-174. 4. Usui-Ouchi A, et al. Life (Basel). 2021;11(2):83.
5. Gonzalez VH, et al. Am J Ophthalmol. 2016;172:72-79. 6. Holekamp NM, Campbell J, Almony A, et al. Am J Ophthalmol. 2018 Oct;194:192. doi: 10.1016/j.ajo.2018.08.023.]. Am J Ophthalmol. 2018;191:83-91. 7. Diabetic Retinopathy Clinical Research Network, Wells JA, Glassman AR, et al. N Engl J Med. 2015;372(13):1193-1203. 7. Dong N, Xu B, Wang B, Chu L. Mol Vis. 2013;19:1734-1746.

NEW DAY Study Overview

Assess the efficacy of ILUVIEN as baseline therapy in patients with early DME; assess the safety and tolerability of ILUVIEN and aflibercept combination in patients with DME



KEY DETAILS

The intent-to-treat (ITT) and safety populations included all randomized patients, regardless of whether they received the treatment.

Primary Endpoint: Mean total # of supplemental aflibercept injections needed during the study from baseline to Week 72 in the ITT population

Select Secondary Endpoints:

- Time to first supplemental therapy from last injection
- Proportion of patients with 15, 10, and 5 letter Early Treatment Diabetic Retinopathy Study (ETDRS) gains from baseline at Week 72 (ITT)
- Mean change from baseline (CFB) in central subfield thickness (CST) in the ITT population on optical coherence tomography (OCT)
- Proportion of patients who do not require any supplemental therapy during the study (ITT)
- **Safety:** Rates of cataract surgery and incidence of intraocular pressure and surgery throughout the study

1. A Study of Intravitreal ILUVIEN® Implant as Baseline Therapy in Patients With Early Diabetic Macular Edema (DME) (NEW DAY). ClinicalTrials.gov identifier: NCT04469595. Accessed November 1, 2024. https://clinicaltrials.gov/study/NCT04469595 2. Data on File, ANI Pharmaceuticals, Inc.

NEW DAY Inclusion and Exclusion Criteria

Inclusion Criteria

- Patients ≥18 years old with a diagnosis of Type 1 or Type 2 diabetes
- Center-involving DME confirmed by SD-OCT and CST of ≥350 µm
- BCVA of ≥35 and ≤80 ETDRS letters in study eye at screening visit

Exclusion Criteria

Proliferative Diabetic Retinopathy

- Glaucoma or ocular hypertension
- Other conditions associated with macular edema
- Patients who received prior laser photocoagulation therapy, including macular grid or PRP at any time in the study eye
- Patients who received the following therapies in the study eye:
  - Intravitreal or periocular steroids
  - Intravitreal injection of aflibercept, brolucizumab, or conbercept ≤12 months prior to screening visit

Patients who received >1 intravitreal injection of ranibizumab or bevacizumab in the last 12 months, or have received ranibizumab or bevacizumab ≤6 weeks prior to screening visit

- Steroid challenge exclusion: At the baseline visit, patients who were determined to have an IOP ≥25 mmHg or an increase ≥8 mmHg from screening visit after being challenged by difluprednate.

NEW DAY: Patient Disposition, ITT

	ILUVIEN Implant N = 154	Aflibercept (2 mg) N = 152
Intent to Treat		
Discontinued Early	N = 30	N = 34
Reasons for Discontinuation	Lost to follow-up: 14 Withdrawal of consent: 7 Death: 3 Noncompliance: 2 Adverse event: 1 Sponsor request: 1 Investigator decision: 0 Other: 2	Lost to follow-up: 10 Withdrawal of consent: 8 Death: 3 Noncompliance: 1 Adverse event: 1 Sponsor request: 2 Investigator decision: 2 Other: 7
Completed Study Overall	N = 124	N = 118

