

UOC Acquisizione Beni e Servizi

**Il dirigente della UOC Acquisizione Beni e Servizi
in virtù della delega conferita con deliberazione N°446/2024
HA ASSUNTO LA PRESENTE DETERMINAZIONE**

N. 776 del 13/09/2024

OGGETTO: Autorizzazione alla liquidazione fatture per la pubblicazione di articoli scientifici di diverse Società: Fondo Ricerca Corrente IRE 2024 CUP H83C24000170001 responsabile Direttore Scientifico IRE. Fondo MUR-PNRR cod. Ifo 22/15/R/37 CUP H83C22000550006 responsabile Dr. M. Maugeri-Saccà. Fondo Ricerca Corrente ISG 2024 CUP H53C23001520001 responsabile Direttore Scientifico f.f.

Esercizi/o e conto 2024-502020197-502020198 Centri/o di costo 1102000- 1101000-1100000

- Importo presente Atto: € € 24.200,02

- Importo esercizio corrente: € € 24.200,02

Budget

- Assegnato: € -

- Utilizzato: € -

- Residuo: € -

Autorizzazione n°: 2024/ ABS SAR 131

Servizio Risorse Economiche: **Giovanna Evangelista**

UOC Acquisizione Beni e Servizi Proposta n° DT-773-2024

L'estensore

Daniela Kolziu

Il Responsabile del Procedimento

Andrea Scotti

Il Dirigente della UOC Acquisizione Beni e Servizi

Andrea Scotti

La presente determinazione si compone di n° 6 pagine e dei seguenti allegati che ne formano parte integrante e sostanziale:

Allegati nr. 21, note protocollo e copia fattura estera da liquidare

Il Dirigente della UOC Acquisizione Beni e Servizi

- Visto il decreto legislativo 30 dicembre 1992 n. 502 e successive modificazioni ed integrazioni;
il decreto legislativo 16 ottobre 2003 n. 288 e il decreto legislativo 23 dicembre 2022 n. 200 di riordino della disciplina degli Istituti di ricovero e cura a carattere scientifico;
- Vista la legge regionale 23 gennaio 2006, n. 2;
- Visto l'Atto Aziendale adottato con deliberazione n. 153 del 19 febbraio 2019 e approvato dalla Regione Lazio con DCA n. U00248 del 2 luglio 2019, modificato e integrato con deliberazioni n. 1254 del 02 dicembre 2020, n. 46 del 2 gennaio 2021 e n. 380 del 25 marzo 2021, approvate dalla Direzione Salute e Integrazione Sociosanitaria della Regione Lazio, con Determinazione n. G03488 del 30 marzo 2021;
- Vista la deliberazione della Giunta Regionale n. 256 del 17 aprile 2024, avente ad oggetto *“Commissariamento dell'IRCCS Istituti Fisioterapici Ospitalieri (Art. 8, comma 7 bis, della legge regionale 16 giugno 1994, n. 18 e s.m.i.)”*;
- Visto il Decreto del Presidente della Regione Lazio n. T00087 del 07 maggio 2024, avente ad oggetto: *“Nomina del Commissario straordinario dell'IRCCS Istituti Fisioterapici Ospitalieri (Art. 8, comma 7 bis, della legge regionale 16 giugno 1994, n. 18 e s.m.i.)”*;
- Visto il D.M. del Ministero della Salute del 20 giugno 2024 di conferma del riconoscimento del carattere scientifico dell'IRCCS di diritto pubblico a Istituti Fisioterapici Ospitalieri (IFO) relativamente alla disciplina di “oncologia” per l'Istituto Nazionale Tumori Regina Elena (IRE) e alla disciplina di “dermatologia” per l'Istituto Santa Maria e San Gallicano (ISG);
- Vista la deliberazione n. 446 del 27 maggio 2024 di attribuzione delle deleghe ai Dirigenti del Ruolo Professionale, Tecnico e Amministrativo degli IFO;

Tenuto Presente il concetto di infungibilità viene collegato agli obiettivi della ricerca individuati dal responsabile scientifico della stessa;

Premesso che con protocollo n. 16070 del 15 dicembre 2023 del Direttore Scientifico ff. ISG, munito di Nulla Osta del Direttore Generale f.f. IFO, è stato autorizzato l'appostamento della Ricerca Corrente 2024 ISG per un importo pari a € 966.909,34;

che con protocollo n. 16053 del 15 dicembre 2023 del Direttore Scientifico IRE, munito di Nulla Osta del Direttore Generale f.f. IFO, è stato autorizzato l'appostamento della Ricerca Corrente 2024 IRE per un importo pari a € 2.847.703,86;

con deliberazione n. 1020 del 30.12.2023, è stata stipulata una Convenzione con il MUR-PNRR, “finanziato dall’Unione europea – Next Generation EU”, per lo svolgimento del Progetto di Ricerca dal titolo: "HEAL ITALIA - Health Extended Alliance for Innovative Therapies, Advanced Lab-research, and Integrated Approaches of Precision Medicine", cod. IFO 22/15/R/37, responsabile Dr. Marcello Maugeri Saccà;

Considerato che il Dr.ssa Diego Orsini con nota protocollo n. 0011809 del 04-09-2024, nota protocollo 0011922 del 06/09/2024 e nota protocollo 0011926 del 06/09/2024, il Dr. M. Maugeri-Saccà con nota protocollo 0011741 del 03/09/2024, la Dr.ssa F. Campo con nota protocollo 0011740 del 03/09/2024 e Dr. G. Bossi con nota protocollo 0011743 del 03/09/2024 hanno chiesto la liquidazione delle seguenti fatture:

