

ReachMD
Treating Severe Eosinophilic Asthma Patients with Comorbid Nasal Polyps

Nucala 
(mepolizumab)
Injection 100 mg/mL



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.

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

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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.

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Dr. Fatteh:

Welcome. My name is Dr. Shahnaz Fatteh, and I'm a practicing Allergist in South Florida. Today we'll be talking about the Treatment of Severe Eosinophilic Asthma in Patients with Frequent Exacerbations and Comorbid Nasal Polyps.



Robert B.
Severe eosinophilic asthma with frequent exacerbations and comorbidities
43 years old
6 ft 1 in, 210 lb
Diagnosed with asthma at age 20

Medical History and Report

Current Medications
High-dose ICS/LABA (13 years) + LTRA (6 years), Nasal corticosteroid spray, Albuterol as needed

Exacerbation History
2 exacerbations in past year, including a hospitalization

Comorbidities
Presence of nasal polyps, history of SCIT

Patient Report
Persistent dyspnea, interferes with life; Chronic sinus congestion


Spirometry


FEV₁: 66% predicted
FEV₁/FVC ratio: 0.69

Laboratory Assessment

CBC with differential
Eosinophil count: 324 cells/μL
Total IgE: 352 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.



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So here's a patient that I might see in my office. This is Robert B., who has severe eosinophilic asthma with frequent exacerbations and comorbidities.

Robert is 43-years-old, and was diagnosed with asthma at age 20. He's on medications for severe asthma, which include: high-dose inhaled corticosteroids/a long-acting beta agonist, and has been on this combination for 13 years, as well as a leukotriene inhibitor for the past 6 years. He uses a nasal steroid spray and albuterol as needed.

In this past year, he's had two exacerbations, including a hospitalization. On physical exam, he has nasal polyps. Although he's taking his medications, his quality of life and day-to-day function is affected by severe dyspnea. He has interference with his daily activities, and chronic sinus congestion.

As we evaluate Robert, his spirometry reveals decreased lung function, with an FEV₁ of 66%; an FEV₁/FVC ratio obstructed at 69%. On laboratory assessment, his CBC differential has an eosinophil count of 324. So, he also has an IgE that's elevated at 352. So Robert is also atopic.

So, what can we do for Robert? He's already taking all these medications and still has symptoms. However, we can think about an add-on therapy: in this case, NUCALA.

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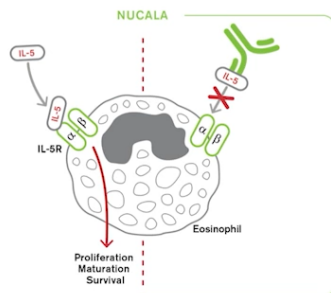
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NUCALA, an IL-5 antagonist for severe eosinophilic asthma



Mechanism of Action

Target IL-5 in severe asthma with NUCALA



The mechanism of action of mepolizumab in asthma has not been definitively established.

- 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 JJ, et al. *Int J Clin Pharmacol Ther*. 2015;53(12):1015-1027.

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So, why NUCALA? One reason is how it works. NUCALA binds to IL-5 and prevents it from binding to the alpha chain of the IL-5 receptor complex on the eosinophil cell surface.

