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Title: Efficacy and safety of omalizumab in real-life practice in India

Dr. Ashok 31180 Mahashur mahashuraa@hotmail.com MD , Dr. Deepak 31181 Talwar dtlung@hotmail.com MD and Dr. Mangala 31182 Kotnis mangala.kotnis@novartis.com MD . [1] Chest Medicine, P.D. Hinduja Hospital, Mumbai, Maharashtra, India, 400012 ; [2] Chest Medicine, Metro Hospitals and Heart Institute, Noida, UP, India and [3] Medical Department, Novartis Pharma India, Mumbai, Maharashtra, India .

Body: A 52-week, post-marketing study to assess the efficacy and safety of omalizumab in an Indian population is ongoing; we present interim 16-week data. This is an open-label, multi-center, observational, post-marketing study in 72 patients (mean age 51.7±14.9 y) with moderate-to-severe persistent allergic asthma. Endpoints are asthma exacerbations, work/college days missed, hospitalizations, ACQ 5 and ACT scores, FEV_1, and ICS use. Safety and tolerability are also being assessed. Qualitative and quantitative variables are analyzed using Chi-Square tests and paired t-tests, respectively. All parameters are compared from baseline to week 16 of omalizumab treatment. 35.9% of patients experienced ≥1 exacerbation at baseline. This reduced significantly to 15.4% at week 16 (p=0.046). The proportion of patients missing college/work and requiring unscheduled hospitalizations also reduced significantly with omalizumab (41.7% to 12.5%, p=0.039; 23.7% to 2.6%, p=0.021, respectively). ACQ scores significantly improved with omalizumab; composite scores decreased by 4.2 (14.8 vs. 10.6, 95%CI -6.5 to -1.9; p=0.001) and mean scores by 0.8 (3.3 vs. 2.5, 95%CI -1.4 to -0.2; p=0.015). ACT scores improved significantly by 5.3 (10.1 vs. 15.4, 95%CI 2.4 to 8.4; p=0.002). FEV_1 improved by 0.51L (1.23 vs. 1.74, 95%CI 0.38 to 0.64; p=0.000), and mean ICS dose decreased by 109µg (700.8µg vs. 591.8 µg, 95%CI -205.4 to -12.5; p=0.028). One gastrointestinal adverse event of moderate intensity (suspected drug related) was reported during the study and resolved with concomitant medication. Omalizumab is an effective and safe therapeutic option in Indian patients with uncontrolled allergic asthma despite high-dose ICS plus LABA.