- Fattura nr. 6687336661 del 13/02/2024 di € 4.276,10 Iva compresa della società Taylor&Francis Group relativa alla pubblicazione del manoscritto dal titolo “Efficacy and Safety of Tildrakizumab in Elderly patients:Real-World multicenter Study(Ester-Study)”nella Rivista scientifica Journal of Dermatological Treatment.
- Fattura nr.6687343582 del 18/05/2024 di € 3.747,84 Iva compresa della società Taylor&Francis Group relativa alla pubblicazione del manoscritto dal titolo” Effectiveness and Safety of Risankizumab in very Severe Olaque Psoriasis: A Real Life Retrospective Study(Vespa-Study) nella Rivista Journal of Dermatological Treatment.
- Fattura nr.6687348967 del 14/08/2024 di € 4.684,80 Iva compresa della società società Taylor&Francis Group relativa alla pubblicazione del manoscritto dal titolo “Efficaccy and safety of bimekizumab in elderly patients:Real-world multicenter

Retrospective study-il PSO(Italian Landscape Psoriasis)” nella rivista Journal of Dermatological Treatment ”.

- Fattura nr. APC600552509 del 10/07/2024 di 4.200 \$(€ 4.739,80 Iva Compresa) della società Copyright Clearance Center (CCC Rights Link) relativa alla pubblicazione del manoscritto dal titolo “Transcriptional phenocopies of deleterious KEAP1 mutation correlate with survival outcomes in lung cancer treated with immunotherapy”.
- Fattura 2939741518 del 15/08/2024 di € 3.375,74 Iva Compresa della società Springer Nature Group relativa alla pubblicazione del manoscritto “The landscape of circulating tumor HPV DNA for surveillance of HPV-oropharyngeal carcinoma:systematic review and meta-analysis”
- Fattura 2939751757 del 19/08/2024 di € 3.375,74 Iva Compresa della società Springer Nature Group relativa alla pubblicazione del manoscritto:”Repurposed AT9283 triggers anti-tumoral effects by targeting MKK3 oncogenic funtion in colorectal cancer” nella rivista scientifica Journal of Experimental&clinical cancer research.

Acquisito	 il parere favorevole del Direttore Scientifico dell’Istituto Regina Elena, apposto in calce alle richieste sopra citate;
Accertata	la disponibilità sui Fondi citati in premessa;
Esperiti	i controlli sulle richieste presentate dai responsabili dei progetti;
Attestato	che il presente provvedimento, a seguito dell’istruttoria effettuata, nella forma e nella sostanza è totalmente legittimo e utile per il servizio pubblico, ai sensi dell’art.1 della legge 20/94 e successive modifiche, nonché alla stregua dei criteri di economicità e di efficacia di cui all’art.1, primo comma, della legge 241/90, come modificata dalla legge 15/2005;

DETERMINA

per i motivi di cui in narrativa che si intendono integralmente confermati di:

1-autorizzare il pagamento delle fatture:

- Fattura nr. 6687336661 del 13/02/2024 di € 4.276,10 Iva compresa della società Taylor&Francis Group relativa alla pubblicazione del manoscritto dal titolo “Efficacy and Safety of Tildrakizumab in Elderly patients:Real-World multicenter

Study(Ester-Study)”nella Rivista scientifica Journal of Dermatological Treatment.

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- Fattura 2939741518 del 15/08/2024 di € 3.375,74 Iva Compresa della società Springer Nature Group relativa alla pubblicazione del manoscritto “The landscape of circulating tumor HPV DNA for surveillance of HPV-oropharyngeal carcinoma:systematic review and meta-analysis”
- Fattura 2939751757 del 19/08/2024 di € 3.375,74 Iva Compresa della società Springer Nature Group relativa alla pubblicazione del manoscritto:”Repurposed AT9283 triggers anti-tumoral effects by targeting MKK3 oncogenic function in colorectal cancer” nella rivista scientifica Journal of Experimental&clinical cancer research.

2 - far gravare la spesa complessiva di € 24.200,02 Iva compresa sui Fondi: Fondo PNRR-MUR cod. Ifo 22/15/R/37 per € 4.739,80 responsabile Dr. M. Maugeri-Saccà, Fondo Ricerca corrente ISG 2024 per € 12.708,74 responsabile il Direttore Scientifico ISG f.f. Fondo Ricerca Corrente IRE 2024 per € 6.751,48 che presentano la necessaria disponibilità.

Ricerca Corrente IRE 2024

- assegnato: € 2.847.703,86
 - utilizzato: € 1.564.839,60
 - presente atto: € 6.751,48
 - residuo: € 1.276.112,78

Ricerca Corrente ISG 2024

- assegnato: € 966.909,34
 - utilizzato: € 438.322,55
 - presente atto: € 12.708,74
 - residuo: € 515.878,05

cod. IFO 22/15/R/37

- assegnato: € 185.138,50

- utilizzato: € 118.612,60
- presente atto: € 4.739,80
- residuo: € 61.786,10

- dare atto che il relativo impegno di spesa andrà a gravare come di seguito meglio precisato:

- € 19.460,22 sul Conto 502020198
- € 4.739,80 sul Conto 502020197

Centro di Costo 1102000- 1101000-1100000

La UOC Acquisizione Beni e Servizi curerà tutti gli adempimenti per l'esecuzione della presente determinazione.

