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Formalities officer

Tissot, Laurent

Date

12.12.2025

Reference O010869EP	OPPO 01	Application No./Patent No. 19793181.9 - 1109 / 3784233
Applicant/Proprietor Spruce Biosciences, Inc.		

BRIEF COMMUNICATION

Subject: ☐ Your letter of
☐ Our telephone conversation of
☐ Communication of
☐

Enclosure(s): ☐ Letter from the proprietor of the patent of
☐ Letter from the opponent of
☒ Copy (copies) Minutes in accordance with Rule 124(4) EPC

Communication:

All annexes to the letter as well as the consolidated list of all opposition citations are available for inspection via the European Patent Register at **www.epo.org/register**. Should you wish to receive these documents in paper format, they will be supplied to you free of charge if specifically requested on receipt of this communication (OJ EPO 2022, A28).



For the Opposition Division



☒ **Registered letter**

EPO Form 2911O 04.22 (11/12/25)



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Application No. / Patent No. 19 793 181.9 - 1109 / 3 784 233 / 01	Ref. O010869EP	Date 12.12.2025
Proprietor Spruce Biosciences, Inc.		

Provision of a copy of the minutes in accordance with Rule 124(4) EPC

The attached copy of the minutes of the oral proceedings is sent to you in accordance with Rule 124(4) EPC.



Tissot, Laurent
Formalities Officer
Tel. No.: +49 89 2399 - 5731

Enclosure(s): Applicants not using the Mailbox can access patent literature via Espacenet
Copy of the minutes (Form 2309)

Application No.:

19 793 181.9

Patent No.:

EP-B-3 784 233

Minutes of the oral proceedings before the OPPOSITION DIVISION

The proceedings were public.

Proceedings opened on 25.11.2025 at 09:04 hours

Present as members of the opposition division:

Chairman:	Langer, Astrid
1st member:	Büttner, Ulf
2nd member:	Basso, Veronica
Minute writer:	Basso, Veronica

Present as or for the party or parties:

- For the Proprietor(s): Spruce Biosciences, Inc.
Mr Michael Nelson, Mr Neil Henry, Mr Robert Scanes and Ms Hsu Min Chung as representatives.
- For the Opponent 1: Neurocrine Biosciences, Inc.
Ms Natalia Wegner and Mr Daniel Wise as representatives.

The identity of the person/s (as well as, if applicable, that of the witness or witnesses) and, where necessary, the authorisation to represent/authority to act were checked.

Essentials of the oral proceedings and relevant statements of the parties:

1 Opening

- 1.1 The oral proceedings were opened at 09:04.
- 1.2 The chairperson began with technical checks and recommendations for the use of Zoom, noting that all badges had been checked in advance and no further ID check was necessary.
- 1.3 The second member confirmed that an email with contact details of the opposition division had been sent, and both the patentee and opponent confirmed receipt.
- 1.4 The language of the proceedings was English.

2 Requests on File

- 2.1 The chairperson summarized the requests by the opponent on file:
 - 2.1.1 The opponent requested revocation of the patent in its entirety based on Article 100(a) EPC in conjunction with Article 56 EPC and Article 100(b) EPC in conjunction with Article 83 EPC and Article 100(c) EPC in conjunction with Article 123(2) EPC. An objection under Rule 116 EPC in conjunction with Article 54 EPC was on file. The latest substantive submission by the opponent was on 17-11-2025, when D79-D87 were filed.
 - 2.1.2 When asked by the chairperson to clarify their request, the opponent declared that they requested not to admit the late-filed auxiliary requests 1a and 1b. The opponent reserved the right to object to the admissibility of further auxiliary requests later. The opponent confirmed that objections under Article 123(2) had been overcome in view of the amended main request, they had no further objections under 123(2) EPC.
- 2.2 The chairperson summarized the requests by the patentee on file:
 - 2.2.1 Main request and auxiliary requests 1-35 filed on 18-06-2025.
 - 2.2.2 Auxiliary requests 36-38 as filed on 19-11-25, to correct the previous auxiliary requests 36-38 that had been filed on 24-10-2025.
 - 2.2.3 Auxiliary requests 1a and 1b as filed on 14-11-2025, with the previous auxiliary request 1 being renamed auxiliary request 1c.
 - 2.2.4 The latest substantive submission by the patentee was on 19-11-2025, when D88 and the corrected version of auxiliary requests 36-38 were filed.

