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RESEARCH LETTER

Super Responder Profile Under Bimekizumab Treatment in Moderate-to-Severe Psoriasis: A Short Term Real-Life Observation—IL PSO (Italian Landscape Psoriasis)

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Key Points

There is still a lack of knowledge on the characteristics of super responders (SRs) during treatment with bimekizumab, since genetic, clinical, and biomarkers investigations are required.

During bimekizumab treatment, a high rate of SRs was demonstrated at early clinical timepoints, with some interesting differences between SRs and non-superrespnders.

1 Introduction

Bimekizumab is a humanized monoclonal antibody, targeting both IL-17A and IL-17F, that has been recently approved for the treatment of moderate-to-severe plaque psoriasis following encouraging results from four phase-III clinical trials [1–4]. Real-word experiences on bimekizumab are limited and there is still limited knowledge about the super responder (SR) patient profile. There is no agreement on the definition of SR with respect to psoriasis even though this term has been used in different clinical studies [5–7].

We conducted a 16-week multicenter, retrospective, observational, real-word study aimed at assessing the SR profile under bimekizumab treatment in patients with moderate-to-severe psoriasis.

2 Materials and Methods

We enrolled patients from 21 Italian dermatologic Departments. Consecutive adult patients with moderate-to-severe plaque psoriasis if they had completed at least 16 weeks of bimekizumab treatment were considered eligible for inclusion in the study. Patient eligibility was assessed according to the rules of the Italian Medicine Agency (AIFA). Bimekizumab was administered at a dosage of 320 mg at weeks 0, 4, 8, 12, and 16 followed by an administration every 8 weeks, according to the summary of product characteristics. Patients whose clinical reports were not available and those who had not reached 16 weeks of follow-up were excluded. Patients signed an informed consent to allow collection and utilization of clinical data for scientific purposes. This study adhered to established standards of good clinical practice. Ethical approvation number 0006349 was obtained from the Comitato Etico Territoriale (CET) Interaziendale AOU Città della Salute e della Scienza di Torino. Effectiveness

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endpoints were the improvement of 75% (PASI 75), 90% (PASI 90), and 100% (PASI 100) in Psoriasis Area and Severity Index (PASI) at different timepoints (week 4 and week 16) as compared to baseline. In this retrospective evaluation we defined as SR a patient achieving PASI 100 at each timepoint, while patients who did not achieve PASI 100 were defined as non-super-responders (NSRs).

2.1 Statistical Analysis

The percentage of patients who achieved PASI 100 at each timepoint (week 4 and week 16) was determined, and the percentage of these individuals with each of the following characteristics was reported: sex, age, body mass index (BMI), comorbidities, arthritis, PASI, special localization, previous systemic therapies, and previous biologic exposure. We conducted univariate analysis on each of these characteristics taking into account the achievement of PASI 100 as outcome variable. Moreover, to evaluate the possible differences in the demographic and clinical variables between the two groups of patients (SR vs. NSR), univariate analysis has been estimated. Categorical values were described by absolute and relative frequencies. Two-sided *p*-values below 0.05 were considered significant.

To evaluate the determinants of SR status achievement at week 16 we constructed a multivariable logistic regression model. The multicollinearity assumption was tested using a variance inflation factor, eliminating variables with high correlation (value > 0.9).

We included all the baseline characteristics in the multivariate regression model, odds ratios (ORs) and 95% confidence intervals (CIs) are provided. Statistical analyses were performed using SAS software v 9.3 (SAS Institute Inc., Cary, NC, USA).

3 Results

We enrolled 137 patients with a mean age of 52.47 ± 15.56 years, mean BMI of 27.43 ± 5.91 and a mean PASI at baseline of 16.00 ± 9.29. Additional demographic and clinical characteristics of our cohort at baseline are shown in Table 1.

At week 4, 72% of patients achieved PASI 75, 50% PASI 90, and 43% of patients achieved complete clearance (PASI 100), defining the SR population at week 4 (Fig. 1A).

At week 16, 93% of patients obtained PASI 75, 77% PASI 90, and 70% of patients experienced complete disease resolution (PASI 100) while only 7% of patients did not achieve PASI 75 (Fig. 1B).

