

# Potential weight loss treatment takes shape with help from patients

Novartis researchers are partnering with advocacy groups to understand the stigma and challenges facing patients with obesity.

By [Veronica Meade-Kelly](#) | Feb 12, 2018

Read an **important program update** below this story.

James Zervios grew up in a time when schoolyard bullying was met with a shrug. Teased for his weight and picked last for sports teams, Zervios sought solace at the end of the day in the comforts of home. In his Italian and Greek household, comfort was often in the form of food. His family celebrated every life event with an Italian feast and gathered each Sunday for a four-course family dinner, so food was not only plentiful – it felt like a reaffirming embrace.

It wasn't until later that Zervios realized that comfort came at the expense of his health. The pounds accumulated over the years, straining his heart.

When Zervios was 28, he received an ultimatum from his doctor: lose weight or start taking blood pressure medication. He opted to change his habits, beginning a weight loss journey that furthered his experience as an advocate for patients with obesity. Zervios is now helping shape the development of an experimental Novartis treatment for weight loss as part of the Novartis Diabetes and Metabolism Patient Advisory Forum.

But he was focused on his immediate health when the doctor delivered the wake-up call. "I was at my highest weight, and I hadn't grown up with the healthiest of habits," Zervios recalls.



By changing his habits, Zervios (shown here with his dog Rocky) lost 65 pounds and has kept it off for six years, but he knows that for many of his peers faced with obesity, the “eat less, move more” mantra is overly simplistic. Photo courtesy of James Zervios

He improved his diet and began exercising – meeting the recommendation most commonly prescribed to patients dealing with obesity: eat less, move more.

For Zervios, it worked. He shed 65 pounds (29.5 kilograms) and has kept it off for six years, but the experience has been eye-opening. He knows that maintaining his current weight will be a lifelong battle. He also knows that for many of his peers faced with obesity, the “eat less, move more” mantra is overly simplistic.

Now vice president of marketing and communications at the [Obesity Action Coalition](#), Zervios works to support and empower those affected by obesity by, among other things, pushing for access to new treatment options and for the eradication of bias and discrimination against those suffering from the disease. It was this role that brought him into the orbit of Novartis.

## Establishing a patient advisory forum

The company is in the process of testing a potential weight loss drug called LIK066. Last year the LIK066 team, led by Andy Bushell, Global Program Head, reached out to the Obesity Action Coalition and several other advocacy groups as part of a new approach. “After speaking in London at the International Alliance of Patient Organizations, I realized we needed to systematically involve the patient voice in the development of new medicine,” says Bushell.

The researchers sought to partner with patients as they developed and tested the experimental treatment with the hope that, by better understanding the needs and challenges of patients, they could design a more effective medicine that meets real patient needs. The result was the Novartis Diabetes and Metabolism Patient Advisory Forum, which brings patient advocates together with clinicians and scientists to make patient needs a central focus during LIK066 development.

“We thought it was important to get a patient perspective because, frankly, existing medicines have not been terribly effective,” explains Deborah Keefe, a Senior Global Program Clinical Head in Global Drug Development at Novartis. “It’s pretty common for patients to drop out of weight loss trials. Only around 50% of participants see them through to the end – and retention is a big factor in having a robust scientific study.”

Obesity is unique in that, no matter what therapy a person tries, if they’re not successful, they always take the blame – both from themselves and others.

**James Zervios**, patient advocate, Obesity Action Coalition; member, Novartis Diabetes and Metabolism Patient Advisory Forum

That lack of effective weight loss treatments has been a matter of increasing urgency. The World Health Organization ranks obesity as the third largest global health threat behind smoking and war because it can lead to so many devastating conditions, including hypertension, arthritis, diabetes and even some cancers. Medical associations across the world are recognizing obesity as a disease and are publishing treatment guidelines.

