

ReachMD
**Treating Severe Eosinophilic Asthma Patients with Frequent Exacerbations
with Comorbid Atopic Status**

Nucala 
(mepolizumab)
Injection 100 mg/mL



*The Autoinjector is for
patients aged ≥12 years.*

INDICATION

- NUCALA is indicated for the add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype. NUCALA is not indicated for the relief of acute bronchospasm or status asthmaticus

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- NUCALA should not be administered to patients with a history of hypersensitivity to mepolizumab or excipients in the formulation.

Please see Important Safety Information for NUCALA throughout this video.
Please see full Prescribing Information, including Patient Information, at NUCALAHCP.com.

Announcer:

NUCALA is indicated for the add-on maintenance treatment of patients 6 years and older with severe eosinophilic asthma.

NUCALA is not for relief of acute bronchospasm or status asthmaticus.

NUCALA should not be used in patients with a history of hypersensitivity to mepolizumab or its formulations.

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IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

- Hypersensitivity reactions (eg, anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash) have occurred with NUCALA (mepolizumab). These reactions generally occur within hours of administration but can have a delayed onset (ie, days). If a hypersensitivity reaction occurs, discontinue NUCALA.

Acute Asthma Symptoms or Deteriorating Disease

- NUCALA should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

Opportunistic Infections: Herpes Zoster

- In controlled clinical trials, 2 serious adverse reactions of herpes zoster occurred with NUCALA compared to none with placebo. Consider vaccination if medically appropriate.

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Hypersensitivity reactions including anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, and rash have occurred. These generally occur within hours of administration but can have a delayed onset. If a hypersensitivity reaction occurs, discontinue NUCALA.

NUCALA should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

In controlled clinical trials, 2 serious adverse reactions of herpes zoster occurred with NUCALA compared to none with placebo. Consider vaccination if medically appropriate.

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IMPORTANT SAFETY INFORMATION (cont.)

WARNINGS AND PRECAUTIONS (cont.)

Reduction of Corticosteroid Dosage

- Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with NUCALA. Decreases in corticosteroid doses, if appropriate, should be gradual and under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection

- Treat patients with pre-existing helminth infections before initiating therapy with NUCALA. If patients become infected while receiving NUCALA and do not respond to anti-helminth treatment, discontinue NUCALA until infection resolves.

Additional important safety information, including adverse reactions, is presented later in this presentation.

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Do not discontinue systemic or inhaled corticosteroids abruptly when initiating NUCALA. Appropriate decreases in corticosteroid doses should be gradual and healthcare-provider supervised. Reduction in corticosteroid dose may be associated with withdrawal symptoms and/or unmask conditions previously suppressed by corticosteroid therapy.

Treat patients with pre-existing parasitic infections before initiating NUCALA. If patients become infected while receiving NUCALA and do not respond to anti-parasitic treatment, discontinue NUCALA until infection resolves.

Additional important safety information, including adverse reactions, is presented later in this presentation.

Dr. Eghrari-Sabet:

The number one thing I want to do for my patients with severe eosinophilic asthma is to help them have less asthma attacks, or exacerbations.

Hello, my name is Dr. Jacqueline Eghrari-Sabet, and I am a practicing allergist. Today I'm going to talk to you about Treating Severe Eosinophilic Asthma Patients With Frequent Exacerbations and Comorbid Atopic Status.

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Chris R.
Severe eosinophilic asthma with frequent exacerbations and comorbid atopic status
37 years old
5 ft 11 in, 192 lb
Diagnosed with asthma at age 16

Medical History and Report

Current Medications

High-dose ICS/LABA + LAMA + LTRA, nasal steroid, albuterol as needed

Exacerbation History

3 exacerbations in past year (outpatient, treated with high-dose OCS)

Comorbidities

Allergic rhinitis; chronic sinus congestion; atopic status: positive (prior SCIT)

Patient Report

Persistent dyspnea, intermittent wheezing, frequent awakenings

Symptoms limit exercise and social activity

Frequent use of rescue inhaler

Spirometry

FEV₁: 64% predicted

FEV₁/FVC ratio: 0.71

Laboratory Assessment

CBC with differential

Eosinophil count: 376 cells/ μ L

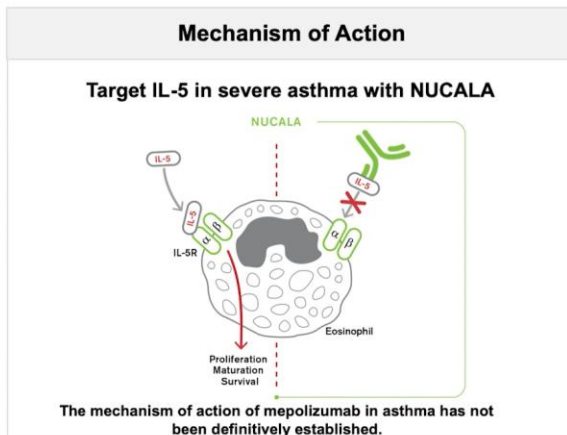
Total IgE 392 kU/L

CBC=complete blood count; FVC=forced vital capacity; LABA=long-acting beta₂-adrenergic agonist;
LAMA=long-acting muscarinic antagonist; LTRA=leukotriene receptor antagonist; SCIT=subcutaneous immunotherapy.

