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- (74) **Agent:** ICOSA; 83 avenue Denfert-Rochereau, 75014 Paris (FR).

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- (84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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— of inventorship (Rule 4.17(iv))

Published:

— with international search report (Art. 21(3))

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19 January 2017



WO 2016/170124 A3

(54) **Title:** NMDA ANTAGONISTS FOR THE TREATMENT OF MENTAL DISORDERS WITH OCCURRENCE OF AGGRESSIVE AND/OR IMPULSIVE BEHAVIOR

(57) **Abstract:** The present invention relates to the use of *N*-Methyl-D-aspartate (NMDA) antagonists at sub-anesthetic doses for the treatment of motor dysfunction in mental or psychiatric disorders with occurrence of aggressive and/or impulsive behavior.

INTERNATIONAL SEARCH REPORT

International application No PCT/EP2016/059032

A. CLASSIFICATION OF SUBJECT MATTER INV. A61K31/135 A61P25/14 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) A61K A61P				
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, WPI Data, BIOSIS, EMBASE				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X	DIOGO R. LARA ET AL: "Antidepressant, mood stabilizing and procognitive effects of very low dose sublingual ketamine in refractory unipolar and bipolar depression", THE INTERNATIONAL JOURNAL OF NEUROPSYCHOPHARMACOLOGY, vol. 16, no. 09, 20 May 2013 (2013-05-20), pages 2111-2117, XP055216617, ISSN: 1461-1457, DOI: 10.1017/S1461145713000485 table 1 <div style="text-align: center;">----- -/--</div>	1-4,6-12		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.				
* Special categories of cited documents : <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> "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 </td> <td style="width: 50%; border: none; vertical-align: top;"> "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 </td> </tr> </table>			"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
"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	Date of mailing of the international search report			
13 October 2016	19/12/2016			
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 Büttner, Ulf			

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/059032

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	BALLARD ELIZABETH D ET AL: "Improvement in suicidal ideation after ketamine infusion: Relationship to reductions in depression and anxiety", JOURNAL OF PSYCHIATRIC RESEARCH, ELSEVIER LTD, GB, vol. 58, 12 August 2014 (2014-08-12), pages 161-166, XP029054096, ISSN: 0022-3956, DOI: 10.1016/J.JPSYCHIRES.2014.07.027 page 163	1-4,6-12
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X	----- US 2014/057988 A1 (WEG STUART [US]) 27 February 2014 (2014-02-27) claims	1-4,6-12
X	----- WO 2011/020061 A2 (PAPALOS DEMITRI [US]) 17 February 2011 (2011-02-17) claims	1-4,6-12
A	----- CONDY C ET AL: "Ketamine-induced distractibility: An oculomotor study in monkeys", BIOLOGICAL PSYCHIATRY, ELSEVIER SCIENCE, NEW YORK, NY; US, vol. 57, no. 4, 15 February 2005 (2005-02-15), pages 366-372, XP027735135, ISSN: 0006-3223 [retrieved on 2005-02-15] cited in the application page 368	1-4,6-12
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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/059032

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	K. SKOBLENICK ET AL: "NMDA Antagonist Ketamine Reduces Task Selectivity in Macaque Dorsolateral Prefrontal Neurons and Impairs Performance of Randomly Interleaved Prosaccades and Antisaccades", JOURNAL OF NEUROSCIENCE, vol. 32, no. 35, 29 August 2012 (2012-08-29), pages 12018-12027, XP055216579, ISSN: 0270-6474, DOI: 10.1523/JNEUROSCI.1510-12.2012 page 12024	1-4,6-12
A	----- US 2013/209585 A1 (KIM STANLEY [US]) 15 August 2013 (2013-08-15) paragraph [0172]	1-4,6-12
X,P	----- IVAN CORDON ET AL: "Coupling in the cortico-basal ganglia circuit is aberrant in the ketamine model of schizophrenia", EUROPEAN NEUROPSYCHOPHARMACOLOGY., vol. 25, no. 8, 1 August 2015 (2015-08-01), pages 1375-1387, XP055278726, NL ISSN: 0924-977X, DOI: 10.1016/j.euroneuro.2015.04.004 page 1382	1-12
A	----- V. DI LAZZARO ET AL: "Ketamine Increases Human Motor Cortex Excitability to Transcranial Magnetic Stimulation", THE JOURNAL OF PHYSIOLOGY, vol. 547, no. 2, 17 January 2003 (2003-01-17), pages 485-496, XP055258211, ISSN: 0022-3751, DOI: 10.1113/jphysiol.2002.030486 page 492	1-4,6-12
X	----- MICHAEL A TAFFE ET AL: "Ketamine impairs multiple cognitive domains in rhesus monkeys", DRUG AND ALCOHOL DEPENDENCE, vol. 68, no. 2, 1 October 2002 (2002-10-01), pages 175-187, XP055278791, IR ISSN: 0376-8716, DOI: 10.1016/S0376-8716(02)00194-1 page 184, column 1 ----- -/--	1-4,6-12

INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>Y GUILLERMAIN: "N-methyl-D-aspartate receptors and information processing: human choice reaction time under a subanaesthetic dose of ketamine", NEUROSCIENCE LETTERS, vol. 303, no. 1, 27 April 2001 (2001-04-27), pages 29-32, XP055278793, IE ISSN: 0304-3940, DOI: 10.1016/S0304-3940(01)01695-0 page 32</p>	1-4,6-12
X	<p>----- D L MURMAN ET AL: "Cognitive, behavioral, and motor effects of the NMDA antagonist ketamine in Huntington's disease", NEUROLOGY, 1 July 1997 (1997-07-01), XP055278797, page 156; table 1</p>	1-4,6-12
X,P	<p>----- ILHAME AMEQRANE ET AL: "A subanesthetic dose of ketamine in the Rhesus monkey reduces the occurrence of anticipatory saccades", PSYCHOPHARMACOLOGY, SPRINGER VERLAG, BERLIN, DE, vol. 232, no. 19, 9 July 2015 (2015-07-09), pages 3563-3572, XP035541940, ISSN: 0033-3158, DOI: 10.1007/S00213-015-4005-Z [retrieved on 2015-07-09] figures</p>	1-4,6-12
X	<p>----- KRUPITSKY E M ET AL: "Ketamine psychedelic therapy (KPT): A review of the results of ten years of research", JOURNAL OF PSYCHOACTIVE DRUGS, vol. 29, no. 2, 1997, pages 165-183, XP002762181, ISSN: 0279-1072 page 166, column 1, paragraph 1 table 3</p>	1-4,6-12
X	<p>----- Anonymous: "Ketamine for Depression and Alcohol Dependence - Full Text View - ClinicalTrials.gov", 1 March 2012 (2012-03-01), XP055304153, Retrieved from the Internet: URL:https://clinicaltrials.gov/ct2/show/NC T01551329 [retrieved on 2016-09-20] the whole document</p> <p>----- -/--</p>	1-4,6-12

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/059032

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>TSUTOMU SUZUKI ET AL: "Effects of the non-competitive NMDA receptor antagonist ketamine on morphine-induced place preference in mice", LIFE SCIENCES., vol. 67, no. 4, 1 June 2000 (2000-06-01), pages 383-389, XP055304334, GB ISSN: 0024-3205, DOI: 10.1016/S0024-3205(00)00639-1 figure 2</p>	1-4,6-12
X	<p>----- KOLESNIKOV Y ET AL: "Blockade of Morphine-Induced Hindlimb Myoclonic Seizures in Mice by Ketamine", PHARMACOLOGY BIOCHEMISTRY AND BEHAVIOR, ELSEVIER, US, vol. 56, no. 3, 1 March 1997 (1997-03-01), pages 423-425, XP027330386, ISSN: 0091-3057 [retrieved on 1997-03-01] figure 3</p>	1-4,6-12
A	<p>----- MAURICIO FORERO ET AL: "Successful Reversal of Hyperalgesia/Myoclonus Complex with Low-Dose Ketamine Infusion", PAIN PRACTICE, vol. 12, no. 2, 16 February 2012 (2012-02-16), pages 154-158, XP055304220, US ISSN: 1530-7085, DOI: 10.1111/j.1533-2500.2011.00475.x page 155, column 2</p>	1-3,5-12
X	<p>----- Jon E Berner: "Intranasal Ketamine for Intermittent Explosive Disorder: A Case Report", The Journal of clinical psychiatry, 1 August 2007 (2007-08-01), pages 1305-1311, XP055304282, Retrieved from the Internet: URL:http://www.psychiatrist.com/JCP/article/_layouts/ppp.psych.controls/BinaryViewer.ashx?Article=/JCP/article/Pages/2007/v68n08/v68n0821.aspx&Type=Article [retrieved on 2016-09-21] the whole document</p> <p>----- -/--</p>	1-3,5-12

