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(71) Applicant: **BOEHRINGER INGELHEIM INTERNATIONAL GMBH** [DE/DE]; Binger Strasse 173, 55216 INGELHEIM AM RHEIN (DE).

(72) Inventors: **THOMA, Christian**; Boehringer Ingelheim International GmbH, Global Patents, Binger Strasse 173, 55216 Ingelheim am Rhein (DE). **DELIC, Denis**; Boehringer Ingelheim International GmbH, Global Patents, Binger Strasse 173, 55216 Ingelheim am Rhein (DE). **FARAG, Ahmed Karim**; Boehringer Ingelheim International GmbH, Global Patents, Binger Strasse 173, 55216 Ingelheim am Rhein (DE). **ROLSER, Marcel**; Boehringer Ingelheim International GmbH, Global Patents, Binger Strasse 173, 55216 Ingelheim am Rhein (DE). **VIS-VANATHAN, Sudha**; c/o VP, IP, Legal, Boehringer Ingelheim USA Corp., 900 Ridgebury Road, P.O. Box 368, Ridgefield, Connecticut 06877-0368 (US).

(74) Agent: **LUTZE, Oliver** et al.; Boehringer Ingelheim International GmbH, Global Patents, Binger Strasse 173, 55216 INGELHEIM AM RHEIN (DE).

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Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

Published:

— with international search report (Art. 21(3))
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
— with sequence listing part of description (Rule 5.2(a))
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— in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE

(88) Date of publication of the international search report:

30 May 2025 (30.05.2025)

(15) Information about Correction:

see Notice of 17 April 2025 (17.04.2025)

(54) Title: METHODS FOR THE TREATMENT AND PREVENTION OF GENERALIZED POSTULAR PSORIASIS (GPP)

(57) Abstract: The present invention relates to the treatment of generalized pustular psoriasis (GPP), including the treatment and prevention of flares in adults and adolescents from 12 years of age with a history of generalized pustular psoriasis (GPP) with anti-IL36R antibodies administered subcutaneously at a first dose of 300mg or 600mg, followed by a dose of 150mg or 300mg q4w or q12w. Use of microRNA RNA 223-3p and 223-5p as biomarkers to monitor treatment.



INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2024/065694

A. CLASSIFICATION OF SUBJECT MATTER INV. C07K16/28 C12Q1/68 C12Q1/6883 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) C07K A61K C12Q Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, BIOSIS, EMBASE, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2022/290239 A1 (BAUM PATRICK [DE] ET AL) 15 September 2022 (2022-09-15)	35-43
A	the whole document paragraph [0163]; figure 2; example 1; table 1	1-34,44
A	----- US 2022/281987 A1 (HALL DAVID B [US] ET AL) 8 September 2022 (2022-09-08) the whole document ----- -/-	1-28
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 12 March 2025		Date of mailing of the international search report 18/03/2025
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Aguilera, Miguel

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2024/065694

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	MORITA AKIMICHI ET AL: "Design of Effisayil(TM) 2: A Randomized, Double-Blind, Placebo-Controlled Study of Spesolimab in Preventing Flares in Patients with Generalized Pustular Psoriasis", DERMATOLOGY AND THERAPY , vol. 13, no. 1 5 November 2022 (2022-11-05), pages 347-359, XP093202737, ISSN: 2193-8210, DOI: 10.1007/s13555-022-00835-6 Retrieved from the Internet: URL:https://link.springer.com/article/10.1007/s13555-022-00835-6/fulltext.html the whole document -----	1-28
A	US 2018/273627 A1 (BOECHER WULF OTTO [DE] ET AL) 27 September 2018 (2018-09-27) paragraphs [0007], [0008], [0303]; claim 1 example 15 -----	1-28
X,P	MORITA AKIMICHI ET AL: "Efficacy and safety of subcutaneous spesolimab for the prevention of generalised pustular psoriasis flares (Effisayil 2): an international, multicentre, randomised, placebo-controlled trial", THE LANCET, ELSEVIER, AMSTERDAM, NL, vol. 402, no. 10412, 19 September 2023 (2023-09-19), pages 1541-1551, XP087433040, ISSN: 0140-6736, DOI: 10.1016/S0140-6736(23)01378-8 [retrieved on 2023-09-19] the whole document -----	1-28
X	BAUM PATRICK ET AL: "Pustular psoriasis: Molecular pathways and effects of spesolimab in generalized pustular psoriasis", JOURNAL OF ALLERGY AND CLINICAL IMMUNOLOGY, vol. 149, no. 4, 1 April 2022 (2022-04-01) , pages 1402-1412, XP093234293, AMSTERDAM, NL ISSN: 0091-6749, DOI: 10.1016/j.jaci.2021.09.035 the whole document -----	35-43
A	----- -/-	29-34,44

INTERNATIONAL SEARCH REPORT

International application No

PCT/EP2024/065694

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	ALATAS EMINE TUGBA ET AL: "Blood microRNA expressions in patients with mild to moderate psoriasis and the relationship between microRNAs and psoriasis activity", ANAIS BRASILEIROS DE DERMATOLOGIA, vol. 95, no. 6, 1 November 2020 (2020-11-01), pages 702-707, XP093234776, BR ISSN: 0365-0596, DOI: 10.1016/j.abd.2020.07.001 abstract; table 3 -----	29-44
A	DELIC DENIS ET AL: "Integrated microRNA/mRNA expression profiling of the skin of psoriasis patients", JOURNAL OF DERMATOLOGICAL SCIENCE, ELSEVIER, AMSTERDAM, NL, vol. 97, no. 1, 30 November 2019 (2019-11-30), pages 9-20, XP086000392, ISSN: 0923-1811, DOI: 10.1016/J.JDERMSCI.2019.11.003 [retrieved on 2019-11-30] page 11, column 2 -----	29-44
A	RAABY L ET AL: "Changes in mRNA expression precede changes in microRNA expression in lesional psoriatic skin during treatment with adalimumab", BRITISH JOURNAL OF DERMATOLOGY (1951), WILEY, vol. 173, no. 2, 14 July 2015 (2015-07-14), pages 436-447, XP071158675, ISSN: 0007-0963, DOI: 10.1111/BJD.13721 page 438, column 2 -----	29-44

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2024/065694

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2022290239 A1		15-09-2022	EP 4305207 A2	17-01-2024
			JP 2024512384 A	19-03-2024
			US 2022290239 A1	15-09-2022
			WO 2022192531 A2	15-09-2022

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			CA 3209006 A1	09-09-2022
			CL 2023002531 A1	01-03-2024
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			TW 202302644 A	16-01-2023
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			US 2024352137 A1	24-10-2024
			WO 2022187434 A1	09-09-2022

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			EP 3601350 A1	05-02-2020
			JP 2020512344 A	23-04-2020
			US 2018273627 A1	27-09-2018
			US 2023044739 A1	09-02-2023
			WO 2018183173 A1	04-10-2018

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-28

Method of treatment of generalized pustular psoriasis (GPP) comprising administering an anti-IL36R antibody subcutaneously.

2. claims: 29-44

Method to detect or monitor a patients response or compliance or efficacy to the treatment with an anti-IL36R antibody to treat GPP

INTERNATIONAL SEARCH REPORT

International application No.

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Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.c of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of a sequence listing:
 - a. ☒ forming part of the international application as filed.
 - b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13*ter*.1(a)).

☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.
2. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this report has been established to the extent that a meaningful search could be carried out without a WIPO Standard ST.26 compliant sequence listing.
3. Additional comments:

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2024/065694

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.