

Dupixent®

Category:

Best Biotechnology Product

Company Name:

Regeneron and Sanofi

Product/Solution Name:

Dupixent®

Compound/Tech Name:

dupilumab

Trade Name:

Dupixent®

Corporate Name:

Dupixent®

Date of Approval:

2017-03-28

Indications:

Physician and patient testimonials:

Atopic Dermatitis (AD)

"I met this family when she [was 6 yr old girl]. Prior treatment was cycles of prednisone, oral antibiotics, pound jars of triamcinolone and chronic sedating antihistamines. The family was in crisis... this girl was miserable... After dupilumab, she is a pistol... We want you to know how grateful we are... [My patient's] quality of life has vastly improved, and so has mine..." [Physician]

"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. Ella's skin was healing... our family was healing... It gave us our child back..." [Amy, mother]

"Getting access to Dupixent remains the single most significant thing that has ever happened to me.\" [Sirish, adult patient]

Prurigo Nodularis (PN)

A 51-year-old woman with PN was experiencing intense itch, multiple skin lesions and negative impact on daily life activities... sleep impairment in the last 20 years... multiple topical and immunosuppressive treatments had been unsuccessful... 18 months [of Dupixent]... she was asymptomatic and had no side effects from treatment.\" [Dermatologist]

Asthma

"Before, I needed to use inhalers [and nebulizers] regularly... hospitalized countless times... put on steroid medications. Now that I found Dupixent, it's like night and day.\" [Tommy, adult patient]

[Dupixent] offers my son the chance to live with improved breathing - breathing is overlooked by those of us fortunate enough to enjoy good health!\" [Natalie, mother]

Chronic Obstructive Pulmonary Disease (COPD)

"I had a severe COPD patient, on oxygen, with labored breathing... I worried I would have to take him to the ED. After Dupixent, he was 'Hop Scotching' through the office and smiling like I had never seen... It changed his life...he no longer relies on oxygen constantly.\" [Jennifer, physician]

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

"I'm finally feeling better for the first time...literally ever in my life. Like, able to breathe, I can smell, I can taste. All these good things. I'm so excited.\" [Jaz, adult patient]

"Dupixent is helping me make up for lost time. My joy is my joy again. I get to travel all over the world without fear of being sick and CRSwNP holding me back.\" [Bailey, adult patient]

Eosinophilic Esophagitis (EoE)

"Eating was always difficult. I was vomiting... gastric tube inserted in my stomach. After starting Dupixent... I started to cry - after the years long journey that I had been on, I finally found something that could help.\" [Bennett, adult patient]

"For years, I struggled with swallowing, choking, and unexplained food impactions... spent so much time undergoing endoscopies and dilations - just trying to feel \"normal.\" It wasn't until much later that I was diagnosed with EoE. Even then, treatment felt like trial and error - until Dupixent became available. It changed everything. For the first time, I could eat without fear. Most people don't think twice

about eating. But for some of us, it's been a source of pain, anxiety, and isolation.\"
[Adult patient]

Therapeutic Areas:

Dupixent® was the world's third-leading medicine last year[1], behind only Keytruda (2022 Galien Golden Jubilee Silver winner for \"Best Biotechnology Product\") and Ozempic (2023 Prix Galien USA Award co-winner for \"Best Pharmaceutical Product\").

Dupixent is a rare example of a true \"first-in-class\" breakthrough medicine, and an even rarer example of a breakthrough therapeutic that can effectively treat multiple previously uncontrollable serious diseases - from the relatively rare (eosinophilic esophagitis [EoE], prurigo nodularis [PN], bullous pemphigoid [BP]) to the exceedingly common (atopic dermatitis [AD], asthma, chronic obstructive pulmonary disease [COPD], chronic rhinosinusitis with nasal polyps [CRSwNP]).[2]

A single biologic approved as a first-in-class treatment for so many seemingly disparate non-oncologic diseases may be unprecedented. A prospective unifying scientific hypothesis predicted that many - if not all - allergic/atopic diseases are due to excess type 2 inflammation driven by interleukin-4 (IL4) and interleukin-13 (IL13).[3] The remarkable efficacy of the first therapeutic blocking IL4 and IL13 (i.e., Dupixent) across so many allergic and atopic disorders validated this unifying hypothesis. Dupixent's remarkable safety reflects the realization that IL4/13-driven type 2 inflammation evolved to fight parasites no longer found in developed countries and is, thus, not necessary to fight currently prevalent pathogens.