Il Dirigente della UOC Acquisizione Beni e Servizi

Andrea Scotti

Documento firmato digitalmente ai sensi del D.Lgs 82/2005 s.m.i. e norme collegate



Al Direttore Scientifico IRE
Prof. Gennaro Ciliberto

Oggetto: Pagamento fattura Copyright Clearance Center n° APC600552509

Con la presente si richiede il pagamento della fattura N° **APC600552509** del 10 Luglio 2024 di 4.200,00 USD relativa alla pubblicazione del manoscritto dal titolo:

"Transcriptional phenocopies of deleterious KEAP1 mutations correlate with survival outcomes in lung cancer treated with immunotherapy"

Scalera S, Ricciuti B, Marinelli D, Mazzotta M, Cipriani L, Bon G, Schiavoni G, Terrenato I, Di Federico A, Alessi JV, Fanciulli M, Ciuffreda L, De Nicola F, Goeman F, Caravagna G, Santini D, De Maria R, Cappuzzo F, Ciliberto G, Jamal-Hanjani M, Awad MM, McGranahan N, Maugeri-Saccà M
sulla rivista "Clinical Cancer Research" (IF 10.0).

Tale impegno di spesa dovrà gravare sul fondo 22.15.R.37, P.I. Dott. Marcello Maugeri-Saccà

Si allega:

- invoice n° **APC600552509**
- copia del lavoro

Cordialmente

Il Principale Investigator del Progetto
Dott. Marcello Maugeri-Saccà

IL DIRETTORE SCIENTIFICO
Istituto Nazionale Tumori "Regina Elena"

INVOICE

Page 1 of 3

Invoice No: APC600552509
Invoice Date: 10-Jul-2024
Account No: 3002475047
CCC Federal ID: 13-2922432
Terms: Due upon receipt

ISTITUTI FISIOTERAPICI OSPEDALIERI
ISTITUTO REGINA ELENA
ATTN: DR. MARCELLO MAUGERI SACCÀ
VIA ELIO CHIANESI, 53
00144, ROME
ITALY

Customer/Author Location:

Tania Merlino
via elio chianesi
00144, Rome
Italy

Payment should be made to **Copyright Clearance Center**.
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Order No: 10000730885
Order Date: 10-Jul-2024
Manuscript ID: CCR-24-0626R2
Other ID: DOI 10.1158/1078-0432.CCR-24-0626

ORCID ID(s): 0000-0003-2287-9581
License: STANDARD

Publication: Clinical Cancer Research

Title: Transcriptional phenocopies of deleterious KEAP1 mutations correlate with survival outcomes in lung cancer treated with immunotherapy

Author/Editor: Marcello Maugeri-Saccà, Stefano Scalera, Biagio Ricciuti, Daniele Marinelli, Marco Mazzotta, Laura Cipriani, Giulia Bon, Giulia Schiavoni, Irene Terrenato, Alessandro Di Federico, Joao Alessi, Maurizio Fanciulli, Ludovica Ciuffreda, Francesca De Nicola, Frauke Goeman, Giulio Caravagna, Daniele Santini, Ruggero De Maria, Federico Cappuzzo, Gennaro Ciliberto

Funder: Ministero della Salute (Italy Ministry of Health), FUNDREF 10.13039/501100003196, GRANT #(s) PE_00000019; Fondazione AIRC per la ricerca sul cancro ETS (AIRC), FUNDREF 10.13039/100020581, GRANT #(s) 24913; Society for Immunotherapy of Cancer (SITC), FUNDREF 10.13039/100011619, GRANT #(s) NA; Conquer Cancer Foundation (CCF), FUNDREF 10.13039/100000982, GRANT #(s) NA; Cancer Research UK (CRUK), FUNDREF 10.13039/501100000289, GRANT #(s) NA; Wellcome Trust (WT), FUNDREF 10.13039/100010269, GRANT #(s) 211179/Z/18/Z; Ministero della Salute (Italy Ministry of Health), FUNDREF 10.13039/501100003196, GRANT #(s) GR-2016-02362025; Fondazione AIRC per la ricerca sul cancro ETS (AIRC), FUNDREF 10.13039/100020581, GRANT #(s) 22940

	Original Price	Tax	Type & Country	Final Price
Publication Fee	2,700.00	0.00	IT	2,700.00 USD
Additional Services	1,500.00	0.00	IT	1,500.00 USD
Subtotals:	4,200.00	0.00		4,200.00 USD

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270 Park Avenue
New York, NY 10017
718-242-5116

Company Bank Account #: 880317081
Bank Routing/ABA #: 021000021

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New York, NY 10017
718-242-5116

Company Bank Account #: 880317081
Bank Routing/ABA #: 021000021
SWIFT Code: CHASUS33
Beneficiary Name: Copyright Clearance Center
Beneficiary Address:
222 Rosewood Drive
Danvers, MA 01923

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Standard Mail Delivery
Copyright Clearance Center
29118 Network Place
Chicago, IL 60673-1291

Overnight Delivery
JPMorgan Chase
Attn: Copyright Clearance Center/LBX 29118
131 S Dearborn, 6th Floor
Chicago, IL 60603

NOTE: Payment must be made in the same currency as displayed on the original invoice.



ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO

UOC RICERCA TRASLAZIONALE ONCOLOGICA

Area

Dipartimentale

Funzionale Alte Tecnologie

UOC Ricerca Traslazionale Oncologica

Roma, 26.08.2024

Alla Direzione Scientifica IRE

All'Ufficio ABS SAR

LORO SEDI

Oggetto: RICHIESTA DI SUPPORTO ECONOMICO SPESE DI PUBBLICAZIONE.

Si richiede il pagamento delle spese di pubblicazione del manoscritto dal titolo:
"REPURPOSED AT9283 TRIGGERS ANTI-TUMORAL EFFECTS BY TARGETING MKK3
ONCOGENIC FUNCTIONS IN COLORECTAL CANCER" by Piastra V. et al., accettato come
Research Article dalla rivista scientifica Journal of Experimental & Clinical Cancer Research. Il costo com-
plessivo, pari a euro 2.767,00 IVA esclusa, potrà gravare sui fondi indicati dal Direttore Scientifico IRE.

Cordiali saluti

Il Responsabile della Ricerca

Gianluca Bossi
TRANSLATIONAL ONCOLOGY RESEARCH UNIT
IRCCS REGINA ELENA
NATIONAL CANCER INSTITUTE

Ok Sn
RC 2024
Voce pubbl'azione
dires. regia f. ca
Q

IL DIRETTORE SCIENTIFICO
Istituto Nazionale Tumori "Regina Elena"

INVOICE

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Our Reference No. > 2939751757	Finance Account No. > 2201923721	Customer Account No. > 3006934732	Purchase Order No. >	Customer VAT ID > IT01033011006	Date 19.08.2024	Pages 1 / 2
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Bill to	Ship to
> IRCCS - Regina Elena Nat. Cancer Inst. via Elio Chianesi 53 00144 Rome Italy	Gianluca Bossi via Ello Chianesi 53 00144 Rome Italy

Quantity	Product No.	Description	List Price	Disc. %	VAT	Amount
1	13046E	Single APC 07 / 2023 to 12 / 2028 Order: 0018279813 Open: Man Apc price Open: man.ReducePr. Open:APC+ Discount Manuscript ID: JECC-D-24-00799R1 DOI:10.1186/S13046-024-03150-4 Journal Name: Journal of Experimental & Clinical Cance Author Name: Gianluca Bossi Manuscript Title:Repurposed AT9283 triggers anti-tumoral effects by targeting MKK3 oncogenic functions in Colorectal Cancer Customer to self-assess VAT (reverse charge), Article 44 & 196 of EC Directive 2006/112	3.390,00 - 678,00 2.712,00		A	2.712,00
1	13046E	Single APC Admin Fee 07 / 2023 to 12 / 2028 Order: 0018279813 Open: Admin Fee Customer to self-assess VAT (reverse charge), Article 44 & 196 of EC Directive 2006/112	55,00		A	55,00
		VAT Reverse Charge, the customer is liable for the VAT due				

	Subtotal	2.767,00
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ISTITUTO NAZIONALE TUMORI

REGINA ELENA

ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO

DIPARTIMENTO DI NEUROSCIENZE

DIVISIONE DI OTORINOLARINGOIATRIA
E CHIRURGIA CERVICO-FACCIALE

Roma 08/08/2024

Al Direttore Scientifico IRE

In relazione alla pubblicazione del lavoro scientifico dal titolo: "The landscape of circulating tumor HPV DNA for surveillance of HPV-opharyngeal carcinoma: systematic review and meta-analysis"

Autori: Flaminia Campo, Oreste Iocca, Francesca Paolini, Valentina Manciocco, Silvia Moretto, Armando De Virgilio5-6, Claudio Moretti, Antonello Vidiri, Aldo Venuti, Paolo Bossi, Giovanni Blandino, Raul Pellini
sulla rivista *Journal of Experimental & Clinical Cancer Research* (IF 11.4) avvenuta in data 03.08.2024, si richiede il pagamento della fattura allegata di euro 2767,00, attraverso il Fondo della Direzione Scientifica IRE (come da autorizzazione del Direttore Scientifico)

Si allega:

- fattura
 - prima pagina del lavoro pubblicato
- Cordiali saluti.

Dott.ssa Flaminia Campo

Dot Raul Pellini

IRE ISTITUTO REGINA ELENA
Dr. Raul Pellini
Ud: 102013002002

FONDI RC 2024 IRE
VOCE PUBBLICAZIONI

IL DIRETTORE SCIENTIFICO
Istituto Nazionale Tumori "Regina Elena"

