ATOPIC ECZEMA/DERMATITIS

A REAL-LIFE ITALIAN EXPERIENCE ON EFFICACY AND SAFETY OF DUPILUMAB IN ADULT PATIENTS WITH ATOPIC DERMATITIS

Maria Concetta Fargnoli [1] - Maria Esposito [1] - Silvia Ferrucci [2] - Giampiero Girolomoni [3] - Annamaria Offidani [4] - Annalisa Patrizi [5] - Ketty Peris [6] - Antonio Costanzo [7] - Giovanna Malara [8] - Giovanni Pellacani [9] - Marco Romanelli [10] - Paolo Amerio [11] - Antonio Cristaudo [12] - Maria Laura Flori [13] - Alberico Motolese [14] - Paola Betto [15] - Cataldo Patruno [16] - Paolo Pigatto [17] - Riccardo Sirna [18] - Giuseppe Stinco [19] - Iris Zalaudek [20] - Luca Bianchi [21] - Valeria Boccaletti [22] - Serafinella Patriza Cannavò [23] - Francesco Cusano [24] - Serena Lembo [25] - Raffaele Mozzillo [26] - Rosella Gallo [27] - Concetta Potenza [28] - Franco Rongioletti [29] - R Tiberio [30] - T Grieco [31] - G Micali [32] - S Persechino [33] - M Pettinato [34] - S Pucci [35] - L Stingeni [36] - A Romano [37] - G Argenziano [38]

University Of L'aquila, Department Of Dermatology, L'aquila, Italy [1] - Fondazione Irccs Ca' Grande Ospedale Maggiore Policlinico, Unit Of Dermatology, Milan, Italy [2] - University Of Verona, Section Of Dermatology And Venereology, Dept Of Medicine, Verona, Italy [3] - Polytechnic Marche University, Dept Of Clinical And Molecular Sciences, Dermatology Unit, Ancona, Italy [4] - University Of Bologna, Dept Of Experimental, Diagnostic And Specialty Medicine, Dermatology Unit, 5dept Of Experimental, Diagnostic And Specialty Medicine, Dermatology Unit, Bologna, Italy [5] - Catholic University, Fondazione Policlinico Universitario A. Gemelli Irccs, Institute Of Dermatology, Rome, Italy [6] - Humanitas University And Humanitas Clinical And Research Center, Dermatology Unit, Dept Of Biomedical Sciences, Rozzano, Italy [7] - Grande Ospedale Metropolitano, Bianchi Melacrino Morelli, Dermatology Dept, Reggio Calabria, Italy [8] - University Of Modena And Reggio Emilia, Dept Of Dermatology, Modena, Italy [9] - University Of Pisa, Dermatology Unit, Dept Of Clinical And Experimental Medicine, Pisa, Italy [10] - G. D'annunzio University, Dept Of Medicine And Aging Science, Dermatologic Clinic, Chieti, Italy [11] - San Gallicano Dermatological Institute-irccs, Unit Of Dermatology, Rome, Italy [12] - University Of Siena, Hospital S. Maria Alle Scotte, Dermatology Section, Dept Of Clinical Medicine And Immunological Science, Siena, Italy [13] - Macchi Hospital, Dept Of Dermatology, Varese, Italy [14] - Ospedale San Bortolo, Ulss8 Berica, Dept Of Dermatology, Vicenza, Italy [15] - University Magna Graecia, Dept Of Health Sciences, Catanzaro, Italy [16] - Irccs Galeazzi Orthopedic Institute, University Of Milan, Dept Of Biomedical, Surgical And Dental Sciences, Clinical Dermatology,, Milan, Italy [17] - Ospedale Della Misericordia, Unit Of Dermatology, Grosseto, Italy [18] - University Of Udine, Dept Of Experimental And Clinical Medicine, Institute Of Dermatology, Udine, Italy [19] - Hospital Maggiore Of Trieste, Dermatology Clinic, Trieste, Italy [20] - University Of Tor Vergata, Dept Of Dermatology, Rome, Italy [21] - University Hospital, Parma, Dept Of Clinical And Experimental Medicine,