Let's start with Chris. He's a severe eosinophilic asthma patient like those I see so frequently in my office. He's 37-years-old at 5'11" and 192 lbs. And like so many of my patients, he was diagnosed with asthma early on in life, at age 16. Right now, Chris is on high-dose inhaled corticosteroids and a LABA, as well as other controller medications. He's using his albuterol as needed, but what we'll see later is, it's pretty frequent. He's had at least three exacerbations in the past year and all of them have been treated with high-dose oral corticosteroids. He has allergic rhinitis. He's actually been on allergy shots before. He's certainly atopic. He has a lot of sinus congestion. He reports persistent dyspnea, intermittent wheezing, frequent awakenings at night. His symptoms limit his exercise and his social activity. In short he's a long-time asthmatic on maximum doses of medication who keeps having these exacerbations. So, what can we do for Chris?

I'd like to introduce you to an option called NUCALA for severe eosinophilic asthma.

NUCALA, an IL-5 antagonist for severe eosinophilic asthma



- NUCALA is an interleukin 5 (IL-5) antagonist (IgG1 kappa)
- NUCALA binds to IL-5 and blocks its binding to the alpha chain of the IL-5 receptor complex on the eosinophil cell surface
 - This inhibits IL-5 signaling and reduces the production and survival of eosinophils

NUCALA reduced blood eosinophil level by 74% within 48 hours^{1*}

Results are descriptive. The clinical significance of these pharmacodynamic data is unknown.

* Data based on mepolizumab IV 75 mg (n=10) at first measurement post-dose from a phase 2 study in 70 adult patients with asthma and blood eosinophil counts ≥ 200 cells/ μ L (mean baseline blood eosinophils: 348 cells/ μ L).^{1,2} Blood eosinophil reduction data based on geometric mean. IV=intravenous.
References: 1. Data on file, GSK. 2. Pouliquen LJ, et al. *Int J Clin Pharmacol Ther*. 2015;53(12):1015-1027.

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NUCALA is an interleukin-5 antagonist. You can see here that it binds to IL-5 and it blocks its binding to the alpha chain of the IL-5 receptor complex.

By doing so, it inhibits the signaling of IL-5 and reduces the production and survival of eosinophils.

In fact, in a Phase 2 study, eosinophil levels decreased by 74% as quickly as 48 hours.

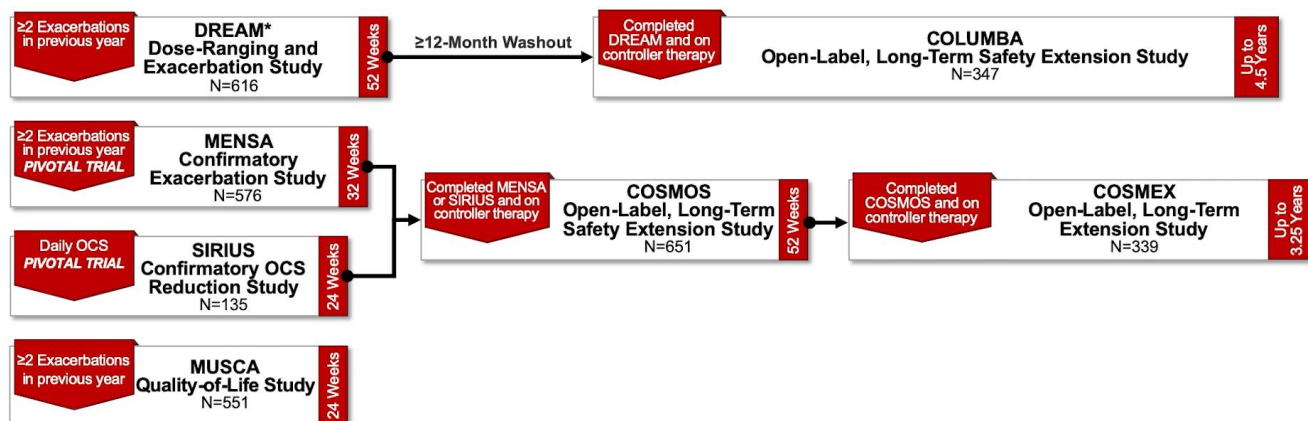
The clinical significance of these pharmacodynamic data is unknown.

