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Cardiovascular and cerebrovascular events among patients receiving omalizumab: Pooled analysis of patient-level data from 25 randomized, double-blind, placebo-controlled clinical trials

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2 omalizumab: Pooled analysis of patient-level data from 25 randomized, doubleblind, placebo-controlled clinical trials 3 4 Carlos Iribarren, MD, MPH, PhD,^a Kenneth J. Rothman, DrPH,^b Mary S. Bradley, 5 MS, c* Gillis Carrigan, PhD, c Mark D. Eisner, MD, Hubert Chen, MD, MPHc 6 7 8 ^aDivision of Research, Kaiser Permanente Medical Care Program, Oakland, Calif, carlos.iribarren@kp.org; bRTI Health Solutions, Research Triangle Park, NC, 9 krothman@rti.org; ^cGenentech, Inc., South San Francisco, Calif, 10 bradley.mary@gene.com, carrigan.gillis@gene.com, esner.mark@gene.com, 11 chen.hubert@gene.com 12 13 *Employee at the time of study 14 Correspondence to: Hubert Chen, MD, MPH, 1 DNA Way, MS #453A, South San 15 Francisco, CA 94080. E-mail: chenh37@gene.com. Tel: 650-225-4619. Fax: 650-467-16 2322. 17 Role of the funding source 18 This analysis was funded by Genentech, Inc., South San Francisco, Calif, and 19 Novartis Pharma AG, Basel, Switzerland. Medical writing support for this manuscript 20 21 was provided by Linda Goldstein, PhD, and Charlotte Kenreigh, PharmD, of Excel Scientific Solutions, Southport, Conn, and funded by Genentech, Inc. and Novartis 22 Pharmaceuticals Corporation. 23

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