**DRAFT – PRIX GALIEN 2022**

*Please note that the sections and word limits outlined below are pre-set by Prix Galien.*

**Section 1: CATEGORY**

Category: Best Biotechnology Product

**Section 2: PRODUCT**

Drug or Device Name:Dupixent®

Compound Technical Name:*dupilumab*

Trade Name:Dupixent®

Date of Approval:

03/28/2017 for adult patients with uncontrolled moderate-to-severe atopic dermatitis;

*To be included if the entry form allows:*

10/19/2018 as an add-on maintenance treatment for patients 12 years and older with uncontrolled moderate-to-severe eosinophilic or oral steroid dependent asthma;

03/11/2019 for adolescents aged 12 to 17 years with uncontrolled moderate-to-severe atopic dermatitis;

06/26/2019 as add-on maintenance treatment for adults with uncontrolled chronic rhinosinusitis with nasal polyposis;

05/26/2020 for patients aged 6 to 11 years with uncontrolled moderate-to-severe atopic dermatitis

10/20/2021 as an add-on maintenance treatment for patients aged 6 to 11 years with uncontrolled moderate-to-severe eosinophilic or oral steroid dependent asthma

05/20/2022 for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE)

06/07/2022 for children aged 6 months to 5 years with uncontrolled moderate-to-severe atopic dermatitis.

Therapeutic Categories:

* Adult atopic dermatitis (Breakthrough Therapy designation; approved under Priority Review by FDA on March 28, 2017)
* Adolescent and adult asthma (approved by FDA on October 19, 2018)
* Adolescent atopic dermatitis (Breakthrough Therapy designation; approved under Priority Review by FDA on March 11, 2019)
* Adult chronic rhinosinusitis with nasal polyposis (approved under Priority Review by FDA on June 26, 2019)
* Pediatric atopic dermatitis (Breakthrough Therapy designation; approved for ages 6 to 11 years under Priority Review by FDA on May 26, 2020; approved for ages 6 months to 5 years on June 7, 2022)
* Pediatric asthma (approved for ages 6 to 11 years by FDA on October 20, 2021)
* Eosinophilic esophagitis (Orphan Drug designation; Breakthrough Therapy designation; approved under Priority Review for ages 12 and older by FDA on May 20, 2022)
* Prurigo nodularis (granted Priority Review by the FDA on May 31, 2022)
* Pediatric eosinophilic esophagitis (in development)
* Chronic obstructive pulmonary disease with evidence of type 2 inflammation (in development)
* Chronic spontaneous urticaria (in development)
* Chronic inducible urticaria – cold (in development)
* Bullous pemphigoid (Orphan Drug designation; in development)
* Chronic rhinosinusitis without nasal polyposis (in development)
* Allergic fungal rhinosinusitis (in development)
* Allergic bronchopulmonary aspergillosis (in development)
* Chronic pruritus of unknown origin (in development)

**Indications (300 words max); Current word count: 298**

Dupixent® (dupilumab) is a rare medicine that can treat a number of seemingly different serious diseases (previously “uncontrolled” with available medications, such as corticosteroids) including asthma, atopic dermatitis, chronic rhinosinusitis with nasal polyposis (CRSwNP), and eosinophilic esophagitis (EoE).1 Dupixent is a “first-in-class” biologic that inhibits signaling of interleukin-4 (IL-4) and interleukin-13 (IL-13).2 Its ability to successfully treat these seemingly different diseases (all of which frequently occur together and are considered “co-morbid”) proves these diseases share an underlying pathologic mechanism – i.e., type 2 inflammation driven by IL-4 and IL-13.3

The unprecedented therapeutic benefit of Dupixent in these diseases shows the major driving role for IL-4 and IL-13: in uncontrolled moderate-to-severe asthma patients (suffering frequent exacerbations with ~60% of normal lung function), Dupixent reduced asthma exacerbations by 56-81% and improved lung function by up to 33%;4 in moderate-to-severe atopic dermatitis patients, 42-75% of patients saw an overall improvement of at least 75% with Dupixent across different age groups – from infancy to adulthood;4 in uncontrolled CRSwNP patients, Dupixent improved hallmark signs and symptoms, while reducing the need for surgery by 83% and systemic corticosteroids by 75%; and in EoE, Dupixent 300 mg weekly improved signs and symptoms of eosinophilic esophagitis, with 10x as many patients on Dupixent achieving histological diseases remission.4 Moreover, patients suffering from multiple co-existing diseases had benefits across the conditions.4 Importantly, Dupixent was well tolerated without the immunosuppressive side effects common to other classes of biologics, and in many studies decreased the risk of associated infections. 4