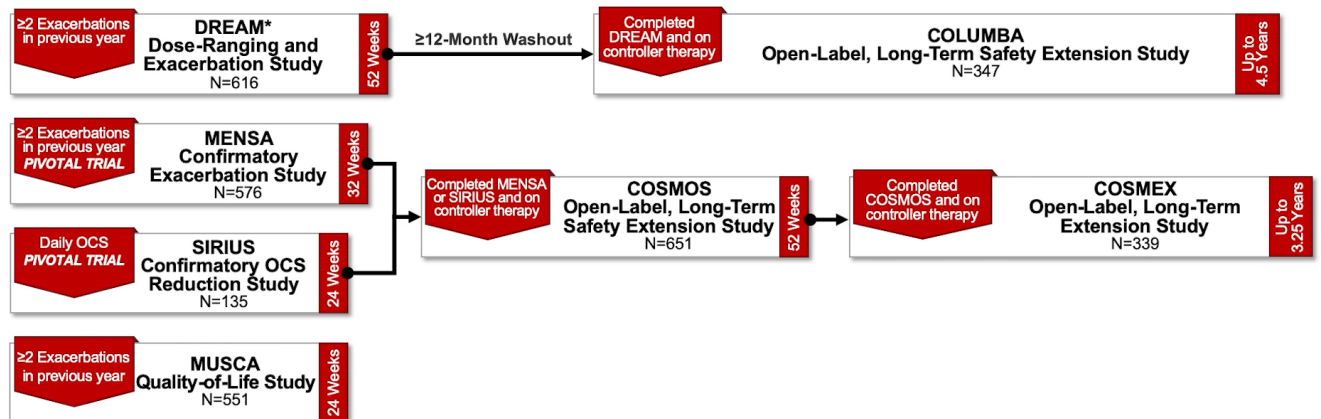
So, eosinophils need IL-5 for survival, for differentiation, maturation, and proliferation.

So by inhibiting IL-5 signaling, eosinophil counts can be reduced. In fact, in a Phase 2 study, NUCALA reduced blood eosinophil levels by 74% in 48 hours.

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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 comprehensive Phase 3 program for NUCALA: Confirmatory Exacerbations, OCS Reduction studies, a quality-of-life study, and multiple open-label long-term studies.

For Robert, we're looking for a reduction in his exacerbation rate.

The DREAM study was a dose-ranging and exacerbation study for 52 weeks.

MENSA was a pivotal confirmatory exacerbation study carried out for 32 weeks.

After at least a 12-month washout, patients from DREAM were enrolled into an open-label study, COLUMBA, which looked at the long-term safety and efficacy of NUCALA.

So, we're going to today, focus on MENSA: exacerbations — which is what Robert has had — and COLUMBA: long-term safety extension studies, to look at the safety and efficacy of NUCALA in reducing exacerbations.

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MENSA: Study Design^{1,2}



≥2 Exacerbations
in previous year
PIVOTAL TRIAL

MENSA
Confirmatory
Exacerbation Study
N=576

32 Weeks



Select Inclusion Criteria

- Blood eosinophil count ≥150 cells/μL at baseline or ≥300 cells/μL 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 μg of FP, or the equivalent, per day in patients aged ≥18 years, and ≥440 μg 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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In MENSA, a 32-week pivotal trial, patients were enrolled who had a blood eosinophil count of at least 150 cells at baseline, or at least 300 cells in the past 12 months.

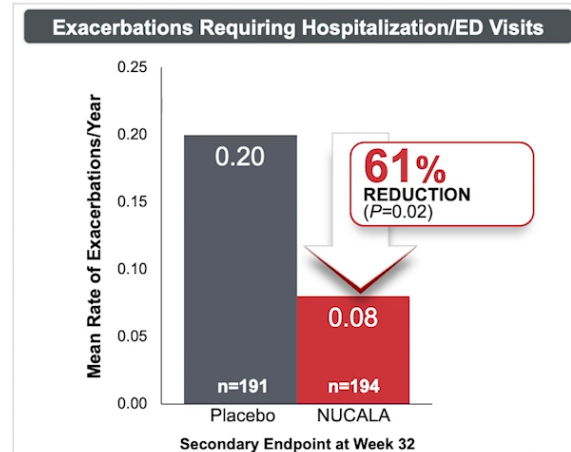
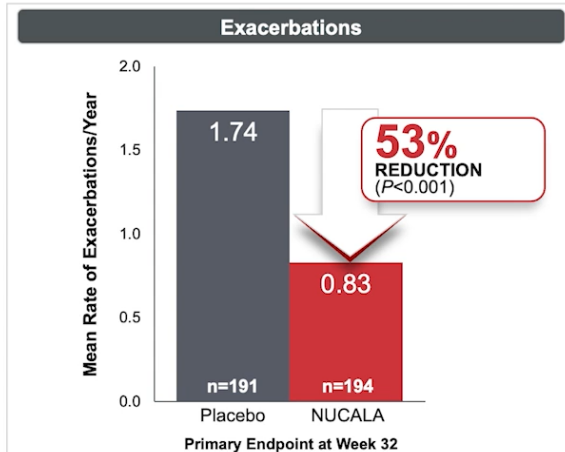
All patients were required to have two or more exacerbations, and they were on standard of care medications, including — like Robert — high-dose inhaled corticosteroids and additional controllers. They may have also been on oral corticosteroids.