Patient Demographics, ITT

	ILUVIEN N = 154	Aflibercept N = 152	Overall N = 306
Age (Years)			
n	154	152	306
Mean (SD)	61.0 (8.08)	61.8 (9.10)	61.4 (8.60)
Median	61.0	61.5	61.0
Min, max	38, 84	36, 86	36, 86
Gender, n (%)			
Female	54 (35.1)	60 (39.5)	114 (37.3)
Male	100 (64.9)	92 (60.5)	192 (62.7)
Race, n (%)			
n	152	151	303
American Indian or Alaska Native	3 (2.0)	3 (2.0)	6 (2.0)
Asian	5 (3.3)	1 (0.7)	6 (2.0)
Black or African American	21 (13.8)	16 (10.6)	37 (12.2)
Native Hawaiian or Other Pacific Islander	1 (0.7)	0 (0.0)	1 (0.3)
White	117 (77.0)	127 (84.1)	244 (80.5)
Other	5 (3.3)	4 (2.6)	9 (3.0)
Ethnicity, n (%)			
Hispanic or Latino	38 (24.7)	38 (25.0)	76 (24.8)
Not Hispanic or Latino	114 (74.0)	111 (73.0)	225 (73.5)
Not reported	2 (1.3)	2 (1.3)	4 (1.3)
Unknown	0 (0.0)	1 (0.7)	1 (0.3)

Baseline Characteristics, ITT

	ILUVIEN N = 154	Aflibercept N = 152	Overall N = 306
Baseline visual acuity			
n	153	152	305
Mean (SD)	66.2 (11.19)	65.7 (11.33)	66.0 (11.24)
Median	69.0	68.0	68.0
Min, max	30, 86	28, 92	28, 92
Baseline median IOP			
n	154	152	306
Mean (SD)	17.2 (3.11)	17.2 (3.40)	17.2 (3.26)
Median	17.0	18.0	17.0
Min, max	9, 26	7, 24	7, 26
Baseline ETDRS Total Letter Score			
n	152	151	303
Mean (SD)	69.5 (14.99)	69.7 (13.37)	69.6 (14.18)
Median	73.0	72.0	72.0
Min, max	10, 96	19, 95	10, 96
Baseline DRSS Scale, n (%)			
n	152	151	303
No DR	1 (0.7)	0 (0.0)	1 (0.3)
Microaneurysms only	2 (1.3)	1 (0.7)	3 (1.0)
Mild NPR	4 (2.6)	3 (2.0)	7 (2.3)
Moderate NPDR	5 (3.3)	2 (1.3)	7 (2.3)
Moderately severe NPDR	2 (1.3)	5 (3.3)	7 (2.3)
Severe PDR	3 (2.0)	6 (4.0)	9 (3.0)
Mild PDR	13 (8.6)	18 (11.9)	31 (10.2)
Moderate NPDR	8 (5.3)	11 (7.3)	19 (6.3)
High-risk PDR	114 (75.0)	105 (69.5)	219 (72.3)
IOP Lowering Medication at Baseline, n (%)			
n	154	152	306
Yes	26 (16.9)	6 (3.9)	32 (10.5)
No	128 (83.1)	146 (96.1)	274 (89.5)
Phakic Patients at Baseline	96 (62)	106 (70)	202 (66)
Patients with Previous Anti-VEGF Treatment	15 (9.7)	14 (9.2)	29 (9.5)

Post Hoc Analysis: Per Protocol (PP) Population

Post Hoc Patient Population

Subset of the randomized patients who did not have major study deviation:

- Randomized/enrolled without meeting eligibility criteria
- Administered incorrect treatment
- Received prohibited concomitant medication/therapy

A total of 44 patients experienced 73 major deviations which excluded them from the post hoc per protocol analysis:

- ~1/2 of the major deviations were cases in which a patient was supposed to receive a supplemental injection, but did not
- ~1/3 of the major deviations were cases in which a patient received a supplemental injection but was not supposed to by protocol guidelines

Patient Disposition, PP

	ILUVIEN Implant	Aflibercept (2 mg)
Intent to Treat	N = 154	N = 152
PP	N = 128	N = 134
Discontinued Early	N = 25	N = 30
Reasons for Discontinuation	Lost to follow-up: 14 Withdrawal of consent: 6 Death: 2 Noncompliance: 1 Adverse event: 1 Sponsor request: 0 Investigator decision: 0 Other: 1	Lost to follow-up: 8 Withdrawal of consent: 8 Death: 3 Noncompliance: 1 Adverse event: 1 Sponsor request: 2 Investigator decision: 1 Other: 6
Completed Study Overall	N = 103	N = 104