So, now let's take a look at the clinical trials for NUCALA.

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Overview of Comprehensive Phase 3 Clinical Program With NUCALA¹⁻⁷



* Evaluated mepolizumab IV (75, 250, or 750 mg).

References: 1. Pavord ID, et al. *Lancet*. 2012;380(9842):651-659. 2. Ortega HG, et al. *N Engl J Med*. 2014;371(13):1198-1207. 3. Chupp GL, et al. *Lancet Respir Med*. 2017;5(5):390-400. 4. Bel EH, et al. *N Engl J Med*. 2014;371(13):1189-1197. 5. Lugogo N, et al. *Clin Ther*. 2016;38(9):2058-2070. 6. Khatri S, et al. *J Allergy Clin Immunol*. 2019;143(5):1742-1751. 7. Data on file, GSK.

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As you can see, there's a robust Phase 3 program. Confirmatory exacerbations and oral corticosteroid reduction studies, a quality-of-life study, and open-label long-term extension studies.

But today we're going to focus specifically on those exacerbation and safety studies. I'd like to draw your attention to both MENSA, which is a confirmatory exacerbation study, and COLUMBA, an open-label, long-term safety study.

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MENSA: Study Design^{1,2}



Select Inclusion Criteria

- Blood eosinophil count ≥ 150 cells/ μ L at baseline or ≥ 300 cells/ μ L within the last 12 months
- ≥ 2 exacerbations* in previous year
- Patients aged ≥ 12 years



Background Therapy

High-dose ICS[†] plus an additional controller(s) with or without OCS



Treatment Arms (every 4 weeks)

- Mepolizumab 75 mg IV + placebo SC
- NUCALA 100 mg SC + placebo IV
- Placebo IV + placebo SC

All patients remained on their existing maintenance asthma therapy standard of care (SOC) throughout the trial.

* Defined as worsening of asthma that required use of oral/systemic corticosteroids and/or hospitalization and/or ED visits; for patients on maintenance oral/systemic corticosteroids, exacerbations were defined as requiring at least double the existing maintenance dose for ≥ 3 days.

[†] Defined as ≥ 880 μ g of FP, or the equivalent, per day in patients aged ≥ 18 years, and ≥ 440 μ g of FP, or the equivalent, per day in patients aged 12-17.

ED=emergency department.

References: 1. Ortega HG, et al. *N Engl J Med*. 2014;371(13):1198-1207. 2. Data on file, GSK.

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The patients in the MENSA study had at least two exacerbations in the previous year. And you'll remember that Chris had three.

And just like Chris, patients were on standard of care, including high-dose inhaled corticosteroids and additional controllers. Some of them were even on oral corticosteroids. They also had blood eosinophil counts of at least 150 cells/ μ L at baseline, or at least 300 cells/ μ L in the past 12 months. Recall that Chris had an eosinophilic count of 376.

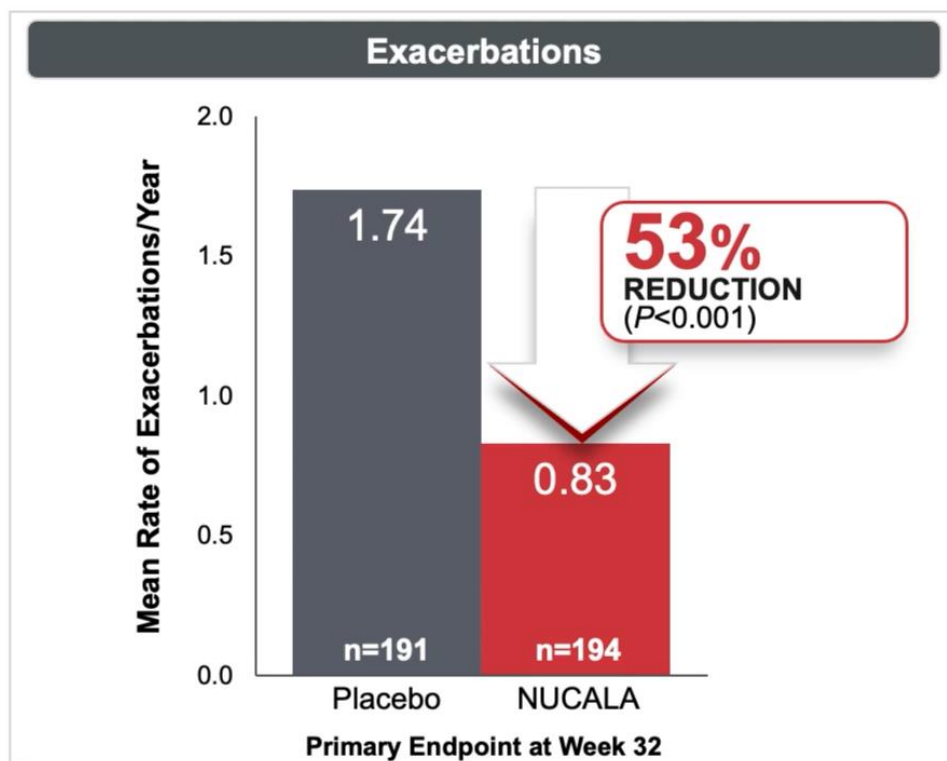
In the treatment arm for MENSA, patients either were on mepolizumab in IV form, NUCALA 100 mg SC, or on placebo, all added to their background therapy.