Section Of Dermatology,, Parma, Italy [22] - University Of Messina, Dept Of Clinical And Experimental Medicine, Dermatology, Messina, Italy [23] - Gaetano Rummo Hospital, Dermatology Unit, Benevento, Italy [24] - University Hospital San Giovanni Di Dio E Ruggi Di Salerno, Hospital Santa Maria Incoronata Dell'olmo, Unit Of Dermatology, Salerno, Italy [25] - "san Gennaro" Hospital, Dermatology And Venereology, Naples, Italy [26] - University Of Genoa, Hospital, Polyclinic San Martino, Dermatology Section, Genoa, Italy [27] - Sapienza University Of Rome, Polo Pontino, Dermatology Operational Unit "daniele Innocenzi", Dept Of Medical-surgical Sciences And Biotechnologies,, Terracina, Italy [28] - University Of Cagliari, Dept Of Medical Sciences And Public Health, Section Of Dermatology, Cagliari, Italy [29] - Dept Of Health Science, University Of Eastern Piedmont, Novara [30] - Dermatology Clinic Umberto I, Sapienza University Of Rome [31] - Dermatology Clinic, University Of Catania, Catania, Italy [32] - Department Of Dermatology, Nesmos Unit, Sant'andrea Hospital, Sapienza University Of Rome [33] - Unit Of Dermatology, University Hospital, Polyclinic Vittorio Emanuele, Catania [34] - Allergology, Hospital Of Civitanova Marche [35] - Dermatology Section, Dept Of Medicine, University Of Perugia [36] - Allergology Unit, Columbus Presidium, Catholic University, Fondazione Policlinico Universitario A. Gemelli Irccs, Rome [37] - Dermatology Unit, University Of Campania Luigi Vanvitelli, Naples [38]

Introduction: Atopic dermatitis (AD) is a chronic inflammatory skin disease with substantial morbidity and quality of life impairment. Dupilumab is an interleukin 4 receptor α-antagonist that inhibits IL-4 and IL-13, recently approved for the treatment of moderate-to-severe AD.

Objective: To assess dupilumab efficacy and safety in a real-life Italian experience.

Materials and Methods: Adult patients affected by moderate-to-severe AD with contraindication/failure/intolerance to ciclosporin, referring to 39 centres, received subcutaneous dupilumab in the context of a national patient access program. Eczema-Area-and-Severity-Index (EASI) score, itch and sleep numerical-rating-score (itch-NRS and sleep-NRS) and Dermatology-Life-Quality-Index (DLQI) were assessed at baseline, after 4 and 16 weeks of treatment.

Results: A total of 109 (71M/38F) patients, with a mean age of 37.8 (range 19-80), was enrolled in the study. Mean age at disease onset was 14.2 (range 0-77). Baseline mean EASI was 33.3 (SD 16.1), mean itch-NRS 8.36 (SD 1.3), mean sleep-NRS 6.99 (SD 2.5) and mean DLQI 17.6 (SD 6.2). After 4 weeks, all outcomes decreased significantly with a mean EASI of 15.3 (SD 12.7), mean itch-NRS of 4.07 (SD 2.3), mean sleep-NRS of 3.32 (SD 2.4) and mean DLQI of 8.3 (SD 6.4) ($p< 0.00001$ for all); patients presenting 50% (EASI50) and 75% (EASI75) reduction from baseline in the EASI score were 59.63% and 28.44%, respectively. After 16 weeks, mean EASI was 9.2 (SD 10.2), mean itch-NRS 2.56 (SD 2.6), mean sleep-NRS 1.93 (SD 2.2) and mean DLQI 5.4 (SD 6.2) ($p< 0.00001$ for all); patients achieving EASI50 were 87.16% and EASI75 60.55%. Adverse events were

observed in 22.0% (24/109) with conjunctivitis being the most frequent (12/109, 11%). One patient discontinued treatment because of gastro-intestinal bleeding.

Conclusions: Dupilumab reduced disease severity, pruritus, sleep loss and improved quality of life in AD with an acceptable safety profile in real-life clinical practice.