Patient Demographics, PP

	ILUVIEN N = 128	Aflibercept N = 134	Overall N = 262
Age (Years)			
n	128	134	262
Mean (SD)	60.8 (7.93)	61.9 (9.35)	61.4 (8.69)
Median	61.0	62.0	61.0
Min, max	38, 84	36, 86	36, 86
Gender, n (%)			
Female	43 (33.6)	51 (38.1)	94 (35.9)
Male	85 (66.4)	83 (61.9)	168 (64.1)
Race, n (%)			
n	126	133	259
American Indian or Alaska Native	3 (2.4)	3 (2.3)	6 (2.3)
Asian	4 (3.2)	1 (0.8)	5 (1.9)
Black or African American	17 (13.5)	15 (11.3)	32 (12.4)
Native Hawaiian or Other Pacific Islander	1 (0.8)	0 (0.0)	1 (0.4)
White	96 (76.2)	112 (84.2)	208 (80.3)
Other	5 (4.0)	2 (1.5)	7 (2.7)
Ethnicity, n (%)			
Hispanic or Latino	30 (23.4)	30 (22.4)	60 (22.9)
Not Hispanic or Latino	97 (75.8)	101 (75.4)	198 (75.6)
Not Reported	1 (0.8)	2 (1.5)	3 (1.1)
Unknown	0 (0.0)	1 (0.7)	1 (0.4)

PP, post hoc per protocol; SD, standard deviation.

1. Data on File, ANI Pharmaceuticals, Inc.

Baseline Characteristics, PP

	ILUVIEN N = 128	Aflibercept N = 134	Overall N = 262	P-Value*
Baseline Visual Acuity				
n	127	134	261	0.872
Mean (SD)	66.3 (11.52)	66.1 (11.10)	66.2 (11.29)	
Median	69.0	68.0	69.0	
Min, Max	30, 86	28, 92	28, 92	
Baseline Median IOP				
n	128	134	262	0.939
Mean (SD)	17.1 (3.09)	17.2 (3.40)	17.2 (3.25)	
Median	17.0	18.0	18.0	
Min, Max	9, 24	7, 24	7, 24	
Baseline ETDRS Total Letter Score				
n	127	134	261	0.579
Mean (SD)	69.5 (15.81)	70.5 (12.67)	70.0 (14.26)	
Median	73.0	72.0	73.0	
Min, Max	10, 96	27, 95	10, 96	
Baseline DRSS Scale, n (%)				
n	127	134	261	0.651
No DR	1 (0.8)	0 (0.0)	1 (0.4)	
Microaneurysms Only	2 (1.6)	0 (0.0)	2 (0.8)	
Mild NPDR	4 (3.1)	3 (2.2)	7 (2.7)	
Moderate NPDR	4 (3.1)	2 (1.5)	6 (2.3)	
Moderately Severe NPDR	2 (1.6)	4 (3.0)	6 (2.3)	
Severe NPDR	2 (1.6)	3 (2.2)	5 (1.9)	
Mild PDR	11 (8.7)	15 (11.2)	26 (10.0)	
Moderate PDR	6 (4.7)	11 (8.2)	17 (6.5)	
High Risk PDR	95 (74.8)	96 (71.6)	191 (73.2)	
IOP Lowering Medication at Baseline, n (%)				
n	128	134	262	<0.001
Yes	23 (18.0)	6 (4.5)	29 (11.1)	
No	105 (82.0)	128 (95.5)	233 (88.9)	

*The difference between ILUVIEN and aflibercept was assessed using a two-sided independent pooled t-test
DR, diabetic retinopathy; DRSS, diabetic retinopathy severity scale; ETDRS, Early Treatment Diabetic Retinopathy Study; IOP, intraocular pressure; PP, modified protocol population; NPR, non-proliferative retinopathy; NPDR, non-proliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy; SD, standard deviation.
1. A Study of Intravitreal ILUVIEN® Implant as Baseline Therapy in Patients With Early Diabetic Macular Edema (DME) (NEW DAY). ClinicalTrials.gov identifier: NCT04469595. Accessed November 1, 2024. https://clinicaltrials.gov/study/NCT04469595 2. Data on File, ANI Pharmaceuticals, Inc.

