Statement by Steven Ainbinder, MD

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To the Food and Drug Administration Pulmonary-Allergy Drugs Advisory Committee

Re: BLA 103976, XOLAIR Omalizumab (Humanized Monoclonal Antibody to Human IgE) for the treatment of allergic asthma

May 15, 2003

Holiday Inn
The Ballrooms
Two Montgomery Village Avenue
Gaithersburg, MD

Good afternoon. My name is Dr. Steven Ainbinder. I am here today from Henderson, Nevada. Thank you for allowing me to testify on my experience with the benefits of Xolair. My comments are on my own behalf, though the Asthma and Allergy Foundation of America has helped make my presence here today possible. I would like to also introduce you to my wife, Ivana, who has been beside me during the worst of my asthma attacks—I frankly don't think I would be here today without her love and support.

I am 32 years old and was diagnosed as a steroid-resistant severe asthmatic a little over three years ago. This came very much as a surprise since my childhood asthma had resolved itself to mild intermittent asthma by age 14. I thought my condition was well under control.

At the time of my new diagnosis, I was working to complete my postdoctoral training at the UCLA Medical Center in Los Angeles, CA, and looking forward to a fellowship in surgical gynecology. I was working about 100 hours each week, and to burn off some steam, I used to try to run about 5 miles in the evenings.

In August 1999, after one such run, I began wheezing uncontrollably and ended up in the emergency room. I was diagnosed with severe asthma. Two weeks later, I experienced a pneumothorax (I blew out a part of my lung) and ended up back in the hospital. Although now I was certain to believe more in the severity of my condition, I still tried to not let it slow me down. I continued in my medical residency for about another year. My colleagues in the operating room had to help me use my inhaler from time to time under my mask while I was performing surgery. In November of 2000, after a few run-ins with near death, the Chairman of my Department at UCLA and my wife convinced me that the smartest thing was to take a brief sabbatical.

Well, 1 month turned in to 3 months turned in to half-a-year and all of a sudden it became clear I could not go back to work anytime soon. Here I was in the prime of my life, with a job I loved dearly…and I had to quit. It was a very difficult thing to do. I'm a trained physician. My father is a physician. I was seen by the best and the brightest doctors

available—by allergists, immunologists, endocrinologists, and rheumatologists. Nothing helped. I had all the access anyone might need to good medicine, yet no product existed that would help me with my steroid-resistant asthma.

That doesn't mean, of course, that I wasn't on a variety of medicines every day. My daily regimen included Medrol, Desloratadine, Formoterol Fumerate, Levolalbuterol, Ipratopium Bromide, two nebulizations, and KCL. My asthmatic attacks were precipitated by pruritic macular and target-shaped lesions that started on my hands and feet. I was hospitalized for my condition about once a month. Without work (I was considered legally disabled) and having to deal with the physical side effects of these serious medications, my psychosocial existence and well being was crumbling.

In August 2001, my physician recommended the randomized clinical trial for Xolair. Being a physician myself and having published some articles in immunology, I did my due diligence prior to joining the trial and was intrigued by the drug's mechanistic approach.

The results were incredible. Within one month of joining the trial, my Medrol medication was reduced from between 40-60 mg daily to about 6 mg. My symptoms dramatically improved, my spirometry significantly improved; I was never hospitalized during the six-month trial, and my rash disappeared. My quality of life was also greatly enhanced. Within a month, I was thinking better, reacting better and increasing my level of activity.

Unfortunately, after the clinical trial ended in April 2002, my symptoms returned and I was again extremely limited in my functionality and ability to control my disease. Then, in September 2002, I was fortunate to again have access to Xolair as part of a clinical trial extension. This time around, my daily steroid dose of Medrol was reduced to 4 mg per day and again, my symptoms, spirometry, and atopy all improved dramatically and I didn't have to be hospitalized. After the extension trial ended, though—about six weeks after my last injection with Xolair in February 2003—I ended up in the hospital

emergency room with an epinephrine drip. My symptoms returned and my daily steroid dose was back up to its previous level. Finally, about two weeks ago, I was approved to receive the drug through the company's compassionate care program and am once again feeling much, much better.

As a patient with severe asthma, as a medical doctor, as a scientist and as a husband, I urge the FDA to approve Xolair. As a physician and scientist, my main message here today is that asthma is truly a heterogeneous disease. In fact, before I was diagnosed with steroid-resistant asthma, I had never even heard of it. I am extremely curious as to how many of the approximately 5,000 deaths in asthma each year are due to steroid resistance? We are learning more and more each day about Beta-2 receptor resistance and how bronchial inflammation comes into play with asthma. The role of an immunoglobulin in the treatment of this disease is a remarkable scientific achievement and medical advancement.

As a patient and a caring husband, I ask that FDA approve Xolair because it is the only drug that helps me—my life depends on it. Its approval will help me and others like me get back to the business of living productively and doing the things they love to do.

Thank you for your time.