Dupixent is in clinical trials for type 2 inflammatory-associated diseases that often co-morbidly occur with the above diseases:

* Pediatric EoE COPD with evidence of type 2 inflammation
* Prurigo nodularis5
* Chronic spontaneous urticaria6
* Chronic inducible urticaria – cold
* Bullous pemphigoid
* CRSsNP
* Allergic fungal rhinosinusitis
* Allergic bronchopulmonary aspergillosis
* Chronic pruritus of unknown origin

**SECTION 3: BACKGROUND (300 words max)**

*Background information and need for drug/device*

**Current Word Count: 297**

Allergic and atopic conditions – including asthma, atopic dermatitis, EoE, CRSwNP, and prurigo nodularis– are increasing at alarming rates, with millions now suffering from severe and uncontrollable disease. Type 2 inflammation has long been associated with these conditions, suggesting they might share a common underlying immune abnormality. IL-4 was discovered in the early 1980s by groups led by Bill Paul (NIH) and Bob Coffman (DNAX Research Institute), and shown to induce type 2 markers such as immunoglobulin E;7 shortly thereafter, IL-13 was discovered and shown to share a receptor system with IL-4, as well as many biologic properties.8

These findings led to the theory that IL-4 and IL-13 were key drivers of type 2 inflammation and associated type 2 inflammatory diseases. They also prompted efforts to treat type 2 inflammatory diseases by blocking IL-4 and IL-13, most notably by Immunex (using a soluble IL-4 receptor, Nuvance) and Amgen (using a HumAb mouse-derived antibody blocking a shared IL-4/IL-13 receptor component). Unfortunately, clinical trials using these early therapeutic candidates failed in asthma, atopic dermatitis and other allergic conditions, causing most to abandon the notion that IL-4 and IL-13 were key drivers of type 2 inflammation.

Regeneron scientists (based on their highly cited work from the 1990s) discovered new complexities in the IL-4 and IL-13 receptor system, and recognized limitations in the Amgen HumAb mouse that had precluded the generation of true blocking antibodies to the complex IL-4/IL-13 receptor. They undertook a multi-year effort to generate a new HumAb mouse (termed *VelocImmune®)*9 that was used to develop a true blocking antibody to the shared IL-4/IL-13 receptor system, which they named dupilumab. Dupilumab provided unprecedented benefits in multiple animal models of type 2 inflammatory disease, compelling Sanofi to partner with Regeneron on a collaborative clinical trial program in type 2 inflammatory diseases.

**SECTION 4: DEVELOPMENT (300 words max)**

*History of the development of the drug/device*

**Current Word Count: 265**

In 2007, Regeneron and Sanofi entered into a global collaboration for the development and commercialization of dupilumab in type 2 inflammatory diseases. To date, Dupixent (dupilumab) has been studied in more than 10,000 patients across more than 60 clinical trials in various chronic diseases driven by type 2 inflammation, including atopic dermatitis, asthma, CRSwNP and EoE, with additional studies in chronic obstructive pulmonary disease (COPD) with evidence of type 2 inflammation, bullous pemphigoid, prurigo nodularis, chronic spontaneous urticaria (CSU), chronic pruritus of unknown origin, chronic inducible urticaria-cold, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, and allergic bronchopulmonary aspergillosis. Dupilumab has demonstrated unprecedented clinical efficacy in six allergic diseases to date, with many more studies underway or planned. Dupixent has already revolutionized the treatment of atopic dermatitis by improving thousands of patients’ lives, including the most recent expansion of the indication to include children as young as six months old. It is also emerging as the treatment of choice for uncontrolled moderate-to-severe asthma and CRSwNP, and is the first ever FDA-approved treatment indicated for specifically for EoE.

Dupilumab has underscored the role of type 2 inflammation across inflammatory skin conditions, as it is the first biologic to demonstrate clinically meaningful reductions in itch and skin lesions for patients with prurigo nodularis.5 In CSU, another burdensome chronic skin condition, dupilumab significantly reduced itch and hives by more than 60% in those who did not respond to standard-of-care antihistamines*.6*

Dupilumab treatment has resulted in unprecedented efficacy in every type 2 inflammatory condition in which results have been available, with a well-established and consistent safety profile across different diseases and age groups.