Dupixent's remarkable efficacy and safety - across so many indications - account for its utilization by millions. Dupixent has resulted in paradigm-changing efficacy in every type 2 condition studied (with efficacy measures showing average improvements up to 70-80%), yielding overwhelmingly positive Phase 3 results across 8 different diseases.[2] Dupixent is now the world's leading biologic in its first 6 FDA-approved indications (AD, asthma, COPD, EoE, CRSwNP, PN), and was the first FDA-approved biologic for 5 of these (AD, COPD, EoE, CRSwNP, PN). Moreover, and unlike other immunomodulators, it is not immunosuppressive, with a safety profile allowing treatment in infants.[2]

Dupixent is also an outlier in terms of being so far ahead of the competition. Most breakthroughs reflect advances of an entire field - thus, new therapeutic classes usually have multiple contemporaneous approvals. For example, the first two anti-TNFs were approved within months of each other, as were Keytruda and Opdivo, while Wegovy and Mounjaro were approved within a year of each other. In contrast, Dupixent has not had any similarly-acting biologics approved since its approval in 2017. This was because most had abandoned the \"IL4/IL13 hypothesis\" due to multiple earlier failures, as previous technologies could not deliver effective blockers of this pathway.

Only one company - Regeneron - persevered in its belief in IL4/13 biology, and where prior technologies had failed, delivered the first effective IL4/IL13 therapeutic blocker.

As allergic diseases steadily increase across the world,[4] this paradigm-changing medicine continues to give hope to millions suffering from debilitating and burdensome allergic diseases. Since initial approval, Dupixent has treated millions of patients globally.

It is worth noting that - coincidentally or not - Regeneron's Dupixent and EYLEA® (aflibercept) Injection are the only two biologics with \$50B-\$100B in cumulative sales in the last decade to never receive a Prix Galien recognition.

General Information File Document upload:

[References_Regeneron Dupixent 2025 Prix Galien Submission.pdf](#)

Background information and need for drug / device:

Millions suffer from severe allergic and atopic conditions, from asthma to atopic dermatitis (AD). While it has long been known that allergic/atopic diseases can often occur comorbidly, it would take decades of scientific discovery and technological innovation - attributed in significant part to Regeneron and its development of Dupixent - to prove that the unifying basis of all these seemingly disparate diseases involves IL4/IL13-driven "type 2 inflammation".[3]

The Dupixent story starts with the discovery of IL4 in the 1980s by the Paul and Coffman laboratories, and the realization that it induced production of IgE - the immunoglobulin long known to be associated with allergies (Regeneron's CSO Yancopoulos, a principle inventor of Dupixent, was a collaborator of both Paul and Coffman).[5] Shortly thereafter, IL13 was discovered and shown to share a receptor system with IL4.[5] These findings prompted efforts by many companies to target IL4 and IL13, or its shared IL4Ralpha receptor component. Most notably, Immunex made a soluble receptor blocker (named Nuvance, technologically analogous to Enbrel)[6], while Amgen used a "first-generation humAb mouse" to generate a fully-human antibody targeting the shared IL4Ralpha receptor component.[6] Unfortunately, the many IL4/IL13 blockers - including Immunex's and Amgen's - all failed in clinical trials.[6] Because of these failures, most abandoned the notion that IL4/IL13 were the critical drivers of allergic diseases.

Yancopoulos and Regeneron's scientific studies of the IL4/IL13 pathway continued to support their belief in the critical role of this pathway, leading them to conclude that the clinical failures were due to failures of the technological approaches used to generate the therapeutic candidates - showing that Immunex's Nuvance was not an effective blocker, and that Amgen's humAb mouse (made by outdated transgenic technology) was profoundly immunodeficient, and could not efficiently generate potent

antibody blockers. To overcome these technological limitations, Regeneron invented a technology (termed VelociGene®)[7] that revolutionized precisely-targeted, large-scale genetic humanizations. They then used VelociGene® to create the first "genetically-humanized humAb mouse" with fully-functional antibody-generating capabilities, which they termed the "VelocImmune® mouse"[8,9]; the VelocImmune mouse represented the largest genetic engineering effort in history, using VelociGene® technology to precisely replace over 6 megabases of mouse immune genes with their human genetic counterparts.[8,9] This remarkable technological achievement resulted in one of the most productive biotechnologies ever invented, already delivering more than ten approved antibodies. Regeneron scientists utilized the VelocImmune mouse, together with their expertise in cytokine receptors[10], to invent a potent antibody blocker of the IL4Ralpha receptor component shared by IL4 and IL13, which is Dupixent. Dupixent is thus a product of breakthrough genetics-based biotechnologies - i.e., VelociGene and VelocImmune - and is a testament to the power of biotechnological innovation.

Dupixent showed remarkable efficacy in its initial clinical trials in AD[11] and asthma[12] - where previous IL4/13 blockers had failed - as was subsequently confirmed and extended by large pivotal trials in every allergic/atopic indication tested (8 total indications, as detailed above).[2] The Dupixent clinical data[2] validate the "unifying hypothesis" that IL4/IL13 are the critical drivers of most, if not all, allergic/atopic diseases[3].