2.2.5 When asked by the chairperson to clarify their request, the patentee confirmed that they formally requested the new ground of objection against the main request under Article 54 EPC, first raised by the opponent on 24-10-2025, not be admitted; and the opponent's submission of 17-11-2025, as well as declarations D79 and D83, not be admitted as late-filed documents. Auxiliarily, the patentee requested to admit D88 if the late filed expert declarations submitted by the opponent were admitted.

2.3 The opponent and the patentee declared that they had no further pending objection or request.

3 **Main Request - Admissibility of new ground under Art. 54 EPC**

3.1 The chairperson stated the preliminary opinion of the opposition division that the new ground under Article 54 EPC should be admitted due to its prima facie relevance and the impact on the underlying claim interpretation for the grounds of opposition already on file.

3.2 The opponent argued that a late-filed ground for opposition should be admitted if it is prima facie relevant, in that it would wholly or partially prejudice the maintenance of the patent. The opponent referenced to the relevant case law in this respect.

The opponent argued this to be the case, as the functional definition "CRF₁ antagonist" in the claims, when interpreted in the light of the broad definition of "antagonist" in the description of the patent, encompasses glucocorticoids, the use of which for the treatment of TART is known (see e.g. D9).

The broad interpretation had been provided by the patentee in the reply to the notice of opposition, hence could not have been filed before. The definition used in the description would broaden the scope of the claims and should thus be taken into account.

3.3 The patentee objected, arguing that the opponent's objection was based on the disclosure of the patent (and therefore should have been filed on time) and on a stretched interpretation of the claimed subject-matter (and was therefore not relevant). The patentee conceded that claims are to be interpreted in the light of the description and drawings (Art. 69 EPC; G1/24), but only in a technically sensible manner, referencing to the relevant case law in this respect. The patentee also submitted that the claims were clear as such, hence the skilled person would not need to turn to the description to interpret them.

3.4 After an interruption from 09:44 to 09:57, the chairperson announced that the opposition division had decided to admit the new ground under Article 54 EPC.

4 Main request - Novelty (Art. 54 EPC)

- 4.1 The chairperson stated, as preliminary opinion, that when reading the granted claims, the opposition division would have been inclined to consider glucocorticoids not be encompassed in the functional definition "CRF₁ antagonist". However, the definitions on §§[0086] and [0094] of the patent specification warranted discussion.
- 4.2 The patentee iterated that the claims must be interpreted in a technically sensible manner and with a mind willing to objectively construe the claim (Case law book, II-A.6; T10/22); and argued that the skilled person would interpret "CRF₁ antagonist" as a non-steroidal substance, based on the overall teaching of the patent and specific passages of the description (§§[0004]-[0006], [0026], [0027], [0036], [0095], [0245], [0280], [0289], [0290], [0304], [0307], [0323]; Fig. 1b and 11b). In particular, according to the patentee, since §[0004] defines the problem to be solved as the lack of non-steroidal, non-surgical solutions to control, shrink or reduce TART; then the solutions proposed in the patent must be non-steroidal solutions. §§[0094] and [0095] would emphasise the receptor antagonism, hence indicating a direct activity on the receptor. The plain meaning of the claims also supported this interpretation, which was initially applied by the opponent and the opposition division as well. According to the patentee, the plain meaning of "CRF₁ antagonist" clearly excludes steroidal substances, in the light of the prior art (e.g., D2, D36). The patentee also noted that they had disclosed the chemical structures of such agents in D36, page 519, Fig. 1; and that the prior art clearly distinguishes CRF₁ antagonists from glucocorticoids (D2, D13, D15, D16, D36, D72). The patentee also remarked that glucocorticoids were never defined as CRF₁ antagonists in the patent.
- 4.3 After an interruption from 10:20 to 10:42 for technical issues, the patentee was invited to comment on §§[0086] and [0094]. The patentee stated that these passages were not in contradiction to the claim interpretation provided, but had to be interpreted in the context of the general teaching of the description as a whole. The skilled person would thus understand that these passages also pertained to non-steroidal solutions.
- 4.4 The opponent argued that §§[0086] and [0094] of the patent should be interpreted broadly, as the rest of the description relates to specific embodiments of these general definitions. In the light of these passages, the functional definition "CRF₁ antagonist" encompasses any substance capable of