Recall that Robert had a blood eosinophil count of 324, and a history of two exacerbations and one hospitalization.

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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.

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The exacerbation rate was reduced by 53% compared to placebo at Week 32. And on a secondary endpoint, exacerbations requiring hospitalizations and emergency visits were reduced by 61%.

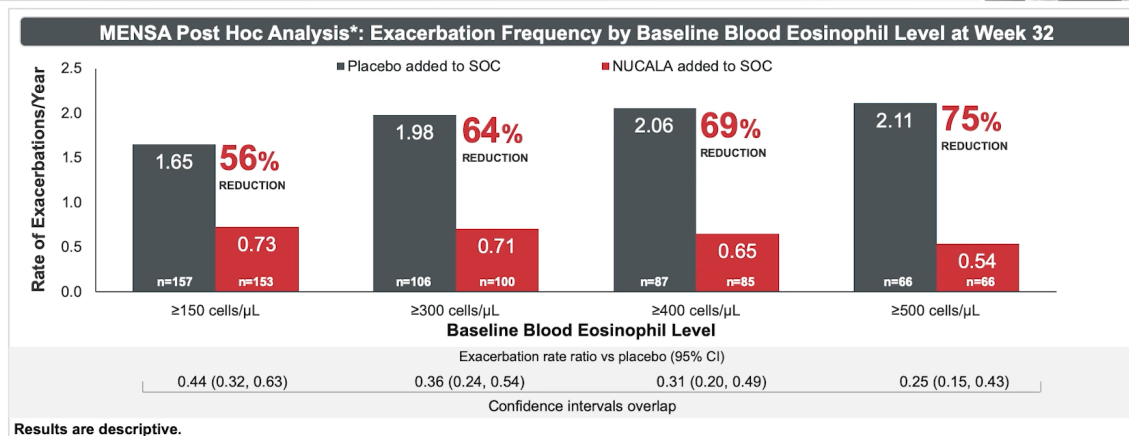
So, the important goals of reducing exacerbations and keeping patients like Robert out of the hospital and out of the emergency room were achieved.

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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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In the post hoc analysis, the higher the patient's blood eosinophil level, the greater the reduction in exacerbation rates. In fact, this trend continues all the way through to the highest eosinophil counts in the study — up to 75% reduction in patients with blood eosinophil counts of 500 or more.

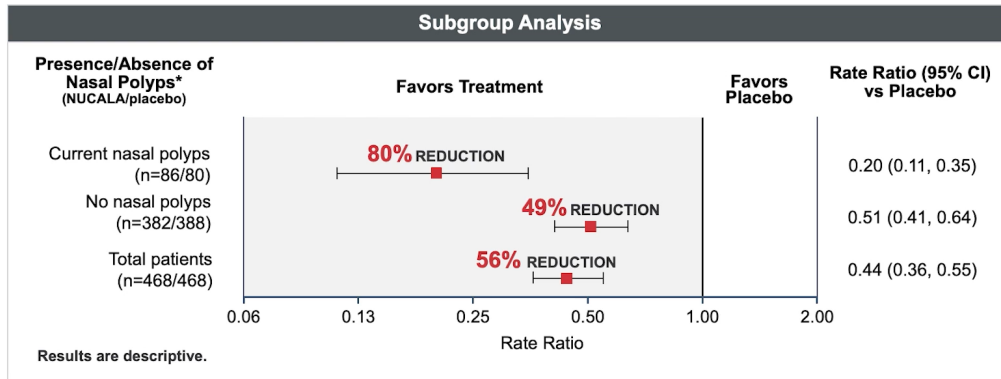
Note that the confidence intervals overlap, so the results are considered similar across the thresholds.