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> 2939741518	> 2202907033	> 3006901573	> 2939723823	> IT01033011006	15.08.2024	1 / 1
Bill to			Ship to			
Springer Nature Customer Service Center GmbH Haberstrasse 7 D - 69126 Heidelberg						
> istituto tumori regina elena			Flaminia Campo			
via elio chianesi 53			via elio chianesi 53			
00144 roma			00144 roma			
Italy			Italy			
Quantity	Product No.	Description	List Price	Disc. %	VAT	Amount
1	43930E	Single APC Article Processing Charge Manuscript ID: JECC-D-24-01411R1 DOI:10.1186/S13046-024-03137-1 Author Name: Flaminia Campo Manuscript Title: The landscape of circulating tumor HPV DNA and TTMV-HPVDNA for surveillance of HPV-oropharyngeal carcinoma: systematic review and me End User: istituto tumori regina elena via elio chianesi 53 00144 roma Italy	2.712,00		A	2.712,00
1	80078E	Single APC Admin Fee Admin fee End User: istituto tumori regina elena via elio chianesi 53 00144 roma Italy VAT Reverse Charge, the customer is liable for the VAT due Customer to self-assess VAT (reverse charge), Article 44 & 196 of EC Directive 2006/112			A	55,00
Net Value Goods C		0,00	Net Value Goods B		0,00	Net Value Goods A 2.767,00
Net Shipping Costs C		0,00	Net Shipping Costs B		0,00	Total Net Value of Goods 2.767,00
Total Net C		0,00	Total Net B		0,00	Total Net Shipping Costs 0,00
VAT C			VAT B			Total Net Due 2.767,00
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						Subtotal 2.767,00
						Prepaid 0,00
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ORSupport@springernature.com		IBAN: DE22 7002 0270 0654 7932 98				
For Remittance Advice and proof of payment, please		BIC: HYVEDEMMXXX				
email them at ARadvice@springernature.com						
For overdue and pre collection letters:		Please contact creditcardstm@springernature.com,				
Collections.OpenAccess@springernature.com		quoting your invoice number,				
For supplier Portal and invoice upload contact		for a secure payment link to be sent to you.				
orsupportadmin@springernature.com		For security purposes never send credit card details.				

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ISTITUTO DERMATOLOGICO

SAN GALLICANO

ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO

All'Ufficio ABS-SAR

Sede

OGGETTO: Richiesta pagamento articolo "Efficacy and Safety of Bimekizumab in elderly patients: Real-world Multicenter Retrospective Study – IL PSO (Italian Landscape Psoriasis)" – Rivista Journal of Dermatological Treatment (IF 2,9; IF N 3,2)

Con la presente si richiede il pagamento della fattura estera in allegato di Euro 3, 840.00 relativa alla pubblicazione in oggetto accettata dalla Rivista scientifica Journal of Dermatological Treatment (IF 2,9, normalizzato 3,2).

La pubblicazione si inserisce all'interno del progetto RC dal titolo "NUOVE TECNOLOGIE NELLO STUDIO DELLA PATOGENESI DI PATOLOGIE DERMATOLOGICHE INFIAMMATORIE: UN FOCUS SU DERMATITE ATOPICA E PSORIASI".

Il costo della pubblicazione di euro 3, 840.00 dovrà gravare sui fondi RC2024.
CdC 110200

Cordiali saluti

Drssa Norma Cameli

Dr Diego Orsini

Letto e approvato

Prof. Gennaro Ciliberto

Direttore Scientifico IRE-ISG ff

INVOICE

INVOICE NUMBER:
6687348967

INVOICE DATE:
14.08.2024

TAX INVOICE

CUSTOMER NUMBER:
7105086
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TERMS:
Payable in 30 Days



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Via Elio Chianesi, 52
00144 ROME
ITALY

DESPATCH TO:
Diego Orsini
Via Elio Chianesi, 52
00144 ROME
ITALY

Customer VAT number:

OUR REF:
ODR1495125
Our TAX Number:
04-3801744

ORDER NUMBER:
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RESEARCH ARTICLE



Efficacy and Safety of bimekizumab in elderly patients: real-world multicenter retrospective study – IL PSO (Italian Landscape Psoriasis)

D. Orsini^a, M. Megna^c, C. Assorgi^c, A. Balato^d, R. Balestri^e, N. Bernardini^f, A. Bettacchi^g, T. Bianchelli^h , L. Bianchiⁱ, G. Buggiani^j, M. Burlando^k , AMG. Brunasso^l, G. Caldarella^{m,n}, N. Cameli^a, A. Campanati^o, E. Campioneⁱ, A. Carugno^p, K. Chersi^q, A. Conti^r, A. Costanzo^{s,t}, E. Cozzani^k, A. Cuccia^u, D. D'Amico^v, G. Dal Bello^w, E. G. Dall'Olio^q, P. Dapavo^x, C. De Simone^{m,n}, E. V. Di Brizzi^d, A. Di Cesare^y, V. Dini^z, M. Esposito^z, E. Errichetti, M. C. Fargnoli^z, C. S. Fiorella, A. Foti, Z. Fratton, F. M. Gaiani, P. Gisondi, R. Giuffrida, A. Giunta^l, C. Guarneri, A. Legori, F. Loconsole, P. Malagoli, A. Narcisi^s, M. Paolinelli^r, L. Potestio^c , F. Prignano^y, G. Rech^e, A. Rossi^o, N. Skroza^f, F. Trovato, M. Venturini, A. G. Richetta, G. Pellacani and A. Dattola