Results in ITT Population

Primary Endpoint	ILUVIEN N = 154	Aflibercept N = 152	P-value*
Mean # of supplemental aflibercept injections	2.4	2.5	0.756

Secondary Endpoints	ILUVIEN	Aflibercept	P-value*
Mean time to first supplemental therapy since last injection in induction phase	185.4 days	132.8 days	<0.001
Proportion of patients without supplemental therapy	32.5%	30.3%	0.678

Total # of injections needed over the course of the study:
ILUVIEN: 3.0
Aflibercept: 7.5

*The difference between FAc and aflibercept was assessed using a two-sided independent pooled t-test.

Results in PP Population

Primary Endpoint	ILUVIEN N = 128	Aflibercept N = 134	P-value*
Mean # of supplemental aflibercept injections	1.8	2.5	0.029

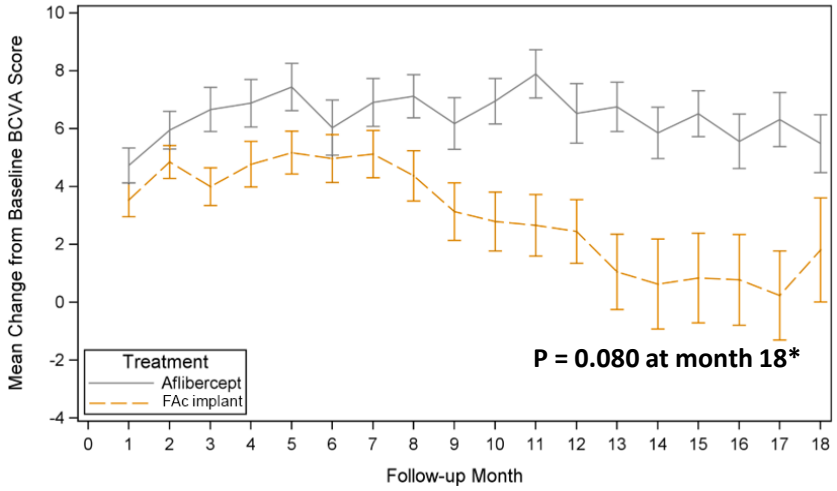
Secondary Endpoint	ILUVIEN	Aflibercept	P-value*
Mean time to first supplemental therapy since last injection in induction phase	189.2 days	131.4 days	<0.001

Total # of injections needed over the course of the study:
ILUVIEN: 2.8
Aflibercept: 7.5

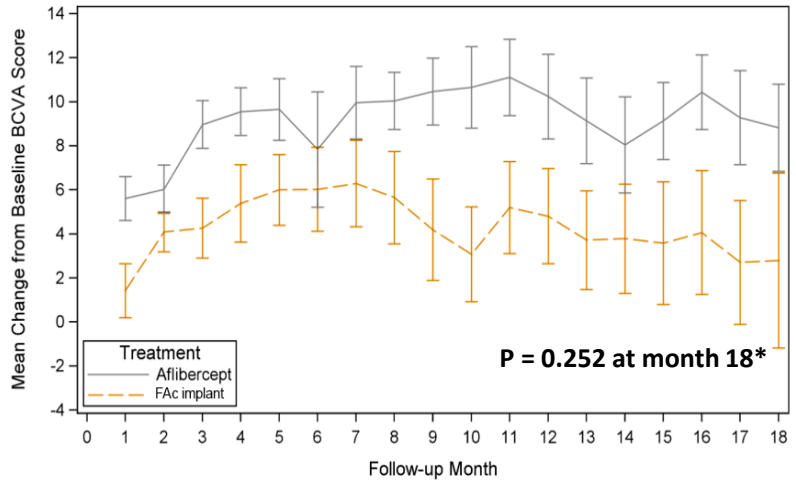
*The difference between FAc and aflibercept was assessed using a two-sided independent pooled t-test.