Table 1 Demographic and clinical characteristics of the study sample

Number of total patients	137
	Mean ± SD
Age (years)	52.47 ± 15.56
BMI	27.43 ± 5.91
mPASI at baseline	16.00 ± 9.29
Males	97 (70.80)
Comorbidities	
None	71 (65.23)
1	39 (28.47)
≥ 2	27 (19.71)
Arthritis	
Yes	17 (12.40)
No	120 (87.60)
Special localization	
Nails	24 (17.52)
Scalp	48 (35.04)
Genital	20 (14.60)
Palmo-plantar	7 (5.11)
Previous systemic therapies	
Mtx	34 (24.82)
Cys	52 (37.96)
Aci	12 (8.76)
Previous biologic exposure	
Naïve	62 (45.26)
< 2	42 (30.65)
≥ 2	33 (24.09)

BMI body mass index, *PASI* Psoriasis Area Severity Index, *MTX* methotrexate, *Cys* cyclosporine, *Aci* acitretin

A univariate analysis of the differences between the SR status at week 4 and week 16 was performed. All the following variables (sex, age, BMI, comorbidities, presence of arthritis, PASI, special localizations, previous systemic therapies, and previous exposure to biological drugs) were analyzed and no significant differences were encountered (data not shown).

A further univariate analysis was conducted to compare patients who achieved the SR status and patients who did not achieved the SR status (NSRs) at week 16 (Table 2). More characteristics differentiated SR from NSR. In detail, male sex ($p = 0.0002$), age ≤ 45 years and age between 46 and 65 years ($p = 00004$ and $p = 0.003$, respectively), BMI < 25 ($p < 0.0001$), absence of comorbidities ($p = 0.001$), absence of arthritis ($p < 0.0001$), baseline PASI between 10 and 20 ($p = 0.004$), scalp and genital localization ($p = 0.002$ both), naïve status and prior exposure to less than two biological treatments ($p = 0.0006$ and $p < 0.0001$, respectively) were more represented in SR subjects (Table 2).

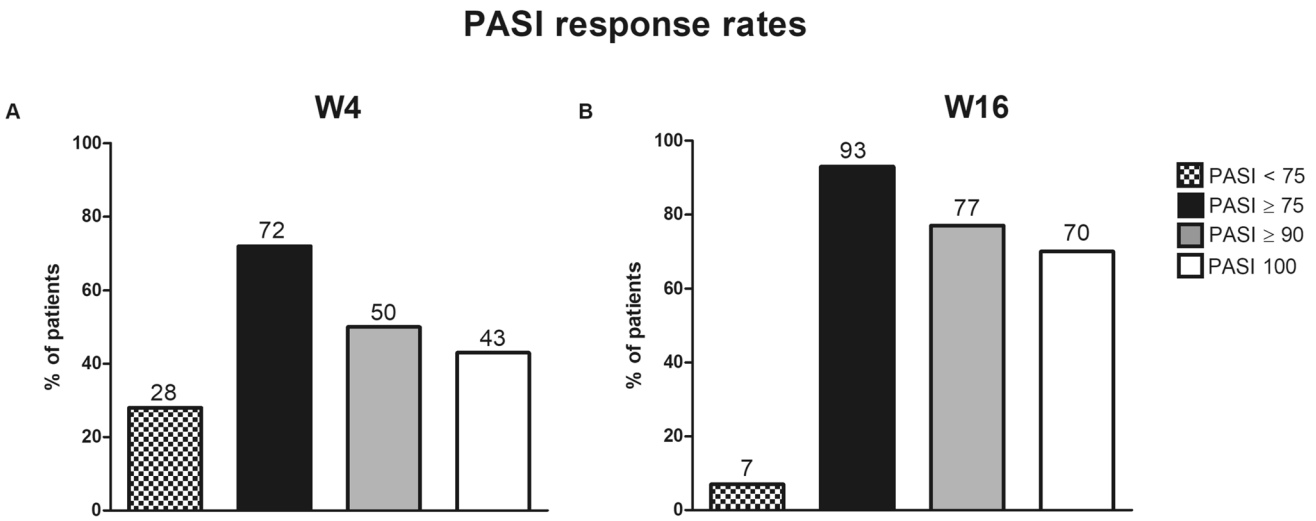

Fig. 1 Bimekizumab clinical effectiveness as assessed by Psoriasis Area Severity Index (PASI) 75, PASI 90, and PASI 100 at week 4 (**A**) and week 16 (**B**)