The MENSA and MUSCA post hoc meta-analysis in patients with severe eosinophilic asthma and nasal polyps is important.

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MENSA/MUSCA Post Hoc Meta-Analysis in Patients With Severe Eosinophilic Asthma: Exacerbation Rate by Presence of Nasal Polyps at Baseline*



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.

Mean baseline blood eosinophil levels for patients with current nasal polyps was 440 cells/ μ L; for patients with no nasal polyps at baseline, 290 cells/ μ L; and for total patients, 330 cells/ μ L.

* Nasal polyps reported by patient and assessed by investigator at baseline.

Reference: Data on file, GSK.

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The data for all patients that were enrolled in these trials and grouped by the presence or absence of nasal polyps at baseline is studied.

You can see the reduction in exacerbations.

In the total patient population, there was a 56% reduction in exacerbations versus placebo. So, reductions were seen regardless of the presence of nasal polyps.

In addition, important to note is that the mean baseline eosinophil count for patients with nasal polyps was higher at 440 cells/ μ L — higher than the mean baseline of 290 cells/ μ L for patients without nasal polyps.

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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 incidence 3% or greater, and more common than placebo reported in the first 24 weeks of MENSA and SIRIUS are shown in this table and 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 (allergic and nonallergic) reactions, compared to 5% in the placebo group. Manifestations included rash, flushing, pruritus, headache, and myalgia, and a majority of these were experienced on the first day of dosing. Also note that patients receiving NUCALA experienced more injection site reactions than the placebo group.

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Let's look at the Use in Specific Populations.



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.mothersandbabies.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 trimester.

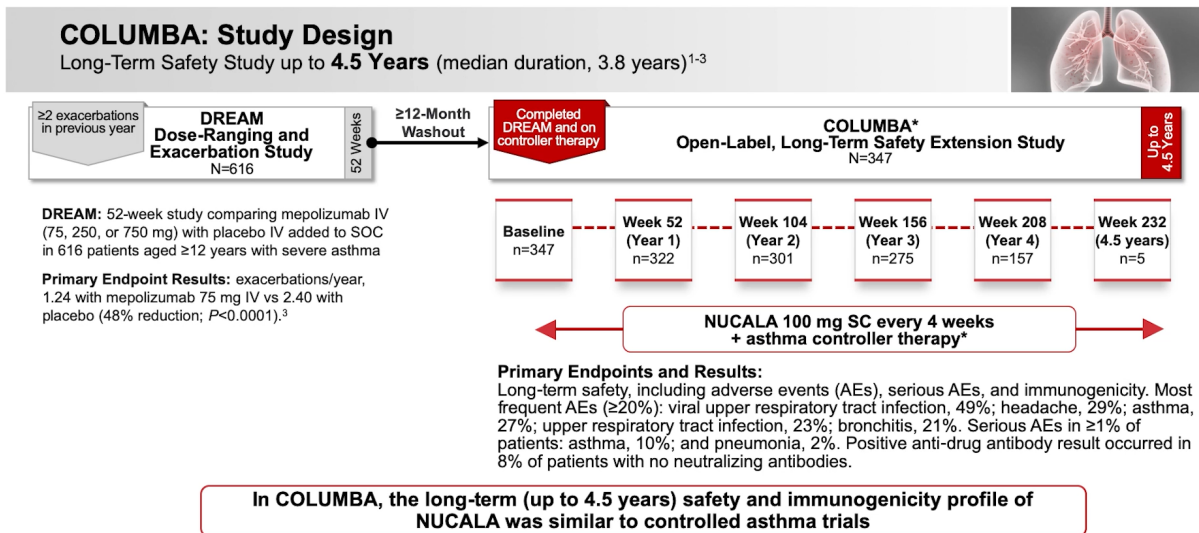
If you have a patient who becomes pregnant while taking NUCALA or after she stops using NUCALA, please consider enrolling her in the mothersandbabies.org website so that the third party administering the observational study can gather safety information that may be useful to future patients receiving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