The results of MENSA were significant.

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Proven Protection Against Exacerbations



All patients remained on their existing maintenance asthma therapy SOC throughout the trial

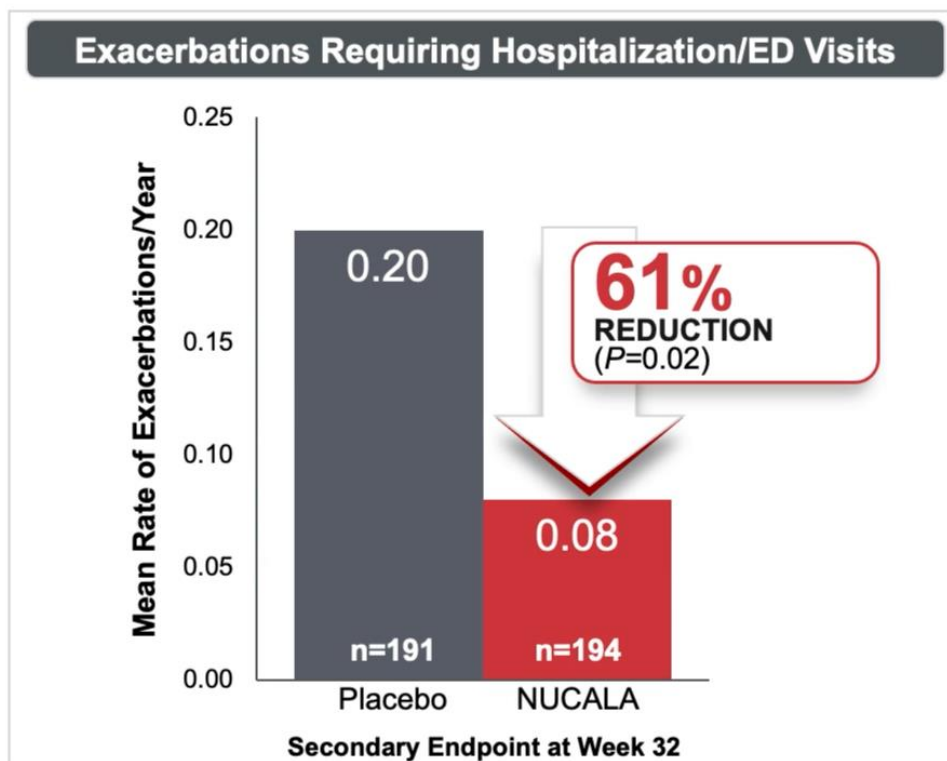
Reference: Ortega HG, et al. *N Engl J Med.* 2014;371(13):1198-1207.

NUCALA patients had a 53% reduction in their overall exacerbation rates at Week 32 compared with placebo patients.

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Proven Protection Against Exacerbations



All patients remained on their existing maintenance asthma therapy SOC throughout the trial

Reference: Ortega HG, et al. *N Engl J Med.* 2014;371(13):1198-1207.

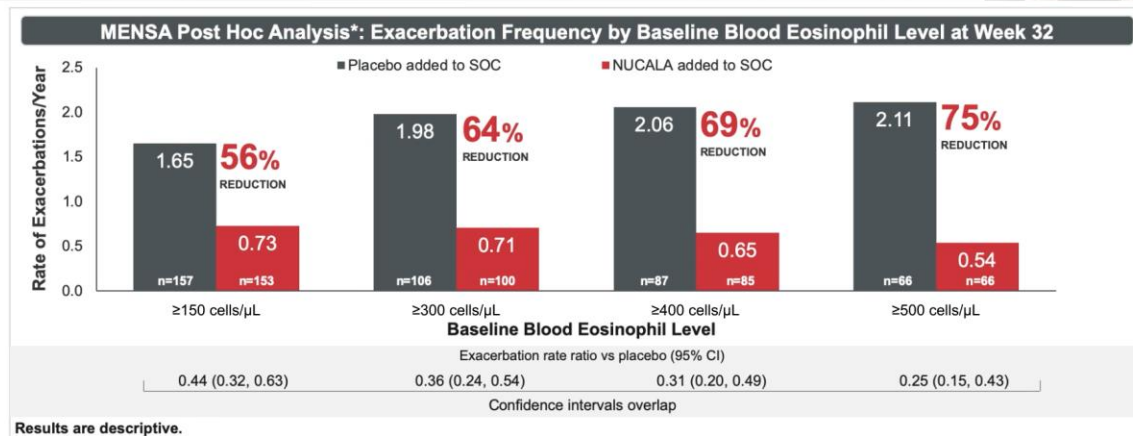
And if you look in particular at exacerbations that required hospitalizations or emergency room visits, there was a 61% reduction.