A multivariable logistic regression model analysis having as outcome PASI 100 at W16 was performed showing that males were more likely to achieve PASI 100 than female patients (OR: 2.692; 95% CI: 1.594–4.482; $p < 0.001$). Patients aged > 65 years were less likely to achieve PASI 100 response as compared to patients aged < 45 years (OR: 0.2778; 95% CI: 0.1371–0.5700; $p < 0.001$). No statistical differences were encountered regarding BMI. The positive predictor of PASI 100 at week 16 was the absence of comorbidities having as reference ≥ two comorbities (OR: 3; 95% CI: 1.653–5.518; $p < 0.001$). Not having a concurrent arthritis also showed greater odds to achieve PASI 100 at week 16 than patients with PsA (OR: 3.5; 95% CI: 2.212–6.100; $p < 0.001$). A baseline PASI score between 10 and 20 was associated with significantly higher odds compared to a baseline PASI score < 10 (OR: 3.100; 95% CI: 1.900–5.920; $p < 0.001$). No statistical differences were encountered regarding special localizations or previous non-biologic treatments. Conversely, previous exposure to at least two biologics was associated with significantly lower odds to achieve PASI 100 at week 16 compared with bio-naïve patients (OR: 0.2391; 95% CI: 0.1158–0.4815; $p < 0.001$). Results of the multivariable logistic regression model at week 16 are shown in Fig. 2.

4 Discussion

Although there is no consensus on the use of the SR concept in the field of psoriasis, the raised bar of effectiveness available during bimekizumab treatment allowed us to define SRs as those reaching PASI 100 at week 4 and at week 16.

Bimekizumab demonstrated a rapid and consistent efficacy associated with a good safety profile in randomized clinical trials (RCTs) [1–4], while, to date, real-life data are limited [8–10]. As a consequence, there is still a lack of knowledge on the characteristics of SRs during treatment with bimekizumab; clinical and genetic factors might be of importance in defining this sub-group.

Some data on the SR status may be deduced from RCTs; in particular, Warren et al. [1] reported PASI 100 response in 15.4% of patients at week 4 and in 60.8% of patients at week 16, while Gordon et al. [2] described complete clearance in 18.9% and 68.2% of patients at weeks 4 and 16, respectively. Reich et al. showed PASI 100 response in 15% of patients at week 4 and in 59% of patients at week 16 in the "BE VIVID" clinical trial [3], while in the "BE RADIANT" clinical trial [4] 13.9% and 61.7% of patients obtained PASI 100 at weeks 4 and 16, respectively. Findings from our real-life experience clearly showed better results compared to RCTs, as PASI 100 was achieved by 40% of patients at week 4 and by 70% of patients at week 16, demonstrating a consistent SR population under bimekizumab treatment.

In order to investigate the dynamic process underlying achievement of the SR status, we analyzed the differences between patients who reached complete clearance at week 4 and week 16, but no significant differences were identified through the analyzed variables.

Our observation delineated a bimekizumab SR profile. The following baseline characteristics were associated with PASI 100 at week 16: male sex, age < 65 years, absence of comorbidities and arthritis, baseline PASI between 10 and 20, naïve status or prior exposure to less than two biological treatments.

Table 2 Description of the clinical and demographic variables according to the patient response profile at week 16. Univariate analysis

Population ($n = 137$)	Week 16		p-value
	NSR n (%)	SR n (%)	
	41 (30)	96 (70)	
Gender			
Male	27 (20)	70 (51)	0.0002**
Female	14 (10)	26 (19)	0.091
Age, years			
≤ 45	10 (7)	36 (26)	0.0004**
≥ 46 to < 65	22 (16)	50 (37)	0.003*
≥ 65	9 (7)	10 (7)	1.000
BMI			
< 25	7 (5)	36 (25)	< 0.0001**
≥ 25 to < 30	25 (18)	32 (24)	0.467
≥ 30	9 (7)	28 (21)	0.005
Comorbidities			
None	20 (14)	51 (38)	0.001*
1	11 (8)	28 (21)	0.017
≥ 2	10 (7)	17 (12)	0.229
Arthritis			
Yes	7 (5)	10 (7)	0.619
No	34 (25)	86 (63)	< 0.0001**
PASI			
< 10	4 (3)	14 (10)	0.028
≥ 10 to < 20	26 (19)	57 (42)	0.004*
≥ 20	11 (8)	25 (18)	0.033
Special localization			
Nails	9 (7)	15 (11)	0.290
Scalp	12 (9)	36 (26)	0.002*
Genital	3 (2)	17 (12)	0.002*
Palmo-plantar	3 (2)	4 (3)	1.000
Previous systemic therapies			
Mtx	10 (7)	24 (18)	0.029
Cys	15 (11)	37 (27)	0.006
Aci	5 (4)	7 (5)	0.770
Previous biologic exposure			
Naïve	16 (12)	46 (34)	0.0006**
< 2	3 (2)	39 (28)	< 0.0001**
≥ 2	22 (16)	11 (8)	0.096