Secondary Visual Acuity Endpoint Results, ITT

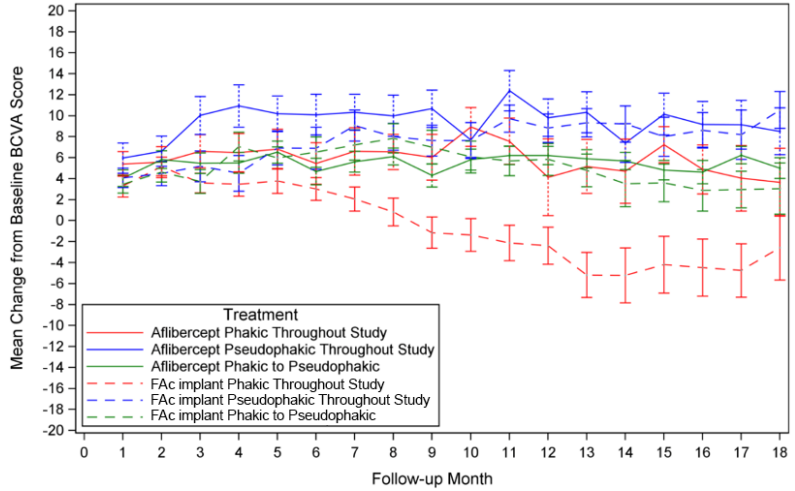
Mean Change From Baseline in BCVA Score Over 18 Months in Patients Who Did Not Meet the Prespecified Non-Inferiority Margin of 4 ETDRS Letters, ITT



Mean Change From Baseline in BCVA Over Time in Non-Rescued Patients was Comparable Between the Two Treatment Arms, ITT



Mean Change from Baseline in BCVA Score Over 18 Months by Lens Status was Comparable Between All Treatment Groups, ITT



*P-value based on difference in means at Month 18.

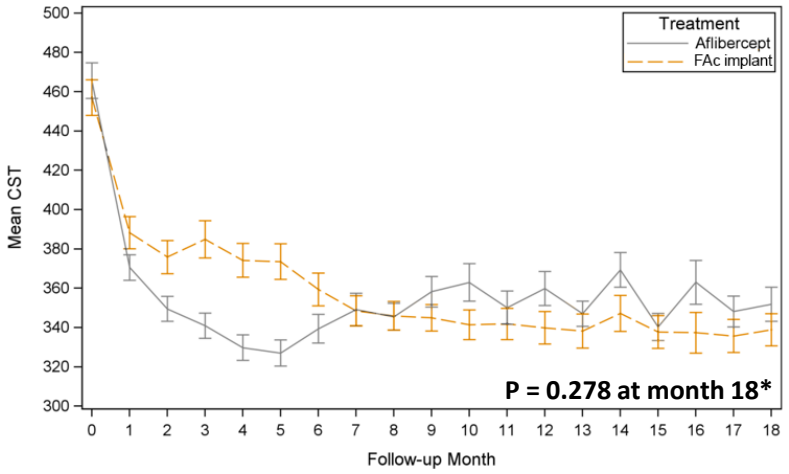
Proportion of Patients With 5, 10, and 15 Letter ETDRS Gains from Baseline, ITT

	ILUVIEN N = 122	Aflibercept N = 117	P-value*
Patients With 5 Letter ETDRS Gain from Baseline at 18 Months	41.0%	49.6%	0.182
Patients With 10 Letter ETDRS Gain from Baseline at 18 Months	23.0%	29.9%	0.222
Patients With 15 Letter ETDRS Gain from Baseline at 18 Months	11.5%	10.3%	0.762

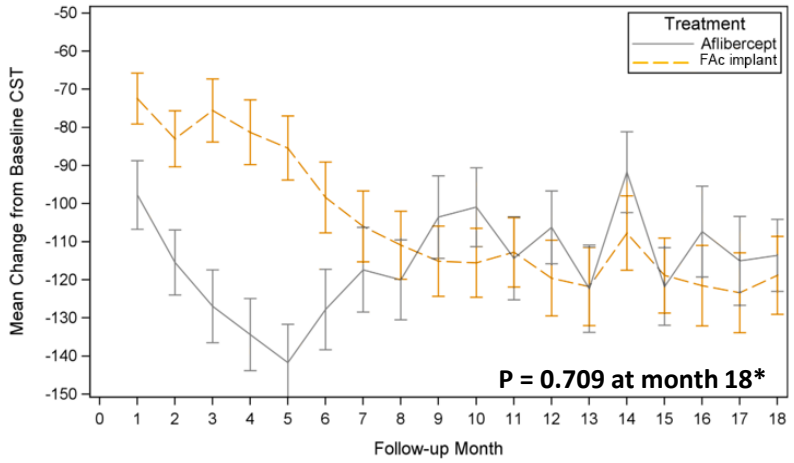
*P-value was assessed using the likelihood ratio chi-square test.