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/059032

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>Sheik Hosenbocus ET AL: "Memantine: a review of possible uses in child and adolescent psychiatry", Journal of the Canadian Academy of Child and Adolescent Psychiatry = Journal de l'Académie canadienne de psychiatrie de l'enfant et de l'adolescent, 1 May 2013 (2013-05-01), page 166, XP055304232, Canada Retrieved from the Internet: URL:http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3647634/pdf/ccap22_2p0166.pdf page 168</p>	1-3,5-12
A	<p>----- HAMILTON MORRIS ET AL: "From PCP to MXE: a comprehensive review of the non-medical use of dissociative drugs", DRUG TESTING AND ANALYSIS, vol. 6, no. 7-8, 26 July 2014 (2014-07-26), pages 614-632, XP055304230, GB ISSN: 1942-7603, DOI: 10.1002/dta.1620 page 623</p>	1-3,5-12
X	<p>----- THOMAS OWLEY ET AL: "A Prospective, Open-Label Trial of Memantine in the Treatment of Cognitive, Behavioral, and Memory Dysfunction in Pervasive Developmental Disorders INTRODUCTION", JOURNAL OF CHILD AND ADOLESCENT PSYCHOPHARMACOLOGY VOLUME, vol. 16, no. 5, 1 January 2006 (2006-01-01), pages 517-524, XP055304474, table 4 -----</p>	1-3,5-12

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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.:

1-12(partially)
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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-4, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of ketamine, wherein said disorder is a personality disorder.

2. claims: 1-4, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of ketamine, wherein said disorder is a impulse control and addiction disorder.

3. claims: 1-4, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of ketamine, wherein said disorder is a neurodegenerative disorder.

4. claims: 1-4, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of ketamine, wherein said disorder is a movement disorder.

5. claims: 1-3, 5-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of metamine, wherein said disorder is a personality disorder.

6. claims: 1-3, 5-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of memantine,

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

wherein said disorder is a impulse control and addiction disorder.

7. claims: 1-3, 5-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of memantine, wherein said disorder is a neurodegenerative disorder.

8. claims: 1-3, 5-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of memantine, wherein said disorder is a movement disorder.

9. claims: 1-3, 5-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of amantadine.

10. claims: 1-3, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of tiletamine.

11. claims: 1-3, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of phencyclidine (PCP).

12. claims: 1-3, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of dizocilpine.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

13. claims: 1-3, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of MK-801.

14. claims: 1-3, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of Argiotoxin 636.

15. claims: 1-3, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of dextrorphan.

16. claims: 1-3, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of HU-211.

17. claims: 1-3, 5-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of Rhynchophylline.

18. claims: 1-3, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of aptiganel.

19. claims: 1-3, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of ifenprodil.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

20. claims: 1-3, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of lanicemine.

21. claims: 1-3, 6-12(all partially)

A composition for use in the treatment of motor dysfunction in a mental or psychiatric disorder with occurrence of aggressive and/or impulsive behavior in a subject in need thereof comprising a sub-anesthetic dose of Remacemide

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/EP2016/059032

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2014057988	A1	27-02-2014	AU 2013305580 A1 CN 104902883 A EP 2887930 A1 JP 2016501828 A KR 20150096370 A SG 11201501292U A US 2014057988 A1 WO 2014031975 A1	09-04-2015 09-09-2015 01-07-2015 21-01-2016 24-08-2015 28-05-2015 27-02-2014 27-02-2014

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