**SECTION 5: INNOVATION (300 words max)**

*Why this drug or device is innovative, the broad implications for future research and/or how it will improve the human condition*

**Current Word Count: 298**

Dupixent (dupilumab) is the first and only approved biologic that simultaneously inhibits IL-4 and IL-13.2 Notably, it has succeeded where prior efforts – by some of the largest biotech companies – had utterly and completely failed; these high-profile failures resulted in a loss of interest in IL-4 and IL-13. Moreover, the dupilumab discovery required development of an entirely new technology – the *VelocImmune ®* HumAb platform. If these efforts had not been undertaken, and if dupilumab had not been brought forward, the world would still be in the dark on the fundamental shared drivers of type 2 inflammatory conditions. In fact, the many clinical studies with dupilumab – across multiple atopic and allergic conditions – provide the first definitive proof that IL-4 and IL-13 are indeed key and central drivers of type 2 inflammation, and of the most prominent type 2 diseases, including asthma and atopic dermatitis.

Dupixent is a rare example of a true “first-in-class” breakthrough in medicine, and even a rarer example of a breakthrough therapeutic that can effectively treat multiple previously uncontrollable serious diseases, collectively affecting millions of people. Unfortunately, type 2 inflammatory diseases have been reaching epidemic levels, and prior to Dupixent, physicians and patients had few weapons to fight back. Now, the millions of patients with serious asthma, atopic dermatitis, CRSwNP, and EoE have an FDA-approved breakthrough medicine that is proven to work where previously available last-line therapies – such as systemic steroids and surgery – have failed or where there were previously no other options specifically for that disease. Moreover, dupilumab provides hope for the many millions more who suffer from type 2 inflammatory conditions which currently lack effective therapies, such as chronic obstructive pulmonary disease with evidence of type 2 inflammation, bullous pemphigoid, and prurigo nodularis. Hopefully, ongoing studies in these conditions will provide new hope for patients.

**SECTION 6: PUBMED**

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**SUPPLEMENTAL INFORMATION**

**Additional Background Information about Dupixent® and Its Impact**

For years, patients with difficult-to-treat asthma, atopic dermatitis (AD, also known as eczema), chronic rhinosinusitis with nasal polyposis (CRSwNP), and eosinophilic esophagitis (EoE) suffered through immunosuppressive treatments, unsuccessful surgeries, other procedures, or had to resort to using therapies not specifically for their disease often without any resolution of their symptoms. Many asthma patients struggled to breathe and maintain a normal life.1 Millions of atopic dermatitis patients struggled with relentless itching, sleep disorders, anxiety, depression and other issues and had exhausted all available treatments.2-4 Thousands of people with CRSwNP had to deal with constant nasal congestion and discharge, decreased ability to smell and taste, as well as facial pressure, with existing treatment options that often left patients with recurring symptoms.5 Thousands with EoE suffer from symptoms that can make eating a challenge.6,7

From the very first Dupixent AD studies, Regeneron heard from a number of patients and investigators who reached out to share their stories, often through tears. By addressing the key inflammatory cause of AD, Dupixent was able to significantly improve patients’ eczema – and give many back their lives as the first biologic approved for AD and remains the only one approved for patients 6 months of age and older. Additionally, Dupixent is the only biologic approved for oral corticosteroid-dependent asthma, regardless of phenotype, and is the first available in the U.S. for at-home use, providing a critical new option for patients at serious risk for asthma attacks. Dupixent was the first biologic approved for CRSwNP, changing the treatment paradigm, and giving new hope to the many patients for whom systemic corticosteroids and surgery did not provide relief. Most recently, Dupixent is the first and only medicine indicated to treat eosinophilic esophagitis in the United States. The approvals of the Dupixent 200 and 300 mg pre-filled pens are an easy-to-use, convenient option – inclusive of technology that provides visual and audio cues, giving patients more support at home.