I would say that that shows powerful protection against exacerbations.

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Trend of Greater Reduction in Exacerbations With Increasing Blood Eosinophil Level^{1,2}



* The post hoc analysis assessed the relationship between baseline blood eosinophil counts and efficacy outcomes after treatment.

References: 1. Ortega HG, et al. *Lancet Respir Med*. 2016;4(7):549-556. 2. Data on file, GSK.

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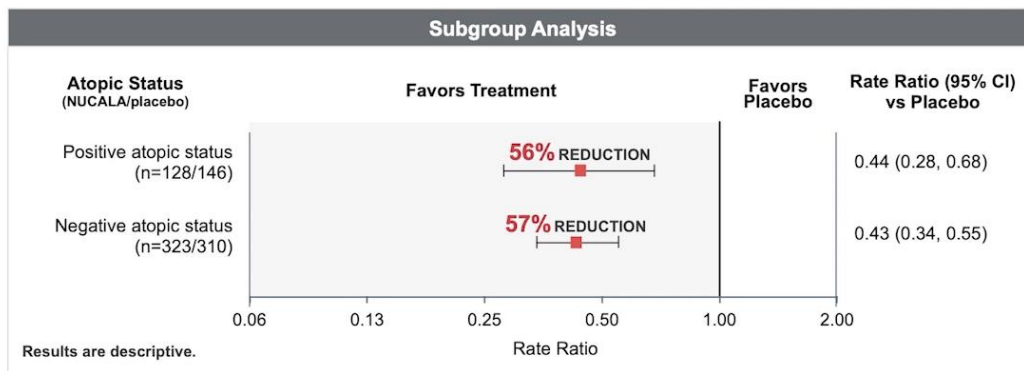
When we break that down even further, and look at the eosinophil levels in the MENSA post hoc analysis, you can see that essentially, there is a trend that the higher the eosinophil level, which ranged from at least 150, all the way up to 500 or more, the greater the reduction. In fact, those patients with 500 or more eosinophils experienced a 75% reduction in exacerbations after 32 weeks.

Chris, our patient, would've fallen into that second column; he had 300 or more, but fewer than 400. As you can see, the finding was a trend and the differences between groups was not statistically significant.

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MENSA/MUSCA Post Hoc Meta-Analysis in Patients With Severe Eosinophilic Asthma: Exacerbation Rate by Baseline Atopic Status^{1,2*}



Of the total population (N=936), 907 patients had analyzable data.

MUSCA Study Description: 24-week study comparing NUCALA 100 mg to placebo added to SOC in 551 patients aged 12 and older with severe eosinophilic asthma. Primary Endpoint Results: Mean change from baseline in St. George's Respiratory Questionnaire total score at Week 24: -15.6 for NUCALA vs -7.9 for placebo ($P<0.0001$). The improvement in both treatment arms was clinically meaningful (a reduction in score of ≥ 4 points).

MENSA/MUSCA Post Hoc Study Design: Post hoc meta-analysis in patients with severe eosinophilic asthma that evaluated annual rate of exacerbations in select subgroups.

* Positive atopic status defined as a radioallergen sorbent test (RAST) score ≥ 3 (ie, High or Very High allergic response) for any of the 5 aeroallergens (house dust mite, dog dander, cat dander, *Alternaria alternata*, cockroach).

References: 1. Humbert M, et al. *Respir Med*. 2019;154:69-75. doi.org/10.1016/j.rmed.2019.06.004. 2. Data on file. GSK.

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When we look at patients with positive atopic status, just like Chris, this post hoc subgroup analysis showed that this characteristic doesn't really make a difference. The treatment results are similar whether the patient's atopic status was positive or negative. NUCALA led to a reduction in exacerbation rates regardless of atopic status.

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IMPORTANT SAFETY INFORMATION (Cont.)