So when we have a patient like Robert that we are thinking about putting on an add-on biologic, what are some of the things patients are concerned about in the long term? Is it safe? Is it going to continue to work? These are the types of questions that the COLUMBA study looked at. COLUMBA was a long-term safety study that looked at patients for up to 4 and 1/2 years.

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* 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.

Nucala
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Let's first look at how patients got into COLUMBA. They started with an exacerbation study called DREAM, in which 616 patients with severe asthma were enrolled. They were treated with an add-on mepolizumab IV or placebo for 52 weeks. After at least a 12-month washout, they didn't receive any medications, eligible patients then were enrolled into COLUMBA and received NUCALA added to their asthma controller therapy. Three hundred forty-seven patients were followed over this 4 and 1/2 years.

The long-term safety and immunogenicity profile of NUCALA over the 4.5 years was similar to controlled asthma trials.

So the most frequent AEs were: viral upper respiratory tract infection, headaches, asthma, upper respiratory tract infection, and bronchitis.

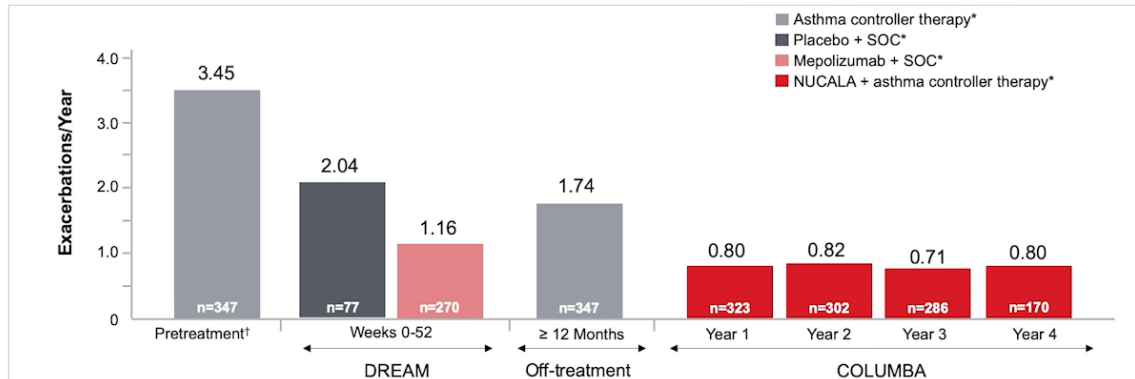
The most frequent serious AEs were worsening of asthma and pneumonia. Note that positive anti-drug antibodies occurred in 8% of patients, but with no neutralizing antibodies.

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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 ACOQ-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 four years.

Patients began the DREAM study with an average of 3.45 exacerbations. In the DREAM study, the patients that were on mepolizumab went down to 1.16 exacerbations per year, compared to 2.04 in patients taking placebo.

After the washout period, patients began COLUMBA with an average of 1.74 exacerbations. So off of mepolizumab, what happened? The rate of exacerbations increased.

Again, remember that our patient Robert had two exacerbations including a hospitalization this past year. That 1.74 exacerbation rate dropped down to about half, 0.8 at year 1, and stayed that low over 4 years.

So keep in mind that over the course of this long-term study, fewer patients remained in the study, so results should be viewed in that way.