Central Subfield Thickness Results

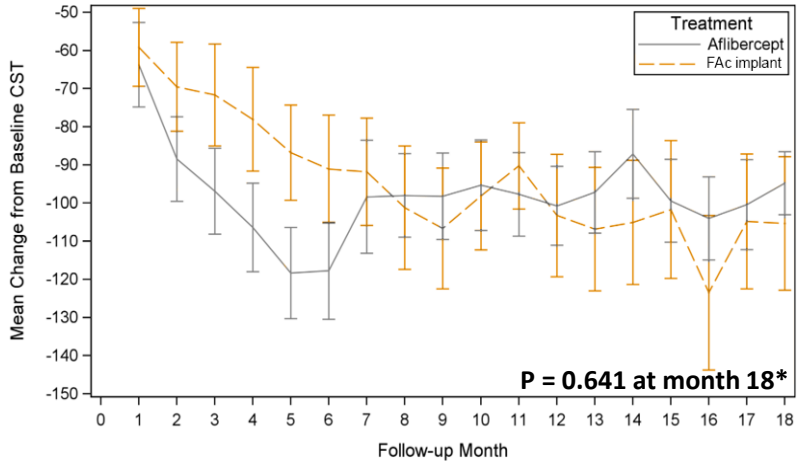
Mean CST Over 18 Months, ITT



Mean Change from Baseline in CST Over 18 Months, ITT



Mean Change from Baseline in CST Over 18 Months in Non-Rescued Patients, ITT



*_P_-value based on difference in means at Month 18.

Overall Safety Summary

	ILUVIEN N = 154	Aflibercept N = 152	Overall N = 306
Any TEAE, n (%)	136 (88.3)	115 (75.7)	251 (82.0)
Treatment-related TEAEs, n (%)	63 (40.9)	5 (3.3)	68 (22.2)
Serious TEAEs, n (%)	38 (24.7)	46 (30.3)	84 (27.5)
Serious treatment-related TEAEs, n (%)	0 (0)	0 (0)	0 (0)

Serious TEAEs With an Incidence ≥1% by System Organ Class

	ILUVIEN N = 154	Aflibercept N = 152	Overall N = 306
Patients with ≥1 TEAE, n (%)	38 (24.7)	46 (30.3)	84 (27.5)
Blood and lymphatic system disorders (overall)	1 (0.6)	1 (0.7)	2 (0.7)
Cardiac disorders (overall)	12 (7.8)	17 (11.2)	29 (9.5)
Eye disorders	1 (0.6)	0 (0.0)	1 (0.3)
Gastrointestinal disorders	1 (0.6)	1 (0.7)	2 (0.7)
General disorders and administration site conditions	3 (1.9)	1 (0.7)	4 (1.3)
Hepatobiliary disorders	0 (0.0)	1 (0.7)	1 (0.3)
Infections and infestations	15 (9.7)	17 (11.2)	32 (10.5)
Injury, poisoning, and procedural complications	6 (3.9)	3 (2.0)	9 (2.9)
Investigations	2 (1.3)	2 (1.3)	4 (1.3)
Metabolism and nutrition disorders	3 (1.9)	2 (1.3)	5 (1.6)
Musculoskeletal and connective tissue disorders	3 (1.9)	0 (0.0)	3 (1.0)
Neoplasms benign, malignant, and unspecified (including cysts and polyps)	2 (1.3)	1 (0.7)	3 (1.0)
Nervous system disorders	4 (2.6)	14 (9.2)	18 (5.9)
Psychiatric disorders	1 (0.6)	1 (0.7)	2 (0.7)
Renal and urinary disorders	7 (4.5)	5 (3.3)	12 (3.9)
Reproductive system and breast disorders	1 (0.6)	0 (0.0)	1 (0.3)
Respiratory, thoracic, and mediastinal disorders	6 (3.9)	7 (4.6)	13 (4.2)
Skin and subcutaneous tissue disorders	2 (1.3)	2 (1.3)	4 (1.3)
Surgical and medical procedures	1 (0.6)	0 (0.0)	1 (0.3)
Vascular disorders	4 (2.6)	2 (1.3)	6 (2.0)

Only specific TEAEs with an incidence ≥1% are shown in the above table.