^aClinical Dermatology Unit, San Gallicano Dermatological Institute (IRCCS), Rome, Italy; ^bSection of Dermatology, Department of Clinical Medicine and Surgery, University of Naples Federico II, Naples, Italy; ^cUnit of Dermatology, University of Campania Luigi Vanvitelli, Naples, Italy; ^dDivision of Dermatology, Psoriasis Outpatient Service, APSS – Azienda Provinciale per i Servizi Sanitari, Trento, Italy; ^eDermatology Unit "Daniele Innocenzi", ASL Latina Department of Medico-Surgical Sciences and Biotechnologies, Sapienza University of Rome, Polo Pontino, Italy; ^fUOC of Dermatology, Hospital of Macerata, ASUR Marche AV3, Macerata, Italy; ^gDermatology Unit, Istituto Nazionale di Riposo e Cura per Anziani, INRCA-IRCCS Hospital, Ancona, Italy; ^hDermatology Unit, Department of Systems Medicine, University of Rome Tor Vergata, Rome, Italy; ⁱS.O.S.D. Dermatologia San Giuseppe, Azienda USL Toscana Centro, Firenze, Italy; ^jDermatologic Clinic, DISSAL, ospedale Policlinico San Martino-IRCCS, Genova, Italy; ^kDepartment of Internal Medicine, Villa Scassi Hospital ASL3, Genoa, Italy; ^lSection of Dermatology, Dipartimento Universitario di Medicina e Chirurgia Traslazionale, Università Cattolica del Sacro Cuore, Rome, Italy; ^mDermatology Unit, Dipartimento di Scienze Mediche e Chirurgiche, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy; ⁿDermatological Clinic, Department of Clinical and Molecular Sciences, Polytechnic Marche University, Ancona, Italy; ^oDermatology Unit, Department of Medicine and Surgery, University of Insubria, Varese, Italy; ^pDermatology Unit, ASUGI Azienda Sanitaria Universitaria Giuliano Isontina, Trieste, Italy; ^qDermatologic Unit, Department of Surgery, Infermi Hospital of Rimini, AUSL Romagna, Rimini, Italy; ^rDermatology Unit, IRCCS Humanitas Research Hospital, Milan, Italy; ^sDepartment of Biomedical Sciences, Humanitas University, Milan, Italy; ^tUnit of Dermatology, San Donato Hospital, Arezzo, Italy; ^uUOC Dermatologia, AOU "R. Dulbecco" – Catanzaro, Catanzaro, Italy; ^vDermatology Unit, ASST Mantova, Mantova, Italy; ^wDepartment of Biomedical Science and Human Oncology, Second Dermatologic Clinic, University of Turin, Turin, Italy; ^xDepartment of Health Sciences, Dermatology Session, University of Florence, Florence, Italy; ^yDermatology Unit, Department of Clinical and Experimental Medicine, Ospedale Santa Chiara, Pisa, Italy; ^zBiotechnological and Applied Clinical Sciences, University of L'Aquila, L'Aquila, Italy; ^{aa}Institute of Dermatology, Department of Medicine, University of Udine, Udine, Italy; ^{bb}Dermatology Unit - Oncology and Ematology Department, PO M.R. Dimiccoli, Barletta, Italy; ^{cc}Unit of Dermatology and Cosmetology, IRCCS Ospedale San Raffaele, Milan, Italy; ^{dd}Department of Dermatology, Dermatology Unit Azienda Ospedaliera San Donato Milanese, Milan, Italy; ^{ee}Department of Medicine, Section of Dermatology and Venereology, University of Verona, Verona, Italy; ^{ff}Department of Clinical and Experimental Medicine, Dermatology, University of Messina, Messina, Italy; ^{gg}Department of Biomedical, Dental Sciences and Morphofunctional Imaging, Section of Dermatology, University of Messina, Messina, Italy; ^{hh}UO Dermatologia, IRCCS Ospedale Galeazzi & Università degli Studi di Milano, Milan, Italy; ⁱⁱDepartment of Dermatology, University of Bari, Bari, Italy; ^{jj}Dermatology Department, University of Brescia, ASST Spedali Civili of Brescia, Brescia, Italy; ^{kk}Dermatology Unit, Department of Clinical Internal, Anesthesiological and Cardiovascular Science, University of La Sapienza, Rome, Italy

ABSTRACT

Purpose of the article: The aim of this multicenter observational study is to report data from real world on the use of bimekizumab in patients aged ≥ 65 years with moderate-to-severe plaque psoriasis. Elderly patients are poorly represented in clinical trials on bimekizumab for plaque psoriasis, and real-world studies are important to guide clinical choices.

Materials and methods: A retrospective multicenter study was conducted in 33 dermatological outpatient clinics in Italy. Patients aged ≥ 65 years, with moderate-to-severe plaque psoriasis and treated with bimekizumab were enrolled. No exclusion criteria were applied. Bimekizumab was administered following the Italian Guidelines for the management of plaque psoriasis and according to the summary of product characteristics, in adult patients who were candidates for systemic treatments. Overall, 98 subjects were included, and received bimekizumab up to week 36. Clinical and demographic data were collected before the initiation of treatment with bimekizumab. At baseline and each dermatological examination (4, 16, and 36 weeks), clinical outcomes were measured by the following parameters: (1) PASI score; (2) site-specific (scalp, palmoplantar, genital, nail) Psoriasis Global Assessment (PGA). At each visit, the occurrence of any adverse events (AEs) was recorded, including serious AEs and AEs leading to bimekizumab discontinuation.

ARTICLE HISTORY

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KEYWORDS

Bimekizumab; psoriasis; elderly; comorbidities

CONTACT Diego Orsini  diego.orsini@ifo.it  Clinical Dermatology Unit, San Gallicano Dermatological Institute (IRCCS), Via Elio Chianesi, 52, Roma, RM 00144, Italy

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patients, and this characteristic may be especially convenient for older subjects with polypharmacy.