Background File Document upload:

[References_Regeneron Dupixent 2025 Prix Galien Submission.pdf](#)

History of the development of the solution/product:

Dupixent is the first and only approved biologic that simultaneously inhibits IL4 and IL13, thereby transforming the treatment of multiple allergic and atopic conditions.[2] Notably, Dupixent succeeded where prior efforts failed.[6] While previous high-profile failures resulted in a loss of interest in this pathway, Regeneron believed in the biology and that a better antibody could be made, which required invention of an entirely new technology - the VelocImmune® HumAb mouse[8,9] - Regeneron's unique platform for generating fully human antibodies.

VelocImmune involved the largest genetic humanization ever performed, resulting in mice engineered to have genetically-humanized immune systems, overcoming limitations of prior HumAb mice[8,9]; genetic engineering of the VelocImmune mouse was only possible because of another Regeneron invented technology, VelociGene®, that allowed large-scale genetic humanizations[7]. Notably, VelocImmune overcomes limitations of prior platforms by allowing nature (i.e. the mouse) to generate fully human antibodies that tightly bind to therapeutic targets, requiring no further optimization or artificial engineering.

If these efforts had not been undertaken, and if Dupixent 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 successful Phase 3 clinical trials with Dupixent - across multiple atopic and allergic conditions - provide the first definitive proof that IL4 and IL13 are indeed THE central drivers of type 2 inflammation, which include the prominent type 2 diseases of asthma, atopic dermatitis, eosinophilic esophagitis, and chronic rhinosinusitis with nasal polyps.

This relentless commitment to scientific discovery and innovation has resulted in an impact few medicines have ever achieved: Dupixent is emerging as the major weapon to fight back against the epidemic of allergic diseases, with 7 indications approved (and an 8th pending) across 60+ countries resulting in millions treated and the potential to improve the lives of millions more.

Development File Document upload:

[References_Regeneron Dupixent 2025 Prix Galien Submission.pdf](#)

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

Very few biopharma advances are truly disruptive: i.e., leapfrogging ongoing progress to re-define the science in their field, years ahead of competitor entrants. For example, 2022 Galien Golden Jubilee Gold winner Humira ("Best-of-the-Best" from 1970-2020; also a previous winner of "Best Biotechnology Product") represented the third-in-class TNF blocker. Further, 2023 Prix Galien USA Award co-winners of "Best Pharmaceutical Product," Mounjaro and Ozempic, represented two products launched in the same category that now includes a total of seven in-market dual or single GLP-1 agonists approved, with the two leading GLP1s for obesity being approved within a year of each other.

Dupixent - now one of the world's top three leading medicines[1] - is distinguished by how far ahead of the field it was and remains:

(1) Dupixent was the first dual blocker of IL4 and IL13 when it was first approved in 2017, and remains the only FDA-approved agent blocking both of these factors:

>>> Understanding prior failures to effectively block IL4/IL13 led Regeneron to invent an entirely new HumAb mouse - termed the VelocImmune® mouse - to deliver Dupixent as the first (and still the only) clinically-validated IL4/IL13 blocker.

(2) Dupixent was the first approved biologic for five of its seven FDA-approved indications: atopic dermatitis, chronic rhinosinusitis with nasal polyps, eosinophilic

esophagitis, prurigo nodularis, and chronic obstructive pulmonary disease; Dupixent has a pending approval in an eighth indication - bullous pemphigoid (PDUFA = June 2025) - for which it may also be the first approved biologic.

(3) Dupixent is also the world's leading biologic for all seven of its approved indications - the above five as well as asthma and chronic spontaneous urticaria.

(4) Dupixent also re-defined the science behind the diseases for which it's the world's leading treatment - demonstrating that these previously disparate-appearing diseases all share the same driving mechanism - i.e., over-activity of IL4/IL13 driving excess type 2 inflammation.

(5) The incredible safety profile of Dupixent (in that it does not cause immunosuppression, but instead decreases risk of most infections) also led to the unexpected realization that IL4/13-driven type 2 inflammation is largely vestigial (in that it evolved to fight parasites that are no longer common in developed countries, and thus this immune pathway is not relevant for fighting prevalent pathogens); this vestigial pathway, unfortunately, becomes inappropriately activated, and thereby contributes to allergic and atopic diseases.

Thus, Dupixent leapfrogged progress in its field to re-define the science underlying the many diseases for which it is now the world's leading treatment.

Innovation File Document upload:

[References_Regeneron Dupixent 2025 Prix Galien Submission.pdf](#)
[Supplemental Information_Regeneron Dupixent 2025 Prix Galien Submission.pdf](#)

Please provide appropriate references (PubMed, Abstract, Website):

Gandhi, Namita A., et al. Targeting key proximal drivers of type 2 inflammation in disease. *Nature reviews drug discovery* 15.1 (2016): 35-50.