Across all approved indications globally, more than 400,000 patients have been treated with Dupixent. In 2021, Dupixent achieved total annual global net product sales of $6.2 billion.8

Many more patients can benefit in the coming years. In the U.S., uncontrolled, moderate-to-severe AD affects approximately 1.6 million adults, an estimated 389,000 adolescents and an estimated 320,000 children aged 6 to 11 years and an estimated 260,000 infants and young children less than 6 years of age.9 AD is misunderstood as a superficial skin disease, but it is often associated with a debilitating rash, intense itching and skin lesions covering much of a person’s body, and problems with sleep and daily living.10-13People with moderate-to-severe forms may not be able to control their symptoms with topical medications and need to be prescribed systemic steroids or broad immune-suppressant medicines,14-15 which run the risk of serious side effects if used long-term.16

Dupixent has revolutionized the treatment of this disease. In AD clinical studies, heavily pre-treated patients saw a remarkable approximately 75% average improvement from baseline and Dupixent was well tolerated, without the immunosuppressive side effects common to other classes of systemic medicines.

Dupixent is also approved for use with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in patients aged 6 years and older whose asthma is not controlled with their current asthma medicines. Moderate-to-severe asthma affects approximately 900,000 people aged 12 years and older in the U.S and an estimated 75,000 children aged 6 to 11 years of age.9 These patients experience difficulty breathing and are at risk of severe asthma attacks (exacerbations) requiring emergency room visits or hospitalizations.1 Oral corticosteroids can provide relief for severe, short-term symptoms, however, current asthma guidelines suggest limiting chronic use to the most severe patients due to the potential for serious side effects.17-19 After its initial approval in October 2018, Dupixent became the first biologic approved for both moderate and severe asthma patients with an eosinophilic phenotype (raised blood eosinophils), oral corticosteroid-dependent asthma (regardless of biomarkers) and with the potential for self-administration at home.20 In clinical studies, Dupixent significantly reduced asthma exacerbations, improved lung function and reduced or eliminated OCS use. In children aged 6 to 11 years, Dupixent is the only biologic medicine to improve lung function in a randomized Phase 3 trial.

Dupixent was the first FDA-approved medicine for adults with uncontrolled CRSwNP. An estimated 90,000 people have CRSwNP in the U.S. and they suffer from a range of debilitating symptoms caused by obstruction of their sinuses and nasal passages.9 These patients can have other type 2 inflammatory diseases as well, which adds to their overall burden of disease.5 Common care for these patients includes systemic steroids or nasal surgery, which often do not provide complete disease control.5 In clinical studies, Dupixent significantly reduced nasal polyp size, improved congestion and loss of smell, while also reducing the need for surgery and systemic corticosteroids.20 With its approval in CRSwNP, another condition with underlying type 2 inflammation, Dupixent’s ability to target this important biological driver of disease was further cemented.

Most recently, Dupixent became the first and only FDA-approved medicine indicated to treat eosinophilic esophagitis. About 160,000 patients with EoE in U.S. are currently being treated with therapies not specifically approved for the disease, of whom approximately 48,000 continue to experience symptoms despite multiple treatments.9 Common treatments for patients with EoE include disruptive and strict elimination diets to avoid food triggers, with some having to resort to invasive procedures or feeding tubes to ensure proper nutrition.21-22 In clinical trials, Dupixent reduced disease symptoms and esophageal inflammation compared to placebo.20 As the first approval in a gastrointestinal disease, the role of Dupixent to address diseases with underlying type 2 inflammation across body systems was further established.

Many people who have been involved in the development of Dupixent have a personal connection to atopic and allergic diseases, which bolsters their commitment to addressing the unmet needs of people with diseases exacerbated by type 2 inflammation. In the early 1990s, the father of George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron, developed severe AD while undergoing lung cancer treatment, and Dr. Yancopoulos witnessed the severity of this disease first-hand. It was in part this experience that motivated Dr. Yancopoulos to initiate and relentlessly lead this program for more than 30 years. Remarkably, his own daughter subsequently developed serious atopic dermatitis and asthma, and she is currently a successful responder to Dupixent treatment. The person who confirmed Dupixent’s action in living cells was Jamie Orengo, Ph.D., Director of Immunology and Inflammation at Regeneron, who is a caregiver to her three children with AD and other allergic diseases.

