

New Drug for Severe Eczema Is Successful in 2 New Trials

By [GINA KOLATA](#) OCT. 1, 2016



Daniela Velasco at her sister's wedding. Before participating in the trial, over 90 percent of her body was covered by an ugly red rash. Within two weeks of trying a new drug, the rash was gone. Credit Rodrigo del Río Lozano

The disease is characterized by an [itching](#), oozing rash that can cover almost all of the skin. The constant itch, to say nothing of the disfigurement, can be so unbearable that many patients consider suicide. There has never been a safe and effective treatment.

On Saturday, the results of two large clinical trials of a new drug offered hope to the estimated 1.6 million adult Americans with an uncontrolled, moderate-to-severe form of the disease, [atopic dermatitis](#), which is a type of eczema.

Most patients who got the active drug, dupilumab, instead of a placebo reported that the itching began to wane within two weeks and was gone in a few months, as their skin began to clear. Nearly 40 percent of participants getting the drug saw all or almost all of their rash disappear.

For some, relief was almost instantaneous.

“I knew immediately I was on the drug” and not the placebo, said Daniela Velasco, an event planner in Playa del Carmen, Mexico. Within a couple of weeks, the ugly red rash that had covered 90 percent of her body was almost gone. Even better, she said, “for the first time I didn’t feel any itch at all.”

Before entering the trial, Mrs. Velasco, 36, had seen 40 doctors about the disease and tried dozens of drugs and treatments, to no avail. To participate in the study, she spent more than \$95,000 to fly to Mount Sinai in New York on a regular basis and stay in hotels. She realized she might get a placebo but also knew that when the study ended everyone, including the placebo patients, would be able get the drug if the trial was successful.

The drug blocks two specific molecules of the immune system that are overproduced in patients with this and some other allergic diseases. The only side effects were a slight increase in [conjunctivitis](#), an inflammation of the outer membrane of the eye, and swelling at the injection site.

“This is a landmark study,” said Dr. Mark Boguniewicz, an atopic dermatitis expert at National Jewish Health and the University of Colorado School of Medicine who was not involved with the study. “For us in atopic dermatitis, we are entering a new era.”

Photo



Daniela Velasco’s arms, left and top, and legs, below right, before the treatment with dupilumab.

Credit Emma Guttman-Yassky

The [studies](#), lasting 16 weeks and involving nearly 1,400 people, were published in the [New England Journal of Medicine](#).

Dr. George D. Yancopoulos, the president and chief scientific officer at Regeneron, which, in partnership with [Sanofi](#), makes the drug, said he expects the [Food and Drug Administration](#) to rule on dupilumab by March 29, 2017. The drug’s brand name will be Dupixent. The agency has [given the drug breakthrough status](#), which provides expedited development and review of drugs for serious or life-threatening diseases.

Dr. Yancopoulos declined to speculate on dupilumab’s price, saying only that it will be “consistent with the value of the drug.” It is a biologic, the most expensive type of drug, and is injected every two weeks.

Atopic dermatitis experts said they have longed for a safe and highly effective treatment. In desperation, some prescribed other drugs off-label, like powerful immunosuppressants or high doses of [steroids](#), which are far from ideal because even if they helped, their side effects can be severe — [kidney failure](#) with immunosuppressants, bone loss and even [psychotic](#) breaks with high-dose steroids.

Patients are miserable, Dr. Boguniewicz said. “Our patients and families haven’t slept through the night, not for days or weeks, but for months or years.”

Many doctors provide no treatments other than perhaps creams and ointments that do not stop the itching or soothe the red and weeping rash, said Dr. Jonathan I. Silverberg of Northwestern University’s Feinberg School of Medicine and a principal investigator in one of the studies.

Many sufferers can relate to the plight of the defense lawyer played by John Turturro in the HBO series “[The Night Of](#).” He [suffers from](#) atopic dermatitis that started on his legs and his feet and later spread to his neck and head. Like so many patients, he tries treatment after treatment — bleach baths, covering the rash in Crisco and wrapping it with plastic wrap, steroids, Chinese medicine. He scratches it with chopsticks and disgusts people near him. But all to no avail.

Such experiences explain the excitement over the new drug, although researchers say they would like to see longer-term data.

“What we are seeing are some really impressive efficacy numbers,” Dr. Silverberg said. “But efficacy alone is not enough. It is the safety profile that is the real key. Everything we are seeing really looks great.”



Herb Bull at a friend’s home in Westfield, N.J. He said the new drug “saved his life.” Credit Bryan Anselm for The New York Times

Dr. Jon M. Hanifin, a professor of dermatology at Oregon Health and Science University and founder of the National Eczema Association, agreed. While not a principal investigator in the study, Dr. Hanifin did oversee the care of some patients enrolled in it.

“It’s wonderful,” he said. “We walk in the room and patients are smiling. These patients are the worst of the worst. Their life was destroyed.”

Dr. Yancopoulos was inspired in part to develop the drug because his father had severe atopic dermatitis, which he developed shortly after he got lung [cancer](#) at 70.

“More so than the cancer and the chemo, this rash and its horrible itch started dominating his life and ruining its quality,” Dr. Yancopoulos said. “Here’s a guy with Stage IIIB lung cancer — basically a death sentence — and he is more concerned and miserable about his skin and his itch.”

One participant in the trial, Lisa Tannebaum, a 53-year-old harpist in Stamford, Conn., was so thrilled that she wrote a letter to Regeneron suggesting they use her before and after photographs in advertisements. She developed a severe form of the disease 14 years ago and tried everything imaginable in conventional and [alternative medicine](#) without relief — specialized diets, immunosuppressive drugs, special clothing, bleach baths. She even had the gold fillings removed from her teeth on the theory that they may be causing an allergic response, but to no avail.

“It was like every day I had [poison ivy](#) and fire ants on myself,” she said. “You don’t sleep at all. You can’t go out, you have staph infections all the time,” because the skin’s protective barrier is broken by the rash. “I couldn’t drive my kids to school because the itching was so bad I couldn’t put my hands on the steering wheel.”

Now, she is performing again and will be playing her harp [at Carnegie Hall on Oct. 30](#).

Herb Bull, 71, a retired Merck scientist in Westfield, N.J., had mild atopic dermatitis for years until three years ago, when it took a turn for the worse. The rash covered his entire body. Sleep was impossible, itching a constant torment. Even walking was difficult.

“He had weeping lesions all over his body,” said his doctor, Dr. Emma Guttman-Yassky, a principal investigator in the trial and professor of dermatology and immunology at the Icahn School of Medicine at Mount Sinai.

“I thought I might as well give up and die,” Mr. Bull said.

It took months for the drug to work, he said, but when it did, the change was miraculous. His rash and the itching went away.

The new drug, Mr. Bull said, “saved my life.”