detectably decreasing the expression or activity of CRF₁, with §[0096] clarifying how decreased expression may be achieved. Glucocorticoids are known to reduce the levels of the CRF₁ agonist CRH and to inhibit the expression of the CRF₁ receptor itself; and, according to the opponent, are thus encompassed by this broad definition of CRF₁ antagonist.

The opponent also argued that §§[0280], [0304], Fig. 1b only distinguish the exemplary Compound 1 from chronic high doses of glucocorticoids, but not all treatment strategies for TART imply high doses of glucocorticoids (e.g., D8, page 705, E6 cites short-term glucocorticoid therapy); and solutions other than Compound 1 are encompassed by the claims. In addition, §[0004] sets the technical problem but is not limited to non-steroidal solutions of that problem, as it cites "Disclosed herein, inter alia, are solutions to these and other problems in the art." (emphasis by the opposition division). Combination therapy with glucocorticoids was also claimed by the patentee, showing an example of a steroid-based solution to the technical problem. A combination of different glucocorticoids may also be a solution to the same problem (e.g., D35, page 95, left column), as would be new and better glucocorticoids.

- 4.5 The patentee replied and emphasised that G1/24 would state that the description should be considered but not that all possible claim interpretation based on the description should be applied. T 1473/19 would limit the effect of the description on claim interpretation. The technical solution could not be a glucocorticoid as the aim was to limit glucocorticoid exposure, even though background glucocorticoid treatment was always necessary. Asked by the opposition division whether compounds having a similar mode of action to glucocorticoids or which would otherwise reduce the gene expression of the CRF₁ receptor were also excluded from the scope of the claims, the patentee replied that the §[0094] had to be read in conjunction with the overall teaching of the description.
- 4.6 After an interruption from 11:42 to 12:08, the chairperson announced that the opposition division had decided that the main request lacked novelty over at least D9, as the mechanism of action of glucocorticoids is explicitly encompassed by claim 1 and glucocorticoids for the treatment of TART are disclosed in D9. The opposition division had taken into account that only Compound 1 had been clearly presented as alternative to the known glucocorticoid therapy.

5 Auxiliary request 1a

- 5.1 The chairperson stated the preliminary opinion of the opposition division that at least one auxiliary request attempting to overcome the lack of novelty of the main request was to be admitted.
- 5.2 After an interruption from 12:12 to 13:13, the chairperson asked the patentee how they wished to proceed further. The patentee stated that they wished to proceed with auxiliary request 1a.
- 5.3 The opponent objected to the admissibility of auxiliary requests 1a and 1b. The opponent agreed that at least one amendment by the patentee would be admissible, in line with EPC GL, E-VI.2.2.2, but remarked that multiple requests were already on file which would overcome the novelty objection; and that auxiliary requests 1a and 1b would add complexity to the procedure by introducing new issues under Art. 123(2) and 87 EPC.
- 5.4 The patentee argued that auxiliary requests 1a and 1b did not introduce issues under Art. 123(2) and 87 EPC as they did not alter the technical teaching of the application as originally filed or that of the priority documents, but merely limited the claimed subject-matter to the plain meaning of the claims as originally filed.
- 5.5 After an interruption from 13:30 to 13:51, the chairperson announced that the opposition division had decided to admit auxiliary requests 1a and 1b.
- 5.6 Auxiliary request 1a was discussed next. The opponent objected under Article 123(2) EPC, arguing that “non-steroidal” is not disclosed as a feature of the invention but only as background information (§[0004] of the description), and its introduction constitutes an intermediate generalization. The opponent cited case law supporting the general principle that caution is needed when deriving basis for amendments from the background section of a patent application. The patentee argued that “non-steroidal” is technically derivable from the application as filed, as it is clear from §[0004] of the description that only non-steroidal solutions to the technical problem are contemplated.
- 5.7 After an interruption from 14:07 to 14:16, the chairperson announced that the opposition division had decided that auxiliary request 1a contravened Article 123(2) EPC.