NSR non-super-responder, *SR* super responder, *BMI* body mass index, *PASI* Psoriasis Area Severity Index, *MTX* methotrexate, *Cys* cyclosporine, *Aci* acitretin

Most of these data have implications from a clinical point of view. Our study delineates a better response profile in male and younger patients, as recently demonstrated by Hagino et al. [12], in the absence of comorbidities and arthritis and in patients with a PASI between 10 and 20. A possible explanation for why patients with PASI <10 do not reach statistical significance may arise from the consideration that a large proportion of patients (55%) in our sample were failure/multifailure patients, possibly representing patients with residual resistant psoriasis localizations and difficult-to-treat areas, despite a low PASI score. However, the small sample size does not allow us to confirm this hypothesis and provide statistical insights. Concerning other clinical disease characteristics, the presence of scalp or genital localization delineated a favorable clinical variant for a complete response to bimekizumab, while nail and palmoplantar psoriasis were demonstrated as more difficult-to-treat locations. A possible explanation of this latter result in an optimally responding population may be that a short-term 16-week observation period may not be sufficient to produce significant improvement on nail disease and palmoplantar localizations. A further long-term update of this analysis will be needed to confirm this clinical hypothesis. Instead, the observation of optimal results on genital psoriasis and on scalp psorias response patterns confirms previously reported positive bimekizumab results, also in the short term [13, 14]. Naïve status and prior exposure to less than two biologics seem to favor a positive response to bimekizumab. This observation is partially in line with a previous real-life report describing 56 patients undergoing bimekizumab treatment and demonstrating lower response in bio-experienced patients at week 4, although the observation was not confirmed at week 16, suggesting that a previous failure of biologics does not seem to affect its therapeutic effectiveness [15]. Notably, all the results were confirmed by the regression analysis.

4.1 Limitations

Limitations of this study were its retrospective nature, the limited sample size, the short follow-up observation period, and the lack of uniformity of clinical assessment with a high number of involved clinicians. The most important findings of the study were the high rate of SR achieved at early clinical timepoints during bimekizumab treatment, with some interesting differences between SRs and NSRs.

In conclusion, our results suggest the optimal bimekizumab patient profile and allow us to identify the place in therapy of this new therapeutical option, although further and larger studies are needed.