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Authors contributions

Study conception and design: Orsini D, Dattola A; collection and interpretation of data: Orsini D, Dattola A, Megna M, Balato A, Balestri R, Bernardini N, Bettacchi A, Bianchelli T, Buggiani G, Brunasso G, Burlando M, Caldarola G, Campanati A, Cameli N, Campione E, Carugno A, Chersi K, Conti A, Cuccia A, Dapavo P, D'Amico D, Dalbello G, Dini V, Esposito M, Errichetti E, Foti A, Fiorella C, Gisondi P, Guarneri C, Legori A, Loconsole F, Malagoli P, Narcisi A, Prignano F, Richetta AG, Trovato F, Venturini M, Pellacani G; statistical analysis: Orsini D, Dattola A; manuscript drafting: D. Orsini, A. Dattola; manuscript editing: Orsini D, Dattola A; approval to submit: Orsini D, Dattola A.

Ethical approval

Institutional review board approval was exempted for this study as its procedure did not deviate from good routine clinical practice. The study was conducted in accordance with the Helsinki Declaration of 1964 and its later amendments.

Informed consent

All patients gave written informed consent for the retrospective retrieval of anonymized data. All patients gave written informed consent for the publication of anonymized data.

Disclosure statement

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ORCID

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RESEARCH ARTICLE



Efficacy and safety of tildrakizumab in elderly patients: real-world multicenter study (ESTER – study)

Diego Orsini^a, Giacomo Caldarola^{b,c}, Annunziata Dattola^d, Elena Campione^e, Nicoletta Bernardini^f, Pasquale Frascione^g, Clara De Simone^{b,c}, Antonio G. Richetta^d, Marco Galluzzo^e, Nevena Skroza^f, Chiara Assorgi^{g,h}, Emanuele Amore^d, Gennaro M. Falco^{b,c}, Ruslana Gaeta Shumak^e, Fabio Artosi^e, Giulia Maretti^{fi}, Concetta Potenza^f, Luca Bianchi^e, Giovanni Pellacani^d, Ketty Peris^{b,c}, Claudio Bonifati^a and Dario Graceffa^a

^aClinical Dermatology Unit, IFO-San Gallicano Dermatological Institute-IRCCS, Rome, Italy; ^bUOC di Dermatologia, Dipartimento di Scienze Mediche e Chirurgiche, Fondazione Policlinico Universitario A. Gemelli - IRCCS, Rome, Italy; ^cDermatologia, Dipartimento di Medicina e Chirurgia Traslationale, Università Cattolica del Sacro Cuore, Rome, Italy; ^dUnit of Dermatology, Department of Internal Medicine and Medical Specialties, Sapienza University, Rome, Italy; ^eDermatology Unit, Department of Systems Medicine, University of Rome Tor Vergata, Rome, Italy; ^fDermatology Unit "Daniele Innocenzi" ASL LATINA, Department of Medical-Surgical Sciences and Biotechnologies, Sapienza University of Rome, Polo Pontino, Italy; ^gOncologic and Preventive Dermatology Unit, IFO-San Gallicano Dermatological Institute-IRCCS, Rome, Italy; ^hSection of Dermatology, Department of Clinical Medicine and Surgery, University of Naples Federico II Napoli Italy; ⁱDepartment of Neurosciences, Mental Health and Sensory Organs, "Sapienza" University of Rome, Rome, Italy

ABSTRACT

Purpose of the article: Interleukin-23 inhibitors, such as tildrakizumab, have emerged as safe and effective options for the management of psoriasis. Yet their efficacy in elderly patients (aged 65 years or more), particularly in those with difficult-to-treat areas involvement, remains insufficiently explored. We conducted this real-life retrospective multicentric observational study to assess the effectiveness of tildrakizumab in elderly patients with moderate-to-severe psoriasis, with involvement of difficult-to-treat areas.

Materials and methods: We enrolled forty-nine patients aged 65 years old or more (mean age 73.1±6.0), all treated with tildrakizumab for at least 28 weeks. The effectiveness of tildrakizumab was assessed by Static Physician's Global Assessment of Genitalia (sPGA-G), fingernail-PGA (f-PGA), palmoplantar PGA (pp-PGA), scalp-specific PGA (sc-PGA), and Psoriasis Area and Severity Index (PASI) scores.

Results: Significant improvements in PASI scores were observed within 28 weeks of treatment, with 77.5%, 60%, and 45.2% of patients achieving PASI75, PASI90, and PASI100, respectively. The mean PASI decreased significantly from baseline (13.6±9.9) to 1.3±1.7 at week 28. More than 90% of patients had clear sPGA-G and pp-PGA scores and over 70% had clear f-PGA and sc-PGA scores after 28 weeks.

Conclusions: Our findings suggest that tildrakizumab could be a valuable option for the treatment of elderly patients, including those with difficult-to-treat areas involvement.

ARTICLE HISTORY

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KEYWORDS

Tildrakizumab;
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treatment; anti-IL-23-biologics;
elderly patients; difficult-to-
treat areas

Introduction

Psoriasis, a chronic inflammatory disease, affects 2%–4% of the global population (1–5), with its prevalence escalating among elderly individuals (aged 65 years old or more) due to increased life expectancy (2,5). Approximately 15% of elderly patients experience moderate-to-severe plaque psoriasis (6).

Conventional systemic drugs are often avoided in this demographic due to higher comorbidity rates and potential drug interactions (4). Additionally, recurrent phototherapy treatments may prove unsuitable for those with limited mobility or dependence on caregivers (4). The challenges in treating patients ≥ 65 years old affected by psoriasis are exacerbated by the development of immunosenescence, a progressive immune system impairment associated with aging, which heightens susceptibility to infections and cancers (7).

