

Correspondence and Replies

How omalizumab came to be studied as a therapy for chronic spontaneous/idiopathic urticaria

TO THE EDITOR:

The recent article by Stokes and Casale¹ deals with the utility of anti-IgE therapy to treat diseases other than allergic asthma. It begins with a discussion of chronic spontaneous/idiopathic urticaria and indicates that “several small studies have demonstrated effectiveness of omalizumab” and then proceeds to describe phase 2 and phase 3 studies that led to Food and Drug Administration approval last year. The first study cited was published in 2011, which gives little indication how the process actually began. A proof-of-concept, investigator-initiated study, funded by Novartis/Genentech, published in 2008, which was single-blind and placebo controlled, demonstrated a significant response in 11 of 12 patients with a 60% complete response rate.² At the same time, an abstract appeared³ describing a double-blind placebo-controlled study supported by Genentech at Johns Hopkins that demonstrated similar efficacy. It is these studies by investigators who thought that omalizumab would be effective in treating urticaria that persuaded Genentech to embark on phase 2⁴ and phase 3^{5,6} studies that led to approval for a new indication. Curiously, a recent review⁷ indicates that reference 3 in the article by Stokes and Casale was also a “proof-of-concept” study published in 2011 about the same time as the phase 2, dose-escalation study,⁴ which is excellent, but is 3 years late for that designation.

We hope this clarifies some of the history regarding those early studies of omalizumab in treating urticaria and to consider its utilities beyond asthma.

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Conflicts of interest: A. P. Kaplan and K. Joseph have received research support from Genentech. S. S. Saini has received consultancy fees from Novartis and Genentech and has received research support from Novartis and AstraZeneca.

Received for publication March 30, 2015; revised April 1, 2015; accepted for publication April 2, 2015.

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2213-2198

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<http://dx.doi.org/10.1016/j.jaip.2015.04.008>

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