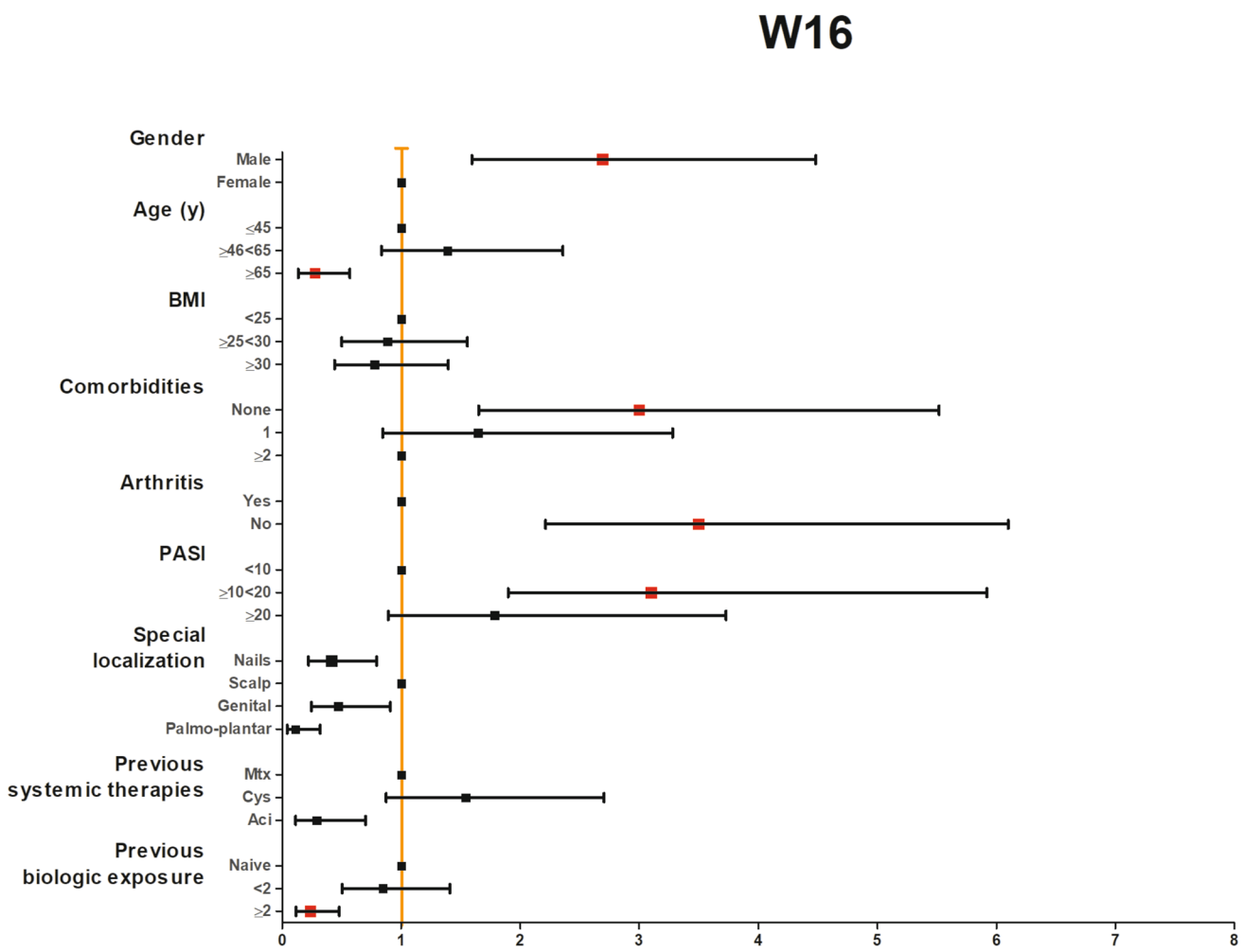

Fig. 2 Results of the multivariable logistic regression model at week 16

Declarations

Funding None.