Paul WE. History of Interleukin 4. *Cytokine* (2015); 75(1): 3-7.

Valenzuela DM, et al. High-throughput engineering of the mouse genome coupled with high-resolution expression analysis. *Nat Biotechnol* (2003); 21(6):652-9.

Macdonald LE, Karow M, Stevens S, et al. Precise and in situ genetic humanization of 6 Mb of mouse immunoglobulin genes. *Proc Natl Acad Sci USA* (2014); 111(14):5147-52.

Murphy AJ, Macdonald LE, Stevens S, et al. Mice with megabase humanization of their

immunoglobulin genes generate antibodies as efficiently as normal mice. *Proc Natl Acad Sci USA* (2014); 111(14):5153-8.

Wenzel S, Ford L, Pearlman D, et al. Dupilumab in persistent asthma with elevated eosinophil levels. *N Engl J Med* (2013); 368(26):2455-2466.

Beck LA, Thaçi D, Hamilton JD, et al. Dupilumab treatment in adults with moderate-to-severe atopic dermatitis. *N Engl J Med* (2014); 371(2):130-139.

Thaçi, D, Simpson EL, Beck LA, et al. Efficacy and safety of dupilumab in adults with moderate-to-severe atopic dermatitis inadequately controlled by topical treatments: a randomised, placebo-controlled, dose-ranging phase 2b trial. *Lancet* (2016); 387(10013):40-52.

Bachert C, Mannent L, Naclerio RM, et al. Effect of subcutaneous dupilumab on nasal polyp burden in patients with chronic sinusitis and nasal polyposis a randomized clinical trial. *JAMA* (2016); 315(5):469-479.

Wenzel S, Castro M, Corren J, et al. Dupilumab efficacy and safety in adults with uncontrolled persistent asthma despite use of medium-to-high-dose inhaled corticosteroids plus a long-acting beta-agonist: a pivotal dose-ranging study. *Lancet* (2016); 388(10039):31-44.

Simpson EL, Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. *N Engl J Med* (2016); 375(24):2335-2348.

Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (LIBERTY AD CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled phase 3 trial. *Lancet* (2017); 389(10086):2287-2303.

Castro M, Corren J, Pavord ID, et al. Dupilumab Efficacy and Safety in Moderate-to-Severe Uncontrolled Asthma. *N Engl J Med* (2018); 378:2486-2496.

Rabe KF, Nair P, Brusselle G, et al. Efficacy and Safety of Dupilumab in Glucocorticoid-Dependent Severe Asthma. *N Engl J Med* (2018); 378:2475-2485.

Bachert C, Han J, Desrosiers M, et al. Efficacy and safety of dupilumab in patients with severe chronic rhinosinusitis with nasal polyps (LIBERTY NP SINUS-24 and LIBERTY NP SINUS-52): results from two multicentre, randomised, double-blind, placebo-controlled, parallel-group phase 3 trials. *Lancet* (2019); 10209:1638-1650.

Simpson E, Paller A, Siegfried E, et al. Efficacy and Safety of Dupilumab in Adolescents With Uncontrolled Moderate to Severe Atopic Dermatitis. *JAMA* (2019); 156(1):44-56.

Cork M, Thaci D, Eichenfield L, et al. A study of dupilumab in the treatment of adolescents with eczema. *BJD* (2020); 182:85-96.

Beck L, Thaci D, Deleuran M, et al. Dupilumab Provides Favorable Safety and Sustained Efficacy for up to 3 Years in an Open-Label Study of Adults with Moderate-to-Severe Atopic Dermatitis. *Am J Clin Dermatol* (2020).

Paller A, Siegfried E, Thaci D, et al. Efficacy and safety of dupilumab with concomitant topical corticosteroids in children 6 to 11 years old with severe atopic dermatitis: a randomized, double-blinded, placebo-controlled phase 3 trial. *JAAD* (2020).

Bacharier L, Maspero J, Katelaris C, et al. Dupilumab in children with uncontrolled moderate-to-severe asthma. *N Engl J Med* (2021); 385: 2230-2240.

Paller AS, Simpson EL, Siegfried EC, et al. Dupilumab in children aged 6 months to younger than 6 years with uncontrolled atopic dermatitis: a randomised, double-blind, placebo-controlled, phase 3 trial. *The Lancet* (2022); 400 908-919.

Yosipovitch, Gil, et al. \"Dupilumab in patients with prurigo nodularis: two randomized, double-blind, placebo-controlled phase 3 trials.\" *Nature medicine* (2023); 1-11.

Bhatt, Surya P., et al. \"Dupilumab for COPD with Type 2 Inflammation Indicated by Eosinophil Counts.\" *New England Journal of Medicine* (2023).

References File Document upload:

N/A