Finally, patients aged 65 years old or more were frequently excluded from randomized clinical trials (RCT), leading to

undertreatment and a lack of established guidelines for this age group (2–5,8). Elderly patients tend to have more serious infections, non-melanoma skin cancer and malignancies than younger patients, possibly due to the aging process and more extensive duration of disease (9,10). However, recent registry data contradicts the notion that discontinuation of biologics due to adverse events occurs more frequently in patients ≥ 65 years old compared to their younger counterparts (11). Despite limited safety and efficacy data, biologics are commonly employed in elderly patients.

Interleukin (IL) inhibitors, including more recent anti-IL-23 therapies have become a focus of interest (12–16). Tildrakizumab, a humanized IgG1 κ monoclonal antibody targeting the p19 subunit of interleukin-23, allows selective inhibition of the IL-23p19 pathway with a decreased risk of impaired immune surveillance compared to broader IL-12/23p40 neutralization (17). It has demonstrated efficacy and safety in patients with moderate-to-severe psoriasis (18), including those aged 65 years or more, in phase

CONTACT Diego Orsini  diegorsini@gmail.com  Clinical Dermatology Unit, San Gallicano Dermatological Institute IRCCS, 00144 Roma (RM), Italy.

This article has been corrected with minor changes. These changes do not impact the academic content of the article.

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RESEARCH ARTICLE



Effectiveness and safety of risankizumab in VErY severe plaque psoriasis: a real-life retrospective study (VESPA-Study)

Diego Orsini^a, Chiara Assorgi^b, Claudio Bonifati^a, Norma Cameli^a, Dario Graceffa^a, Luca Potestio^b  and Matteo Megna^b

^aDepartment of Clinical Dermatology, San Gallicano Dermatological Institute, IRCCS, Rome, Italy; ^bSection of Dermatology - Department of Clinical Medicine and Surgery, University of Naples Federico II, Napoli, Italy

ABSTRACT

Background: The recent introduction of biological drugs specifically targeting the interleukins involved in psoriasis pathogenesis revolutionized the therapeutic scenario of moderate to severe forms of psoriasis. Among these, risankizumab, an anti-IL-23, was shown to be effective both in clinical trials and real-life experiences. However, data on its use on very severe forms of psoriasis, defined by a Psoriasis Area Severity Index (PASI) of at least 30, are scant. In this context, our study aimed to investigate the outcomes of patients with very severe psoriasis, and the involvement of difficult-to-treat areas treated with risankizumab for up to 2 years.

Methods: A retrospective, observational study enrolled patients with very severe plaque psoriasis and the involvement of difficult-to-treat areas undergoing treatment with risankizumab. Clinical and demographic data were collected at baseline. Moreover, at baseline and each dermatological examination (16, 28, 40 and 104 weeks), clinical improvement was measured using the percentage of patients achieving PASI 75/90/100 response, site-specific Psoriasis Global Assessment and Dermatology Life Quality Index.

Results: At baseline, the mean PASI was 35.1 ± 5.1 . A significant reduction was observed since week 16 and maintained up to week 104. Moreover, the Psoriasis Global Assessment and Dermatology Life Quality Index improved as well.

Conclusions: Risankizumab showed to be effective and safe in patients affected by very severe forms of psoriasis with the involvement of difficult-to-treat areas.

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Introduction

Psoriasis is a chronic relapsing cutaneous disease with an estimated prevalence of 2–4% of the worldwide population [1]. Plaque psoriasis is the most common clinical presentation (up to 90% of cases) [1].

Moreover, several comorbidities can be associated with psoriasis, such as psoriatic arthritis, cardiovascular diseases, diabetes, inflammatory bowel disease, etc.

The knowledge of psoriasis pathophysiology, particularly the role of the interleukin (IL)-23/17 axis, has greatly advanced in the last decades, leading to the development of new target treatments and allowing improved outcomes [2].

The treatment of plaque psoriasis changes with the disease severity. Indeed, mild cases are usually managed with topical prescription therapy, while mild-to-severe cases need systemic interventions. The choice of systemic treatments depends on the level of severity, previous treatments, comorbidities, and the patient's history, which may show personal issues in responsiveness and tolerability.

Beyond classic systemic drugs, such as methotrexate, acitretin, dymethyl fumarate and ciclosporin, several biologics are available for the systemic treatment of psoriasis, targeting cytokines, including IL-17, IL-23, IL-12/23 and TNF- α [3, 4]. As a result, goals, such as 90% improvement (Psoriasis Area and Severity Index score [PASI] 90) of severe psoriasis and successful management of very serious cases, have been achievable [5, 6].

Risankizumab, an IgG1-humanized monoclonal antibody, is a recently approved IL-23 inhibitor that has been licensed for the treatment of moderate to severe plaque psoriasis, psoriatic arthritis, and Chron's disease [7]. Its efficacy and safety have been demonstrated by several clinical trials [8–11] and was confirmed by studies in the real-life setting [12–15]. Further investigation of data retrieved from the clinical practice may improve knowledge about the durability of responses, interactions with comorbidities, and possible patients' profiles, suggesting populations with higher or reduced probability of benefit. Specifically, clinical trial data are not easily generalizable to patients with very severe disease, as they are usually excluded by specific trials' criteria, which tend to enroll

CONTACT Diego Orsini  diegorsini@gmail.com  Department of Clinical Dermatology, San Gallicano Dermatological Institute, IRCCS, Via Elio Chianesi, 52, 00144 Roma (RM), Italy.

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