6 **Auxiliary request 1b**

- 6.1 Auxiliary request 1b was then discussed. The opponent objected under Articles 123(2) and 84 EPC, arguing that deleting a paragraph containing a definition from the description changes the meaning of the claims, leading to added

matter and clarity issues. The chairperson mentioned, as a preliminary opinion, that such deletion may also have consequences under Article 123(3) EPC. The opponent endorsed this opinion.

- 6.2 The patentee argued that the amendment restricted the claim to the plain meaning already disclosed in the application as filed, namely to a CRF₁ antagonist binding to the CRF₁ receptor, and referenced relevant case law. The patentee maintained that this plain meaning would have been clear to the person skilled in the art, in the light of e.g. D13. The patentee also argued that the deletion of §[0096] did not cause any issue under Article 123(3) EPC, as only an optional feature was deleted.
- 6.3 After an interruption from 14:52 to 15:20, the chairperson announced that the opposition division had decided that auxiliary request 1b contravened Articles 123(3) and 84 EPC.
- The chairperson also stated the preliminary opinion of the opposition division that the novelty objection raised for the main request would also apply to auxiliary requests 1c, 2-5.

7 **Auxiliary request 1c filed during Oral Proceedings at 15:44**

- 7.1 The chairperson asked the patentee how they wished to proceed further. The patentee stated that they wished to file a new auxiliary request 1c to address the objections under Articles 123(3) and 84 EPC, which were not mentioned until today. Auxiliary request 1c was filed by email at 15:44. The patentee requested that previous auxiliary request 1c would remain after the newly filed auxiliary request 1c.
- 7.2 After an interruption from 15:22 to 15:47, auxiliary request 1c was discussed. The patentee stated that auxiliary request 1c was admissible as it addressed new grounds; and that the amendments were based on original claim 1 and §§[0026] and [0027] of the application as filed, by incorporating disclosed embodiments of additional chemotherapeutic agents, i.e., specific CRF₁ antagonists.
- 7.3 After an interruption from 15:51 to 16:16, the opponent objected to the admissibility of auxiliary request 1c, citing procedural economy, lack of convergence with previous requests, lack of prima facie relevance and discretion of the opposition division not to admit this request (EPC GL, E-VI. 2.2.3). The opponent also raised objections under Articles 123(2) and 84 EPC: the first due to alleged selections from multiple lists, the latter regarding the unclear chemical structure of the fourth compound listed in the claim, which

displayed an impossible quadruple carbon bond. The opponent submitted that such error was evident but might be corrected in a number of different ways, and therefore its correction was not obvious in the sense of Rule 139 EPC. The opponent also argued that the claim as currently formulated did not imply the therapeutic efficacy of both therapeutic agents in the combination therapy.

7.4 The patentee argued that the amendment was a fair response to new objections; that no added matter was present as only shrinkage of a single list from §[0027] had been carried out; and that the skilled person would understand that the contested chemical structure bore an obvious error which could be corrected under Rule 139 EPC (namely, a quadruple carbon bond that may only be corrected to a triple bond without conflicting with the plain bond connecting the previous carbon), and would thus understand which chemical structure was intended instead. The patentee also argued that the expression "wherein the use further comprises" in the claim clearly conveyed that both therapeutic agents must have therapeutic activity.

