

PATENT
Attorney Docket No. 50535-710.303

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: Alexis HOWERTON	Group Art Unit: Unassigned
Application No.: 18/941,832	Examiner: Unassigned
Filing Date: November 8, 2024	Confirmation No.: 9905
Title: METHODS FOR TREATING TESTICULAR AND OVARIAN ADRENAL REST TUMORS	Customer No.: 21971
	CERTIFICATE OF TRANSMISSION I hereby certify that this correspondence, and any attachment, is being transmitted via the U.S. Patent and Trademark Office's electronic filing system on 2-5-2026. By: <u>/Robert Olinski/</u> Robert Olinski

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

PRELIMINARY AMENDMENT

Dear Commissioner:

Prior to examination on the merits of the above-identified application, please amend the application as follows:

Amendments to the Claims begin on page 2.

Remarks begin on page 6.

The Conclusion is on page 7.

AMENDMENTS TO THE CLAIMS

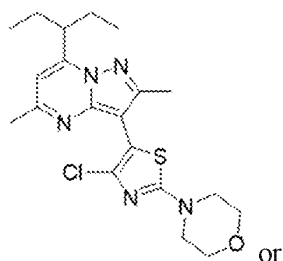
This listing of claims replaces all prior versions and listing of claims in the above-referenced patent application. The following amendments do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed. Deletions are denoted by ~~strike through~~ or ~~[[double brackets]]~~ and additions are denoted by underline.

Complete Listing of the Claims

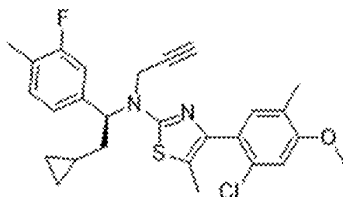
1-91. (Cancelled)

92. (New) A method of treating congenital adrenal hyperplasia (CAH), comprising administering to a subject in need thereof a pharmaceutical composition comprising:

a small molecule corticotropin-releasing factor type-1 (CRF₁) antagonist, or a pharmaceutically acceptable salt thereof, wherein the small molecule CRF₁ antagonist is:



or



, or a pharmaceutically acceptable

salt thereof; and

one or more pharmaceutically acceptable or physiologically acceptable diluents, carriers or excipients,

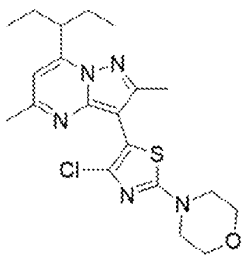
wherein the pharmaceutical composition is orally administered twice daily,

wherein the small molecule CRF₁ antagonist is administered at a dose of about 25 mg, about 50 mg, about 100 mg, or about 200 mg,

wherein the subject is in a fed state, and

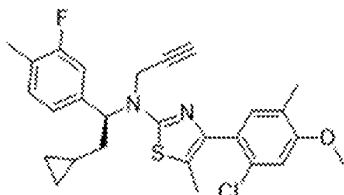
wherein at least one of the twice daily administered doses is administered in the evening.

93. (New) The method of claim 92, wherein the small molecule CRF₁ antagonist is:



, or a pharmaceutically acceptable salt thereof.

94. (New) The method of claim 92, wherein the small molecule CRF₁ antagonist is:



, or a pharmaceutically acceptable salt thereof.

95. (New) The method of claim 92, wherein the pharmaceutical composition is administered for a period of up to at least about 14 days.
96. (New) The method of claim 92, wherein the subject is on a regimen of a glucocorticoid.
97. (New) The method of claim 96, wherein the glucocorticoid is beclomethasone, betamethasone, budesonide, cortisone, dexamethasone, hydrocortisone, methylprednisolone, prednisolone, prednisone, or triamcinolone.
98. (New) The method of claim 92, the method further comprising administering to the subject a glucocorticoid.
99. (New) The method of claim 98, wherein the glucocorticoid is beclomethasone, betamethasone, budesonide, cortisone, dexamethasone, hydrocortisone, methylprednisolone, prednisolone, prednisone, or triamcinolone.
100. (New) The method of claim 92, wherein the subject is a child.