Short of invasive bariatric surgery, which makes the stomach smaller to reduce the amount of food a person eats, there are few treatments for obesity. Available drugs often come with side effects and fail to produce the weight loss patients desire, and the “eat less, move more” approach is hard to maintain and frequently doesn’t work. Research shows, for example, that when some people try to lose weight, their body’s metabolism slows

down in response. And when a treatment doesn't work, patients are often saddled with the responsibility for that failure.

"I would say obesity is unique in that, no matter what therapy a person tries, if they're not successful, they always take the blame – both from themselves and others. If a treatment is not successful, people think the patient probably did something wrong," Zervios says.

It's part of a larger stigma that accompanies the disease. Those with the condition face a social cost. Studies show they're promoted less and face discrimination when applying to education programs. In popular culture, it's still acceptable to mock those who are overweight.

Even in healthcare, those with the disease are often thoughtlessly shamed; hospital gowns and blood pressure cuffs often don't fit, staff have been known to send patients to be weighed on freight scales, and some patients see doctors who refuse to prescribe anything beyond the one-size-fits-all "fix" of lifestyle change. The experience can be so alienating, Zervios says, that some patients stop going to see doctors altogether.



Patient advocate Zervios (with his wife Danielle) knows firsthand how difficult it can be to lose weight. He says that both promotional and informational materials on potential treatments don't help because they often dehumanize people with obesity. Photo courtesy of James Zervios

The Novartis forum, which met for the first time in October 2016, is addressing many of these issues, and Keefe says the meetings have been eye-opening.

"There's a difference between how patients perceive being overweight and how physicians perceive it. Physicians tend to focus on the medical aspects, whereas patients are really focused on overcoming the social and functional limitations of obesity – they want to be able to do things with their families and to be respected and accepted by society at large," she says.

## **Influencing the clinical trial design**

That perspective, the researchers say, has informed every element of the current Phase IIb clinical trial for

LIK066. Input from forum participants, for example, influenced the language used in study and consent forms (the study is called a “weight loss trial,” not an “obesity trial” – and there are no references to “obese patients,” just as one wouldn’t talk about “cancerous patients”). Steps were also taken to ensure that trial sites are patient-friendly, with appropriately sized chairs in the waiting room and adequate medical equipment that doesn’t make participants feel self-conscious about their size.

Additionally, patient advocates advised on how the trial should be marketed, as promotional and even informational materials often dehumanize those with obesity. They drew researchers’ attention to the fact that individuals with obesity are often depicted as headless bodies. In response, the researchers made a point to show patients as whole people, engaged in daily activities.

The researchers believe that running the LIK066 development program in this more patient-centric way will prove to have cost and efficiency benefits, as more satisfied patients are less likely to drop out. That, in turn, could lead more quickly to a product that more precisely meets patient needs.

“Understanding the challenges of people living with obesity is something that has been extremely useful,” says Bushell. “We can only understand the real psychological pressures patients are dealing with on a daily basis by meeting them and hearing what they have to say.”

And Zervios says that so far, advocates have felt heard.

“When you’re sharing insights from the patient perspective, it’s a vulnerable position. You’re exposing yourself,” he says. “But with this group, in this forum, within 30 minutes I’d say, everybody felt comfortable – the dynamics felt like family.”

*Main image: James Zervios, an avid catch-and-release fisherman, is a member of the Novartis Diabetes and Metabolism Patient Advisory Forum. Photo courtesy of James Zervios.*

**Important program update:** *Despite early Phase II data showing a positive dose response, the magnitude of the weight loss with LIK066 was not sufficient to deliver transformational benefit to patients as a monotherapy in consideration of the evolving marketplace and available treatment options. Novartis has made the decision not to proceed to Phase III with the current program and will therefore begin closing selected clinical studies according to standard regulatory protocols. Novartis is grateful to the LIK066 investigators, trial site personnel, patients and patient advocates whose passion and participation contributed to an outstanding trial design and helped advance our knowledge of weight loss and the metabolic effects of LIK066. Novartis remains committed to developing transformational medicines that help extend and improve the lives of people living with cardio-metabolic diseases.*

Novartis is working to improve #weightloss trials with help from patient advocates.

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