ADVERSE REACTIONS

MOST COMMON ADVERSE REACTIONS WITH NUCALA WITH ≥3% INCIDENCE AND MORE COMMON THAN PLACEBO REPORTED IN THE FIRST 24 WEEKS OF TRIAL 2 (MENSA) AND TRIAL 3 (SIRIUS)

Adverse Reaction	NUCALA (n=263), %	Placebo (n=257), %
Headache	19	18
Injection site reaction	8	3
Back pain	5	4
Fatigue	5	4
Influenza	3	2
Urinary tract infection	3	2
Abdominal pain upper	3	2
Pruritus	3	2
Eczema	3	<1
Muscle spasms	3	<1

Systemic Reactions, including

Hypersensitivity Reactions: In 3 clinical trials, the percentages of subjects who experienced systemic (allergic and nonallergic) reactions were 3% for NUCALA and 5% for placebo. Manifestations included rash, flushing, pruritus, headache, and myalgia. A majority of the systemic reactions were experienced on the day of dosing.

Injection site reactions (eg, pain, erythema, swelling, itching, burning sensation) occurred in subjects treated with NUCALA.

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The most common adverse reactions with NUCALA with an incidence of 3% or more, and more common than the placebo reported in the first 24 weeks of MENSA and SIRIUS are shown in this table and they include: Headache, injection site reaction, back pain, fatigue, influenza, urinary tract infection, upper abdominal pain, pruritus, eczema, and muscle spasms.

In 3 clinical trials, 3% of subjects who received NUCALA experienced systemic reactions, allergic and nonallergic, compared to 5% in the placebo group. Manifestations included rash, flushing, pruritus, headache, and myalgia, and a majority of these were experienced on the date of dosing.

Note that the patients receiving NUCALA experienced more injection site reactions than the placebo group.

So, let's look at the Use in Specific Populations.

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IMPORTANT SAFETY INFORMATION (cont.)

USE IN SPECIFIC POPULATIONS

- A pregnancy exposure registry monitors pregnancy outcomes in women exposed to NUCALA during pregnancy. To enroll call 1-877-311-8972 or visit www.mothersbaby.org/asthma.
- The data on pregnancy exposures are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as mepolizumab, are transported across the placenta in a linear fashion as the pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimesters.

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Pregnant women were excluded from the studies, and women of childbearing age were required to use effective birth control. Keep in mind that monoclonal antibodies do cross the placenta, particularly in the second and third trimesters.

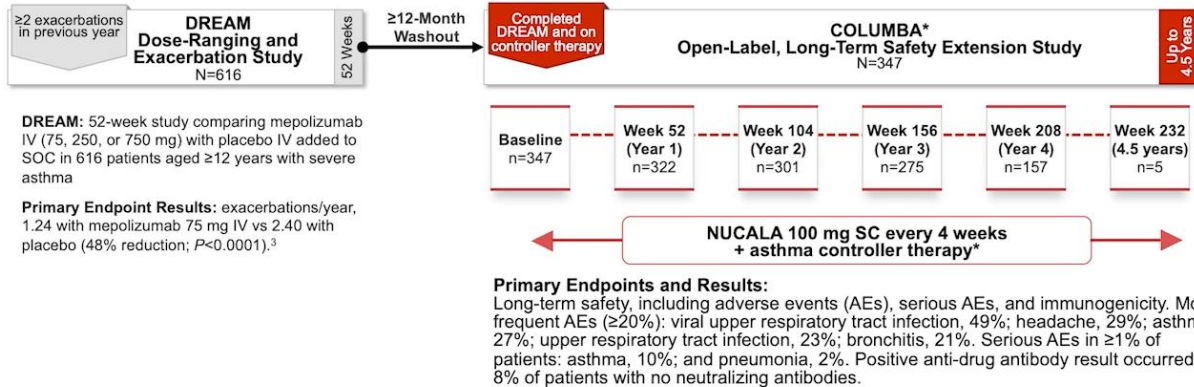
If you have a patient who becomes pregnant while taking NUCALA or after she stops taking NUCALA, please consider enrolling her into the mothersbaby.org website so that the third party administering this observational study can gather safety information that may be useful to future patients receiving NUCALA.

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COLUMBA: Study Design

Long-Term Safety Study up to **4.5 Years** (median duration, 3.8 years)¹⁻³



In COLUMBA, the long-term (up to 4.5 years) safety and immunogenicity profile of NUCALA was similar to controlled asthma trials

* Patients continued in COLUMBA until a protocol-defined stopping criterion was met.

References: 1. Data on file, GSK. 2. Khatri S, et al. *J Allergy Clin Immunol*. 2019;143(5):1742-1751. 3. Pavord ID, et al. *Lancet*. 2012;380(9842):651-659.

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Well, let's look at another study.