Ocular TEAEs by System Organ Class

	ILUVIEN N = 154	Aflibercept N = 152	Overall N = 306
Patients with one or more treatment-emergent adverse events related to study treatment, n (%)	63 (40.9%)	5 (3.3%)	68 (22.2%)
Eye disorders	56 (36.4%)	4 (2.6%)	60 (19.6%)
Borderline glaucoma	1 (0.6%)	0 (0.0%)	1 (0.3%)
Cataract	46 (29.9%)	1 (0.7%)	47 (15.4%)
Cataract subcapsular	4 (2.6%)	0 (0.0%)	4 (1.3%)
Conjunctival hemorrhage	2 (1.3%)	0 (0.0%)	2 (0.7%)
Corneal abrasion	1 (0.6%)	0 (0.0%)	1 (0.3%)
Endophthalmitis	0 (0.0%)	1 (0.7%)	1 (0.3%)
Eye hemorrhage	0 (0.0%)	1 (0.7%)	1 (0.3%)
Eye pruritus	1 (0.6%)	0 (0.0%)	1 (0.3%)
Glaucoma	2 (1.3%)	0 (0.0%)	2 (0.7%)
Keratitis	1 (0.6%)	0 (0.0%)	1 (0.3%)
Ocular hypertension	6 (3.9%)	0 (0.0%)	6 (2.0%)
Vitreous floaters	1 (0.6%)	1 (0.7%)	2 (0.7%)
General disorders and administration site conditions	2 (1.3%)	0 (0.0%)	2 (0.7%)
Injection site pain	1 (0.6%)	0 (0.0%)	1 (0.3%)
Ocular implant exposure	1 (0.6%)	0 (0.0%)	1 (0.3%)
Investigations	12 (7.8%)	1 (0.7%)	13 (4.2%)
Intraocular pressure increased	12 (7.8%)	1 (0.7%)	13 (4.2%)

No retinal detachments or endophthalmitis in ILUVIEN arm

Safety: Patients With an IOP Increase

	ILUVIEN N = 154	Aflibercept N = 152
Patients that experienced any IOP increase event, n (%)	24 (15.6)	5 (3.3)
IOP increase event description, n (%) Change in IOP ≥10 mmHg from baseline IOP ≥25 mmHg IOP ≥35 mmHg	 4 (2.6) 17 (11.0) 3 (1.9)	 1 (0.7) 4 (2.6) 0 (0.0)

Safety: Patients Who Underwent IOP Lowering Laser Therapy and Surgery

	ILUVIEN N = 154	Aflibercept N = 152	Overall N = 306
Any laser and incisional IOP-lowering interventions during study, n (%)	7 (4.5)	2 (1.3)	9 (2.9)
Laser (SLT and PI)	4 (2.6)	2 (1.3)	6 (2.0)
Incisional surgery	3 (1.9)	0	3 (1.0)