101. (New) The method of claim 100, wherein the pharmaceutical composition is administered for a period of up to at least about 14 days.
102. (New) The method of claim 92, wherein the subject is 18 years or older.
103. (New) The method of claim 102, wherein the small molecule CRF₁ antagonist is orally administered twice daily at a dose of about 100 mg or about 200 mg.
104. (New) The method of claim 103, wherein the pharmaceutical composition is administered for a period of up to at least about 14 days.
105. (New) The method of claim 92, wherein the administering reduces a concentration of one or more biomarkers comprising 17 α -hydroxyprogesterone (17-OHP), adrenocorticotrophic hormone (ACTH), testosterone, androstenedione (A4), or a combination thereof.
106. (New) The method of claim 105, wherein the one or more biomarkers is ACTH.
107. (New) The method of claim 105, wherein the one or more biomarkers is A4.
108. (New) The method of claim 105, wherein the concentration of the one or more biomarkers is reduced by at least 10% to about 90% from baseline.
109. (New) The method of claim 106, wherein the concentration of ACTH is reduced by about 60% to about 80% from baseline.
110. (New) The method of claim 107, wherein the concentration of A4 is reduced by about 10% to about 90% from baseline.
111. (New) The method of claim 92, wherein the pharmaceutical composition is formulated as a capsule or tablet.
112. (New) The method of claim 111, wherein the pharmaceutical composition is formulated as a liquid solution.
113. (New) The method of claim 92, wherein the subject has a benign tumor.

REMARKS

Amendments to the Claims

Previously presented claims 1-71 have been cancelled without prejudice or disclaimer. Previously presented claims 72-91 have been canceled herein without prejudice or disclaimer. Applicant reserves the right to pursue the subject matter of the cancelled claims in this or any other appropriate patent application. New claims 92-113 are presented herein. Support for the new claims is found in the original claims and throughout the as-filed specification. No new matter is believed to be introduced by any amendment made herein.

Upon entry of this amendment, claims 92-113 will be under examination.

CONCLUSION

Applicant respectfully solicits the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned at (858) 350-2240.

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment to Deposit Account No. 23-2415, referencing Attorney Docket No. 50535-710.303.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION # 18/941,832	RECEIPT DATE / TIME 02/05/2026 05:09:41 PM Z ET	ATTORNEY DOCKET # 50535-710.303
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Title of Invention

METHODS FOR TREATING TESTICULAR AND OVARIAN ADRENAL REST TUMORS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	9905	FILED BY	ROBERT OLINSKI
PATENT CENTER #	74355034	FILING DATE	11/08/2024
CUSTOMER #	21971	FIRST NAMED INVENTOR	Alexis HOWERTON
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Victoria Cheng

Documents

TOTAL DOCUMENTS: 3

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
50535-710_303- Preliminary_Amendment.pdf	6	-	215 KB
50535-710_303- Preliminary_Amendment- A.PE.pdf	(1-1) 1	Preliminary Amendment	96 KB
50535-710_303- Preliminary_Amendment- CLM.pdf	(2-4) 3	Claims	206 KB
50535-710_303- Preliminary_Amendment- REM.pdf	(5-6) 2	Applicant Arguments/Remarks Made in an Amendment	97 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
50535-710_303- Preliminary_Amendment.pdf	47F1D93275C38CCDBC45BE3A0239EBC64016B6D93FC06E4 3B74BA4026286520EDA48FEFC7EE022386C9D80C3DFF95960 5539846E9219A64407BE8FE194DC5BF
50535-710_303- Preliminary_Amendment- A.PE.pdf	FAF8BAF2F5B9520DB39CBE34F1D6D57045E8CD7906F370E3 024642BE377F2ADD7B31E80E65D85DD7B554ECBE090440F35 D58A31808564704D20B633652C36A59
50535-710_303- Preliminary_Amendment- CLM.pdf	62326571F829A9FEB0DA25EC394604DEC0B21A754D3B7D857 E1599DEB0EA71CAE62DC5C30A5881E5F2CA3500293E9EF18 F467B23BEACB0863CFB7BE26643409A
50535-710_303- Preliminary_Amendment- REM.pdf	5C68C53E9F10FADCAD0E38CDF06427F60F491F073D9346C3 797CE632A9C97BEC251D90A2B903993629E3A36C8B82B3AB CB8BE29820F7572630FD19D99A17C364

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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Payment Information

PAYMENT METHOD DA / 232415	PAYMENT TRANSACTION ID E202625H11478313	PAYMENT AUTHORIZED BY ROBERT OLINSKI
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FEE CODE	DESCRIPTION	ITEM PRICE(\$)	QUANTITY	ITEM TOTAL(\$)
1202	EACH CLAIM IN EXCESS OF 20	200.00	2	400.00
TOTAL AMOUNT:				\$400.00

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