7.5 After an interruption from 16:57 to 17:14, the chairperson announced that the opposition division had decided to admit auxiliary request 1c but had found it not allowable under Article 84 EPC.
The chairperson also stated the preliminary opinion of the opposition division that the possible correction suggested by the patentee would not be allowable under Rule 139 EPC.

8 Other requests and decision of the Opposition Division

8.1 The chairperson asked the patentee how they wished to proceed further. After an interruption from 17:16 to 17:36, the patentee withdrew auxiliary requests 22-26, 34, 35, 37, and 38, and requested a decision on all other requests on file. The opposition division noted that novelty issues for auxiliary requests 6-11 had not been discussed, but the patentee indicated these auxiliary requests would also be withdrawn if considered, and that, in view of the previous decisions taken, auxiliary requests 6-11 were not novel in view of D9, Table 3.

8.2 After an interruption from 17:41 to 17:57, the opponent requested that sufficiency and inventive step be discussed for the remaining requests, although this would be procedurally unusual.
After an interruption from 18:05 to 18:10, the chairperson replied that they could not admit this request because the patentee had the right to withdraw requests at any time, and the revocation requested by the opponent was not to be limited to any particular ground.

8.3 The chairperson then announced the decision of the opposition division on all requests.

The main request was found to lack novelty.

Auxiliary request 1a was not allowable under Article 123(2) EPC.

Auxiliary request 1b was not allowable under Articles 123(3) and 84 EPC.

Auxiliary request 1c was not allowable under Article 84 EPC.

Auxiliary requests 1c filed in writing before the oral proceedings and auxiliary requests 2 to 5 were found not novel.

Auxiliary requests 6-11 were found not novel.

Auxiliary requests 12-21 were not allowable under Article 123(2) EPC.

Auxiliary requests 22-26, 34, 35, 37, and 38 were withdrawn.

Auxiliary requests 27-29 were found not novel.

Auxiliary requests 30-33 were not allowable under Article 123(2) EPC.

Auxiliary request 36 was found not novel.

8.4 The chairperson announced that, as none of the requests from the proprietor were allowable, the European patent is revoked under Article 101(3)(b) EPC. The decision will be notified as soon as possible and is appealable. The oral proceedings were closed at 18:15.

After deliberation of the opposition division,

- the chairman announced the following **decision** :

"The European patent is revoked."

Regarding the reasons for the decision, the chairman referred to:

The division's opinion is that, even taking into consideration the amendments made by the proprietor of the patent during the opposition proceedings, the patent does **not** meet the requirements of the Convention (Article 101(3)(b)EPC)

The main request was found to lack novelty. Auxiliary request 1a was not allowable under Article 123(2) EPC. Auxiliary request 1b was not allowable under Articles 123(3) and 84 EPC. Auxiliary request 1c was not allowable under Article 84 EPC. Auxiliary requests 1d and 2 to 5 were found not novel. Auxiliary requests 6-11 were found not novel. Auxiliary requests 12-21 were not allowable under Article 123(2) EPC. Auxiliary requests 22-26, 34, 35, 37, and 38 were withdrawn. Auxiliary requests 27-29 were found not novel. Auxiliary requests 30-33 were not allowable under Article 123(2) EPC. Auxiliary request 36 was found not novel. Auxiliary requests 37 and 38 were withdrawn.

The party/parties was/were informed that the minutes of the oral proceedings and a written reasoned decision (including an indication of the possibility of appeal) will be notified to him/them as soon as possible.

The chairman **closed the oral proceedings** on 25.11.2025 at 18:15 hours.



signed:

Langer, Astrid

.....
Chairman

signed:

Basso, Veronica

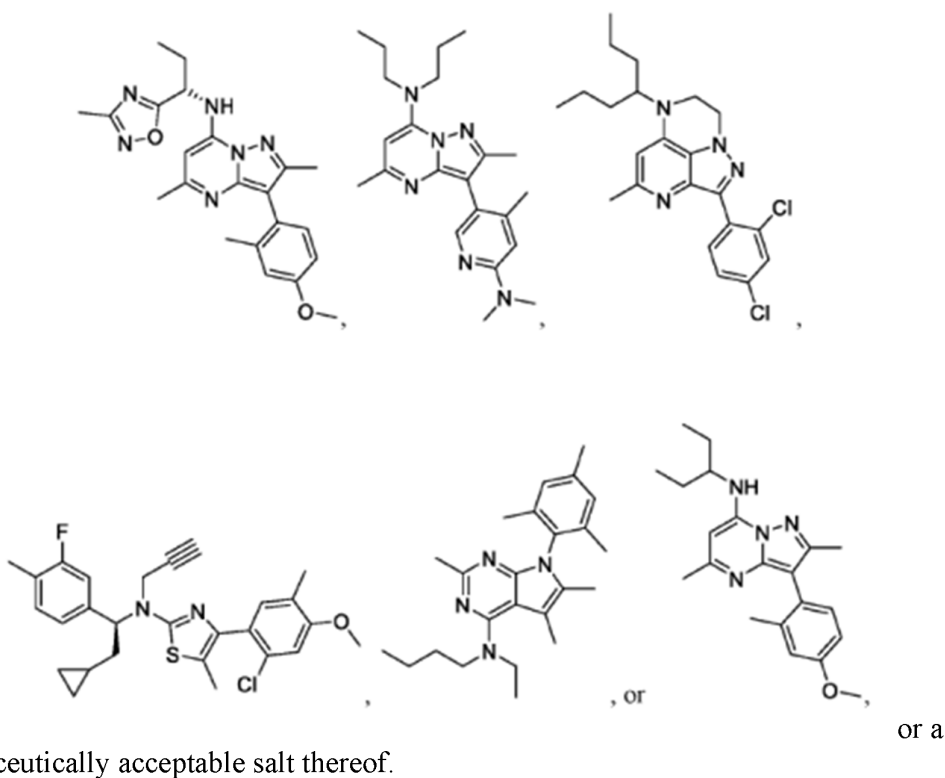
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Minute Writer

Enclosure(s):

Aux1c_25_11_2025_1544_clean, Aux1c_25_11_2025_1544_tracked, email_25_11_2025 1544

AUXILIARY REQUEST 1c

1. A corticotropin-releasing factor type-1 (CRF₁) antagonist or a pharmaceutically acceptable salt thereof, for use in the treatment or prevention of testicular adrenal rest tumors (TART) or ovarian adrenal rest tumors (OART) in a subject in need thereof, wherein the use further comprises administering to the subject an additional chemotherapeutic agent, wherein the additional chemotherapeutic agent is another CRF₁ antagonist, wherein the additional CRF₁ antagonist is:



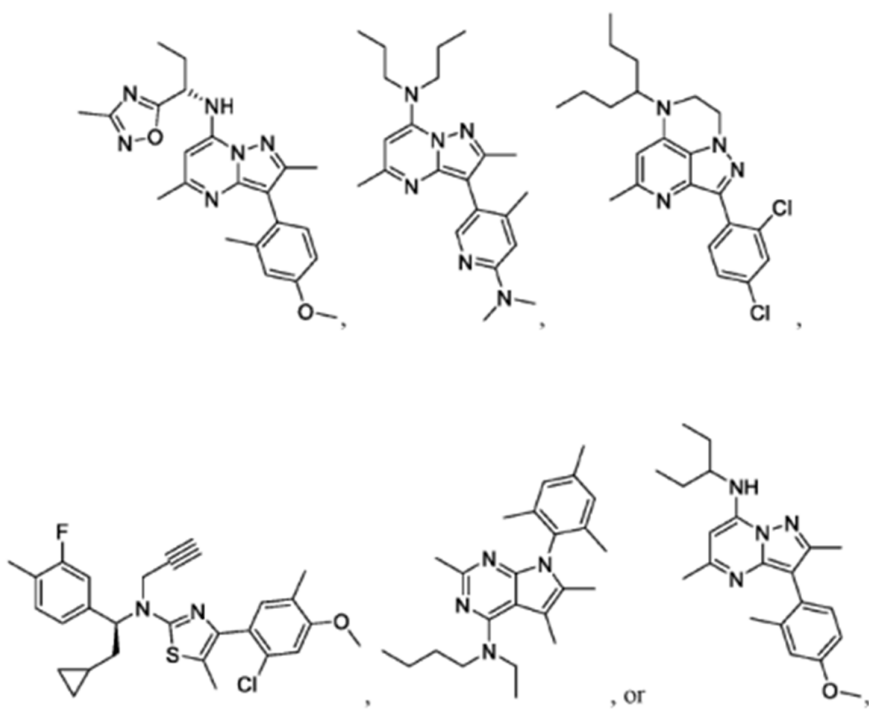
AUXILIARY REQUEST 1c

1. _____ A corticotropin-releasing factor type-1 (CRF₁) antagonist or a pharmaceutically acceptable salt thereof, for use in the treatment or prevention of testicular adrenal rest tumors (TART) or ovarian adrenal rest tumors (OART) in a subject in need thereof,

wherein the use further comprises administering to the subject an additional chemotherapeutic agent,

wherein the additional chemotherapeutic agent is another CRF₁ antagonist,

wherein the additional CRF₁ antagonist is:



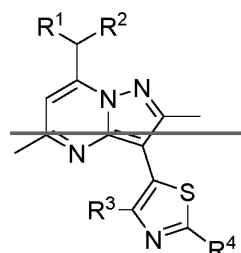
-or- a

pharmaceutically acceptable salt thereof.

1. _____ The CRF₁ antagonist for use according to claim 1, wherein the subject has congenital adrenal hyperplasia (CAH):

2. _____ The CRF₁ antagonist for use according to claim 1, wherein the treatment is a reduction in the size and/or the number of the tumors.

3. _____ The CRF₁ antagonist for use according to claim 1, wherein the CRF₁ antagonist comprises is a compound of structural Formula (I):



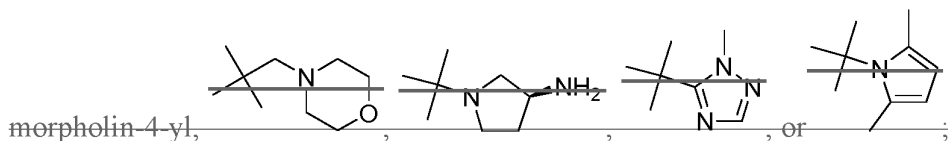
(I), or a pharmaceutically acceptable salt thereof,

wherein:

R^1 and R^2 are independently ethyl or n-propyl;

R^3 is hydrogen, Cl, Br, methyl, trifluoromethyl, or methoxy; and

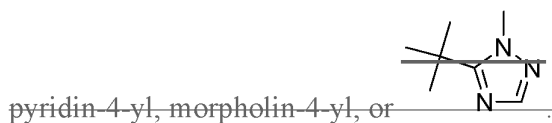
R^4 is hydrogen, Br, $R^a R^b N$ -, methoxymethyl, n-butyl, acetamido, pyridin-4-yl,



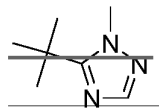
R^a and R^b are independently hydrogen, C_1 - C_3 alkyl, $H_2NCH_2CH_2$ -, $(CH_3)_3COC(O)NHCH_2CH_2$ -, or $CH_3CH_2CH_2NHCH_2CH_2$ -.

4. — The CRF_1 -antagonist for use according to claim 4, wherein R^3 is Cl, Br, or methyl.

5. — The CRF_1 -antagonist for use according to claim 4, wherein R^4 is Br, $R^a R^b N$ -,

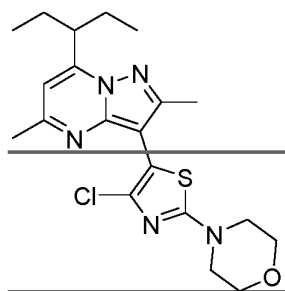


6. — The CRF_1 -antagonist for use according to claim 4, wherein R^4 is morpholin-4-yl or



7. — The CRF_1 -antagonist for use according to claim 4, wherein R^4 is hydrogen, Br, $R^a R^b N$ - and R^a and R^b are independently C_1 - C_3 alkyl.