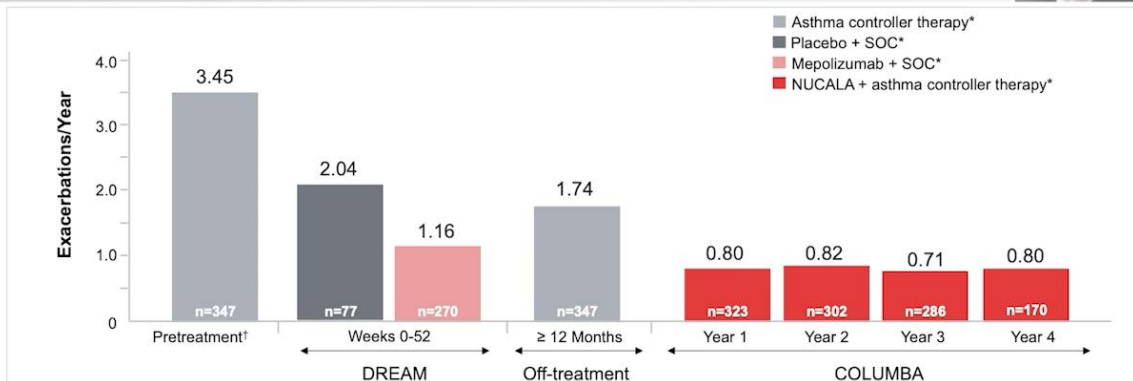
This is COLUMBA, a long-term safety study that looked at patients for up to 4-1/2 years. How patients got into COLUMBA is really interesting. They started with a study called DREAM, a year-long study that looked at the use of mepolizumab IV. The 616 patients in DREAM had to have at least two exacerbations in the previous year. They were treated with an add-on mepolizumab IV or placebo for 52 weeks. After at least a 12-month washout, eligible patients were enrolled in COLUMBA and received NUCALA added to their asthma controller therapy. 347 patients were followed for a 4.5-year period of this study.

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Lasting Exacerbation Rate Observed for 4 Years

Post Hoc Analysis: Exacerbation Rate by Year^{1,2}



All results are descriptive. Results should be interpreted with additional care, as results in the latter stages of the COLUMBA trial are based on fewer patients (due to attrition) compared with the first 2 to 3 years.

COLUMBA: Select Secondary Endpoints

Annualized exacerbation rate: 0.68 (95% CI: 0.60, 0.78).

Mean change in ACQ-5 score from baseline: -0.47 points at Week 12 and end of study.

Mean change in pre-bronchodilator FEV₁ from baseline: 124 mL at week 12; gradually declined to approximate baseline values at end of study.

* DREAM: ≥880 µg of FP, or equivalent, per day; COLUMBA: required to be on ≥1 asthma controller medication for ≥12 weeks prior to study start.

[†] Pretreatment refers to the 12 months prior to enrollment in DREAM.

References: 1. Khatri S, et al. *J Allergy Clin Immunol*. 2019;143(5):1742-1751. 2. Data on file, GSK.

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This post hoc analysis looked at exacerbation rates over those four years.

Patients began the DREAM study with an average of 3.45 exacerbations in the previous year. And you'll remember that Chris, our patient, was similar. He had three exacerbations.

In the DREAM study, the patients that were on mepolizumab went down to 1.16 exacerbations compared to 2.04 in patients taking placebo.

After that washout period, patients began COLUMBA with an average of 1.74 exacerbations in the previous year. That 1.74 exacerbation rate dropped down to about half, 0.8 at Year 1, and stayed down over the next 4 years.

As a reminder, these results are part of a post hoc analysis of the open-label study. Also keep in mind that over the course of the study, fewer patients remained in the study, so results should be reviewed in that way.

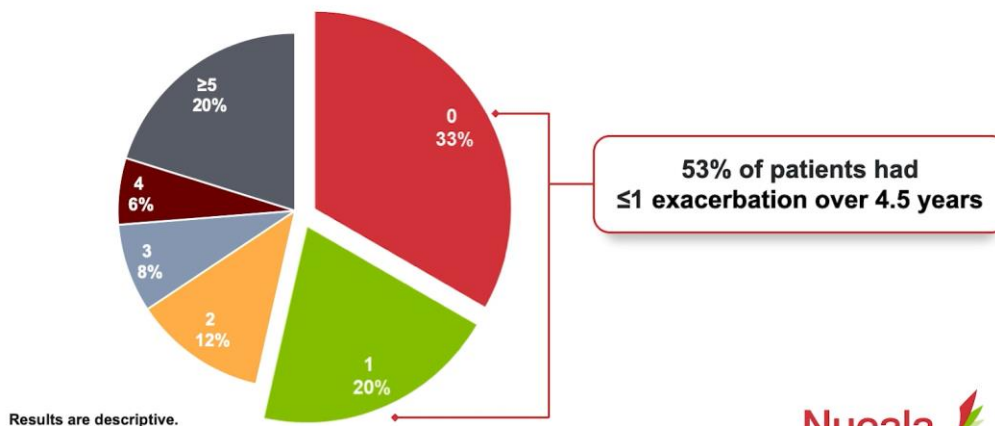
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A Third of Patients Had Zero Exacerbations Over the 4.5-Year Study



COLUMBA: Number of Exacerbations*
All Patients, N=347



* Based on exacerbations reported from the time a patient enrolled in COLUMBA until study withdrawal.