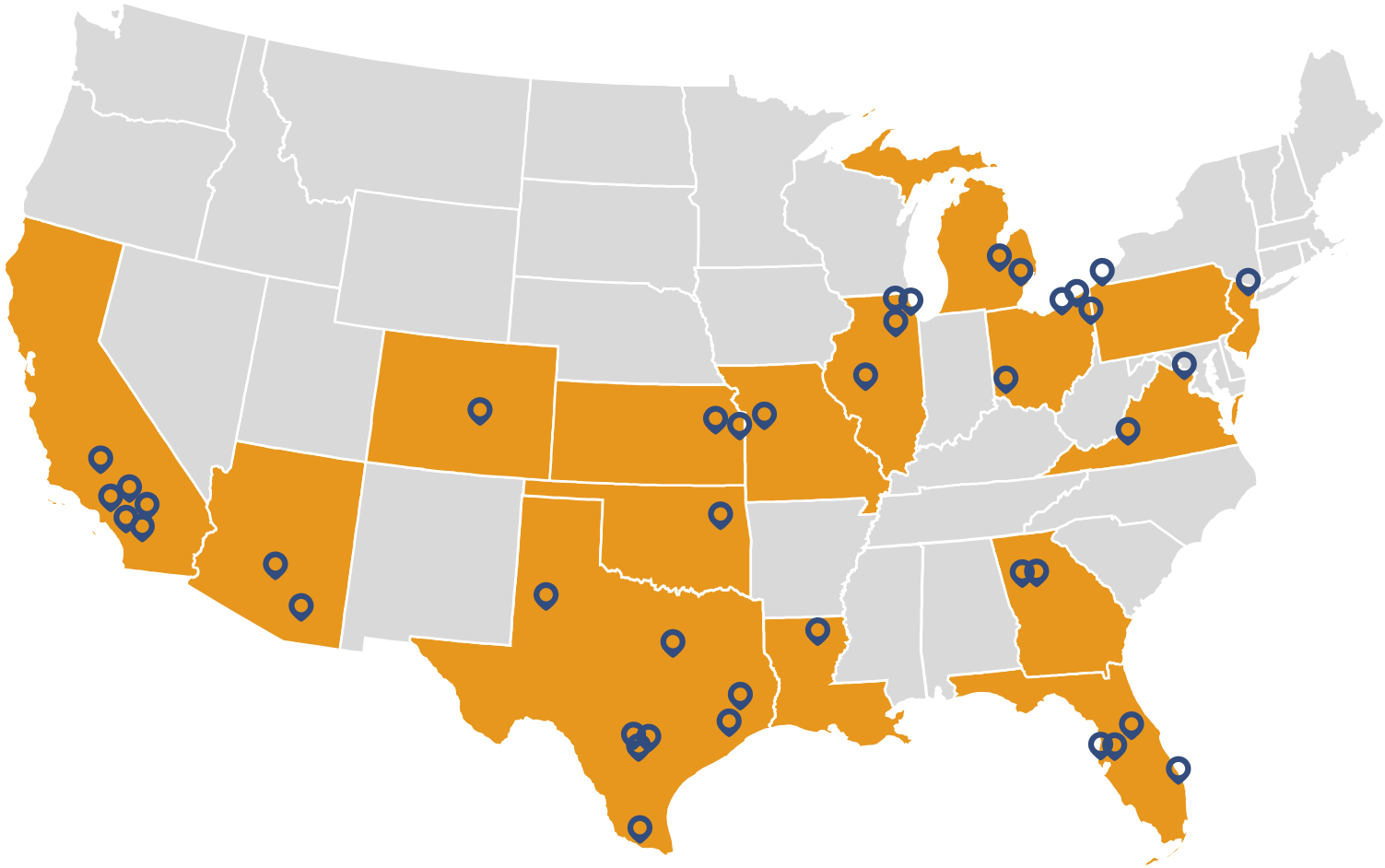
NEW DAY Clinical Trial Summary

Primary Endpoint, ITT	**Mean number of supplemental aflibercept injections:** Results favored the ILUVIEN arm, but the difference was not statistically significant (2.4 vs. 2.5 injections, p=0.756) and therefore the endpoint was not met (N=154 in ILUVIEN arm, N=152 in aflibercept arm)
Secondary Endpoints, ITT	• Statistically significant increase in mean time from last treatment injection to first supplemental injection of 185.4 vs. 132.8 days (p<0.001, N=154 in ILUVIEN arm, N=152 in aflibercept arm) • Visual acuity and anatomic changes demonstrated non-inferiority between both arms • ~1/3 of the patients to remain free of supplemental injections in both arms • Showed similar safety rates in terms of cataract and IOP as previous FAc implant studies with no retinal detachments or endophthalmitis
Per-Protocol Population, PP	• Results demonstrated a statistically significant difference in mean number of supplemental aflibercept injections in favor of the ILUVIEN arm (1.8 vs. 2.5 injections, p=0.029, N=128 in ILUVIEN arm, N=134 in aflibercept arm) ○ Lower total number of aflibercept injections needed (2.8 vs. 7.5 injections)

Closing Remarks

Thank You to All the NEW DAY Study Sites and Patients

306 eyes across 42 sites in the United States



Questions and Answers