This commitment to developing a safe and effective first-of-its-kind treatment for AD has been shown in the more than 52 completed and ongoing clinical trials of Dupixent in AD, including an extensive Phase 3 clinical program of 15 trials in nearly 5,000 patients worldwide.23

**Regeneron and Sanofi are committed to bring Dupixent to younger patients with severe AD because of stories like the following from a physician who reached out in a letter.**

“*I met this family when she was first admitted to my children’s hospital (transferred by ambulance from a community hospital ~3 hours away). Prior treatment had been cycles of prednisone, oral anti-Staph antibiotics, pound jars of triamcinolone and chronic daily sedating antihistamines.*

*The family was in crisis. During hospitalizations from November through February, this girl was miserable, and unable to interact with hospital staff….THIS IS A TRULY HORRIBLE DISEASE...we had to restrain her so wouldn’t scratch herself constantly and bleed and get infections.*”This is how she looked when she was admitted:



“*After three doses of dupilumab, she is a pistol*…*THIS IS WHAT DUPILUMAB CAN DO*:”



*“We all want you to know how grateful we are for dupilumab...[My patient’s] quality of life has vastly improved, and so has mine…* *As a scientist, I don’t think there is anything more rewarding than seeing that you can use the power of science to do this, to change a little girl’s life…and I think that’s why many of us do what we do…”*

**Many patients with AD have proactively contacted Regeneron and Sanofi to tell us how Dupixent has changed their lives or shared their experiences publicly:**

*“Getting access to Dupixent remains the single most significant thing that has ever happened to me. It has changed the course of my life in ways that were unimaginable only a few years ago.” –Sirish (adult with AD), via email24*

*Images provided by Sirish during the clinical trial:*



*“…I am so passionate about Dupixent. This drug has been life changing for me…” –Sue (adult with AD), via email24*

*“After two weeks my old skin started to shed and I had new, normal skin for the first time in my life…I don’t think I slept a full night in my entire adolescence…This medicine [Dupixent] has totally changed my way of life.” –Anne (adult with AD), via email24*

*"Dupixent has been life changing for me. I was diagnosed at age 6 and I am currently 32 years of age. I have severe eczema and typically dress completely covered to prevent the stares, questions and comments. I have not been able to wear my wedding ring for 7 years because of the dyshidrotic eczema on my hands. I have never been bowling with my children, the oldest being 12. I have a hard time allowing anyone to touch me because my skin is so hypersensitive, it drives me insane. I have never slept all the way through the night. My self-esteem is highly affected and exercise is nearly impossible with the sweat pouring and irritating the wounds. Sometimes, just getting out of bed, walking, or taking a shower is enough to send me to tears. Dupixent has given me a new life. It has given me life back. I now know what all eczema took from me and I am forever grateful for the opportunity to be on this medication." –Nicole25*

*"I have had AD for at least 67 years of my 70 years on this earth. My life as a child was hell because of weeping medicated baths and teasing by other children. My adult life has also been equally affected by the use of corticosteroids on my skin, which is now permanently affected due to chronic steroids. When my new dermatologist brought up Dupixent about six months ago I was skeptical and scared. I started March 22. I STOPPED itching in 24 hours. It has been a MIRACLE.” –Pinkas24*

*"I love Dupixent! Before I started injections I was beyond miserable. If there’s a worse word for it... I’ve been using Dupixent since January 17, 2018 and within the first day of taking it I noticed a drastic change. The itch started to cease quickly and all of my eczema patches started to dry up and peel off. After about a month, many of my active spots healed. The hyperpigmentation on my face, hands and legs have lightened up. My derm said hyperpig can take a year to go away. I’m fine with that because I never thought I’d be able to look myself in the mirror and not cry. I rejoice quite often because I have a normal life again. I can cook, clean and go to work consistently without having to book an appointment.” –Sam25*

*"I’ve been suffering from eczema my entire life. In the past few years I’ve had major break outs, really major. You know, the ones when you can’t sleep, stop scratching, and you’re covered in sores. Nothing works, not even rounds and rounds of prednisone where the only thing you get are horrible side effects. Ugh! No fun. I’ve taken Dupixent 5 times so far, one being the initial dose of 2 units and the other 3 self-administered and it’s been a miracle for me. I also suffer from hideous asthma (of course) and my side effect from Dupixent has been NO asthma episodes! Already! I feel like I’d imagine a normal person feels. I CAN BREATHE AND DO THINGS! And I’m not dying of asthma attacks all the time…There aren’t enough stars to rate Dupixent as high as I want to. It really is magical unicorn fairy dust!!" –Zia25*