8. — The CRF_1 -antagonist for use according to claim 4, wherein the compound is



or a pharmaceutically acceptable salt thereof.

9. — The CRF_1 -antagonist for use according to claim 4, wherein a dosage regime of the compound of Formula (I) CRF_1 -antagonist, or a pharmaceutically acceptable salt thereof, is administered at a dose of about 105 mg/day to about 400 mg/day to the subject.

10. — The CRF_1 -antagonist or a pharmaceutically acceptable salt thereof for use according to claim 1, for use in oral administration.

11. — The CRF_1 -antagonist for use according to claim 1, wherein the CRF_1 -antagonist, or a pharmaceutically acceptable salt thereof, is formulated as a capsule or tablet.

12. — The CRF₁-antagonist of claim 1 and an additional chemotherapeutic agent, for use in the treatment or prevention of testicular adrenal rest tumors (TART) or ovarian adrenal rest tumors (OART) in a subject in need thereof, wherein the additional chemotherapeutic agent is a glucocorticoid, a mineralocorticoid, an ACAT1 inhibitor, or an anti-androgen.

13. — The CRF₁-antagonist and the additional chemotherapeutic agent for use according to claim 1113, wherein the glucocorticoid is beclomethasone, betamethasone, budesonide, cortisone, dexamethasone, hydrocortisone, methylprednisolone, prednisolone, prednisone, or triamcinolone.

14. — The CRF₁-antagonist for use according to claim 4, wherein R³ is Cl, Br, or trifluoromethyl.

Veronica Basso

From: Neil Henry
Sent: 25 November 2025 15:44
To: Veronica Basso; Ulf Büttner; Astrid Langer
Subject: RE: Contact data opposition division EP 3 784 233
Attachments: New AR1c (clean).pdf; New AR1c (tracked).pdf

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Dear OD,

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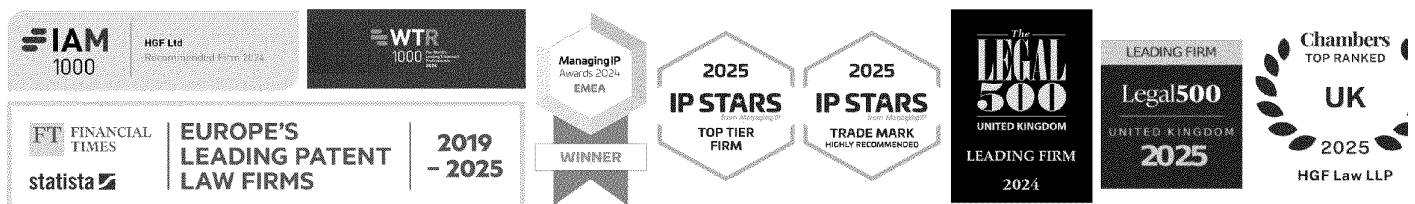
Thank you.

Best wishes,
Neil

Neil Henry
Partner

For and on behalf of HGF GmbH
Austria, France, Germany, Ireland, Netherlands, Switzerland, United Kingdom
OBC Suisse AG | Aeschengraben 29 | Basel | 4051 | Switzerland

When sending instructions, always send a copy by email to docketing@hgf.com and ensure you receive a personal acknowledgement c



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From: Veronica Basso
Sent: Tuesday, 25 November 2025 08:49
Subject: Contact data opposition division EP 3 784 233

External

To whom it may concern,

If you have any technical problems, you can contact the chairperson on +49 8923997809.

Please acknowledge receipt of this email as soon as possible and provide a phone number we can contact you on during the oral proceedings if there are any technical problems.

Best regards / Mit freundlichen Grüßen / Sincères salutations

Veronica Basso
PE examiner Team Biopharma 1 medical use | Dir. 1.1.0.9
European Patent Office
Grasserstr. 9 | 80339 Munich | Germany