Reference: Data on file, GSK.

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Looking at the study another way, on a pie chart, it shows that 53% of patients had one or less exacerbations over that 4-1/2 years. And a third of the patients had zero exacerbations over 4-1/2 years. Remember again, these patients came in at the very beginning of the DREAM study with more than three exacerbations per year. Imagine what that may mean to patients like Chris.

NUCALA: Power to Choose



 **AT HOME**
Autoinjector



 **IN OFFICE**
Lyophilized Powder

NUCALA Autoinjector: easy to use¹

9 OF 10

patients with severe eosinophilic asthma found the Autoinjector very or extremely easy to use

99%

of patients with severe eosinophilic asthma successfully used the Autoinjector

The NUCALA Autoinjector and prefilled syringe are only for use in patients ≥12 years of age.

Study Description: 12-week, open-label study assessed the correct use of the NUCALA Autoinjector in patients aged ≥12 years with severe eosinophilic asthma (N=104). NUCALA 100-mg was administered SC every 4 weeks by patient or caregiver after training on proper technique at baseline. Successful use was determined by investigator observation using a checklist of steps based on Instructions for Use and inspection of the Autoinjector after the third dose. Ease of use was measured on a 5-point scale (not at all, a little, moderately, very, and extremely) at study end in the 102 patients with successful use.

Reference: 1. Bernstein D, et al. [published online ahead of print, June 28, 2019]. *J Asthma*. doi.org/10.1080/02770903.2019.1630641.

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If he wanted to inject NUCALA at home and his doctor agreed, I'd talk to Chris about how so many patients found the Autoinjector easy to use and train him how to inject it. Of course, he would have the option of coming into the office and getting his injection there.

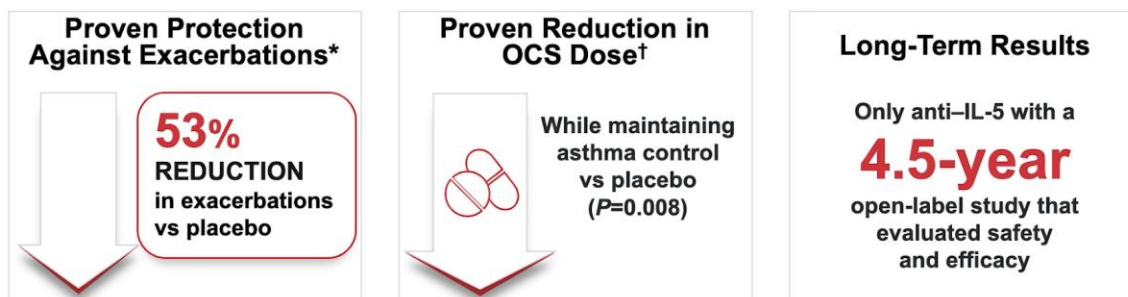
The NUCALA Autoinjector and prefilled syringes are only for use in patients 12 years of age or older.

I think it's so important that we explain to our patients about what results have been seen in these studies.

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Prescribe NUCALA With Confidence for Severe Eosinophilic Asthma¹⁻³



*MENZA (Trial 2): 53% reduction vs placebo (0.83/year vs 1.74/year respectively; $P<0.001$).

†SIRIUS (Trial 3): 24-week study comparing NUCALA 100 mg to placebo in 135 patients with severe eosinophilic asthma receiving prednisone 5-35 mg (or equivalent) per day and regular use of high-dose ICS and 1 other controller. Primary Endpoint Results: Percent reduction in daily OCS dose (Weeks 20 to 24) while maintaining asthma control vs placebo; $P=0.008$.

References: 1. Ortega HG, et al. *N Engl J Med*. 2014;371(13):1198-1207. 2. Bel EH, et al. *N Engl J Med*. 2014;371(13):1189-1197. 3. Khatri S, et al. *J Allergy Clin Immunol*. 2019;143(5):1742-1751.

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Patients experienced a 53% reduction in exacerbations. If they're on oral corticosteroids they may see a reduction in their oral corticosteroid dose. And I would suggest to a patient like Chris to imagine how he might feel over the next 4-1/2 years.

I appreciate your attention during this presentation, and I hope it's been helpful to you in treating your patients. I believe you can prescribe NUCALA with confidence in your patients with severe eosinophilic asthma.

Thank you very much.

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