*“We were following the success of dupilimab in teen and adult AD sufferers for a while and eagerly awaiting for it to be approved in Ella’s age group… at 5 and a half years old, she was approved. Within 4 weeks, we began to see a noticeable decrease in her AD symptoms, particularly her itching. A child that had been spending 5 and a half years itching relentlessly was sitting quietly, reading a book, something she never was able to sit through prior to this, and engaging in normal childhood activities. This was a huge change for us. 2 months in and we weren’t using any topicals to control her AD and she wasn’t needing bleach baths, and we weren’t using any wet wraps. On February 6 2021, just shy of her 6th birthday, Ella slept through the night for the first time in her entire life. I cannot overstate the miracle that this was for us. Ella’s skin was healing, her body was healing, our family was healing. We had finally found a therapy that worked for Ella and it truly changed the course of her life. It gave us our child back.” – Amy (mother of child with AD)26*

**U.S. physicians have also spoke out that they are impressed that Dupixent has lived up to its promise as the first biologic medicine to target the underlying type 2 inflammation in AD:**

*“We heard many times that patients even considered suicide because their disease was so bad. Some said they were about to destroy their marriage, and one patient was about to close his law office. But this drug basically enabled them to have a life.” -Dr. Emma Guttman-Yassky, Mount Sinai27*

*“That's the most impactful patients mostly are bothered a lot of times by the itching and improvement can be seen as quickly as two weeks…Patients just say 'this has changed my life. For the first time I don't itch at night for the first time I can leave my house I can wear shorts.” – Dr. Anabelle Garcia, Sonterra Dermatology28*

**Dupixent has also been shown to improve lung function in moderate-to-severe asthma patients. The reaction from patients and U.S. physicians to Dupixent has been overwhelmingly positive.**

“*My son has poorly controlled asthma despite adhering to his medication regime and being extremely well cared for by his consultant. [Dupixent] offers him the chance to live with improved breath – breathing is overlooked by those of us fortunate enough to enjoy good health!” –Natalie29*

*"This medication appears to have efficacy in a much broader range of patients than the currently available biologics. It has the potential to be a game changer for some patients, but we won't really know until it is out in the real world." –Dr. Sally Wenzel, University of Pittsburgh30*

**Dupixent is the first and only FDA-approved medicine indicated for eosinophilic esophagitis. Although it is a rare disease, EoE has a large impact on patients’ lives. People with EoE are more likely to have depression and anxiety, especially as they get older, which can be related to fears about disease progression and difficulties with managing their disease, such as adapting eating habits to adhere to strict diets.31-33**

**Patients with EoE saw a remarkable 69% reduction in disease symptoms with Dupixent, compared to 32% for placebo.34 Dupixent is the first and only biologic to show positive and clinically-meaningful results in this population as part of a Phase 3 trial. Dupixent may improve underlying biological processes related to tissue damage in EoE, as shown by the normalization of expression of genes association with scarring and barrier function in these patients.35**

“*The hardest part, I would say, of this disease on my life probably was in high school. I was extremely small for my age. I was 15 and was about 60 pounds and I was around 4’5” or 4’6”, so I clearly looked very different than the rest of my friends. And as a freshman in high school it’s hard in general. Everyone has a tough time, but having a disease that makes you look and feel so isolated and different. That was a really big challenge.” – Jori, person with EoE24*

*“My husband has EoE. And then three of our four kids. Charlie is eleven; and Gage is nine; and Tinley is six. The kids definitely have different takes on the disease. With Charlie not having a feeding tube and he has a lot more in his diet, it’s easier for him. Gage hates all of it. He hates the disease and he hates that he has a feeding tube, and he wants it to all go away.” – Kara, caregiver to family with EoE24*

**Additionally, Dupixent has as shown positive and clinically meaningful results in two skin diseases beyond atopic dermatitis: patients with uncontrolled prurigo nodularis, a chronic skin condition that has the one of the highest impacts on quality of life among inflammatory skin diseases with intense, chronic itch, and patients with chronic spontaneous urticaria who have failed standard-of-care antihistamines, characterized by the sudden onset of hives on the skin and/or swelling deep under the skin.**

We believe that future generations will look back and regard Dupixent as a significant landmark in the management of chronic type 2 inflammatory conditions. This biological treatment is a tangible demonstration of how addressing the root cause of a problem can bring exciting, multi-tasking innovative therapies for diseases with high unmet medical needs.

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