Conflicts of Interest M. Esposito has served as a speaker/board member for Abbvie, Almirall, Eli Lilly, Janssen, Leo Pharma, Novartis, Sanofi, UCB. A. Balato has received honoraria for participation in advisory boards, meetings, or as a speaker for AbbVie, Celgene, Janssen-Cilag, Eli Lilly, Novartis Pharma, Pfizer, Sanofi-Genzyme, and UCB Pharma. P. Malagoli has been a speaker for AbbVie, Lilly, Novartis, Janssen-Cilag, Celgene, Leopharma, and Almirall. G. Caldarola reports consulting fees or honorarium and payment for lectures from Lilly and Novartis. P. Gisondi has been a consultant and/or speaker for Abbvie, Almirall, Amgen, Janssen, Leo-Pharma, Eli-Lilly, Novartis, Pierre Febre, Sandoz, Sanofi, and UCB. C. Carrera has served as a board participant or speaker for Abbvie, Lilly, Janssen, Novartis, Celgene, Almirall, and Leopharma. P. Dapavo has been a speaker for Novartis, Abbvie, Sanofi, UCB, Janssen, Lilly, and LeoPharma. F. Gaiani acted as a speaker or consultant for Novartis, Abbvie, Eli Lilly, Celgene, LeoPharma, and Almirall. A.Giunta received grants or is an investigator for Biogen and Lilly; and is a consultant/advisory board/speaker for AbbVie, Almirall, Celgene, Janssen, Leo Pharma, Eli Lilly, Merck Sharpe Dohme, Novartis, Pfizer, Sandoz, and UCB. F.Loconsole served on advisory boards and/ or received honoraria for lectures from Abbvie, Janssen-Cilag, Novartis, Lilly, Sanofi. A.V. Marzano reports consultancy/advisory board disease-relevant honoraria from AbbVie, Boehringer Ingelheim, Novartis, Pfizer, Sanofi and UCB. M. Megna has served as a speaker/board member for Abbvie, Almirall, Amgen, Eli Lilly, Janssen, Leo Pharma, Novartis, UCB. M. Venturini served as a speaker or advisory board member for Abbvie, Almirall, Amgen, Eli-Lilly, Galderma, Leo Pharma, Novartis, Pierre Fabre, and UCB Pharma. A. Costanzo has served as an advisory board member, consultant and has received fees and speaker's honoraria or has participated in clinical trials for Abbvie, Almirall, Biogen, LEO Pharma, Lilly, Janssen, Novartis, Pfizer, Sanofi Genzyme, and UCB-Pharma. A. Narcisi has served on advisory boards, received honoraria for lectures and research grants from Almirall, Abbvie, Leo Pharma, Celgene, Eli Lilly, Janssen, Novartis, Sanofi-Genzyme, Amgen, and Boehringer Ingelheim. A. Carugno has served as a speaker/board member for Abbvie, Almirall, Boehringer Ingelheim, Eli Lilly, Janssen, Leo Pharma, Novartis, UCB Pharma. C. De Simone served as a speaker or advisory board member for Almirall, AbbVie, Amgen, Eli Lilly, Janssen, Leopharma, Novartis, Sanofi and UCB Pharma. M.C.

Fargnoli has served on advisory boards, received honoraria for lectures and/or research grants from AMGEN, Almirall, Abbvie, Boehringer-Ingelheim, BMS, Galderma, Kyowa Kyrin, Leo Pharma, Pierre Fabre, UCB, Lilly, Pfizer, Janssen, MSD, Novartis, Sanofi-Regeneron, Sunpharma. M. Burlando. served as a speaker or advisory board member for Almirall, AbbVie, Amgen, Eli Lilly, Janssen, Leopharma, Novartis, and UCB Pharma. D. Orsini has been a speaker and/or consultant for Abbvie, LeoPharma, UCB, Bristol-Meyer Squibb and Boehringer-Ingelheim. The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Ethics Approval Patients signed an informed consent to allow collection and utilization of clinical data for scientific purposes. This study adhered to established standards of good clinical practice. Ethical approvation number 0006349 was obtained from the Comitato Etico Territoriale (CET) Interaziendale AOU Città della Salute e della Scienza di Torino.

Consent to Participate All patients gave written informed consent for the retrospective retrieval of anonymized data. All patients gave written informed consent for the pubblication of anonymized data.

Consent for Publication Not applicable.

Availability of Data and Material Additional data supporting the findings of this study are avaiabile from the corresponduing author on reasonable request.

Code Availability Not applicable.

Authors'Contributions Study conception and design: Maria Esposito, Paolo Gisondi, Chiara Assorgi, Francesco Bellinato, Pina Brianti, Martina Burlando, Giovanna Brunasso, Stefano Caccavale, Giacomo Caldarola, Elena Campione, Piergiacomo Calzavara Pinton, Anna Campanati, Carlo Giovanni Carrera, Andrea Carugno, Emanuele Cozzani, Antonio Costanzo, Francesco Cusano, Paolo Dapavo, Annunziata Dattola, Clara De Simone, Roberta Di Caprio, Federico Diotallevi, Maria Concetta Fargnoli, Francesca Gaiani, Alessandro Giunta, Piergiorgio Malagoli, Angelo Valerio Marzano, Matteo Megna, Santo Raffaele Mercuri, Edoardo Mortato, Alessandra Narcisi, Diego Orsini, Luca Potestio, Pietro Quaglino, Antonio Giovanni Richetta, Francesca Romano, Paolo Sena, Emanuele Vagnozzi, Marina Venturini, Francesco Loconsole, Anna Balato; manuscprit editing: Maria Esposito, Paolo Gisondi, Francesco Loconsole, Anna Balato; approval to submit: Maria Esposito, Paolo Gisondi, Francesco Loconsole, Anna Balato.

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