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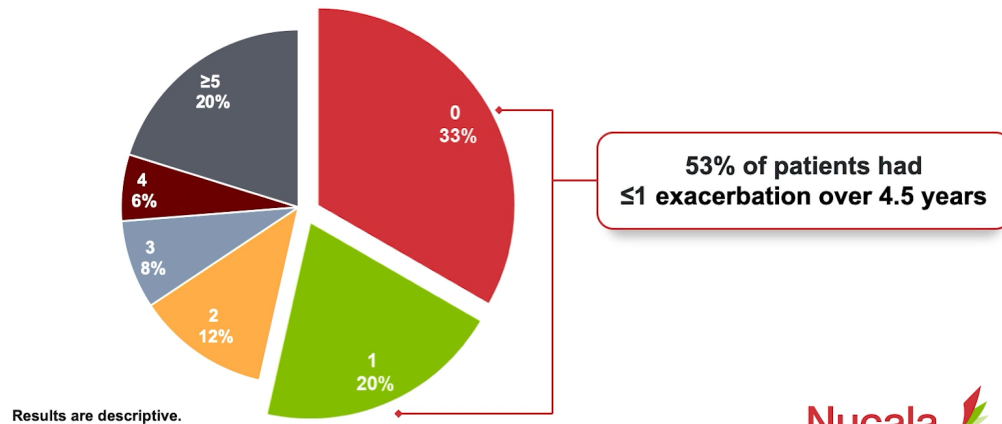
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A Third of Patients Had Zero Exacerbations Over the 4.5-Year Study



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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So, looking at the data from a different perspective, we can see that 33% of patients had zero exacerbations. And 20% had one. So, over the 4 and 1/2 years, 53% of patients had one or less exacerbation while on NUCALA.

Earlier I asked about what we could do to help our patient, Robert. I think NUCALA gives us a good option as an add-on therapy. We can share decision-making with our patients to help them determine how they would like to have NUCALA provided for them, particularly someone like Robert who lives far away from the office.

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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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NUCALA has an Autoinjector for at-home use. Looking at the data, almost all patients could successfully self-administer the Autoinjector, and found it very or extremely easy to use.

The Autoinjector and pre-filled syringe are indicated for patients 12 and older.

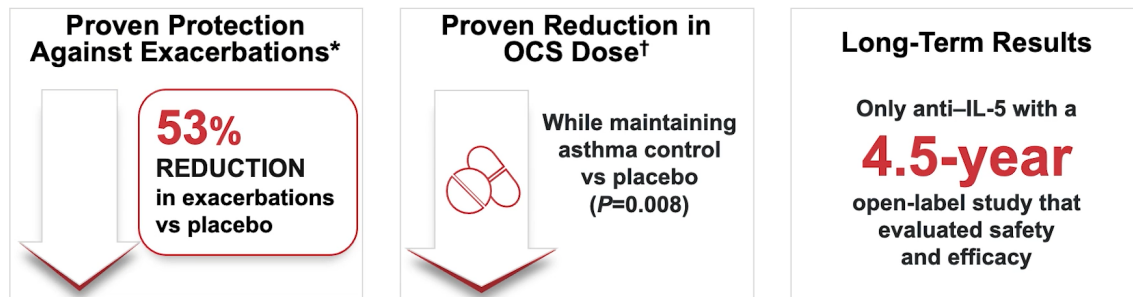
We can also give NUCALA in the office using a lyophilized powder formulation.

Now we can talk to the patient about both options and see which is more appropriate and preferred by the patient.

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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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One of the goals that we wanted to achieve with our patient, Robert, was reduction in exacerbations. The MENSA study demonstrated a 53% reduction in exacerbation.

The reduction in oral corticosteroid dosing is very important so that we can reduce OCS use while maintaining asthma control.

And the COLUMBA trial evaluated safety and efficacy, including exacerbation rates, out to 4 and 1/2 years.

I believe we can prescribe NUCALA with confidence for our patients like Robert, with severe eosinophilic asthma.

Thank you.

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