



(12) Translation of  
European patent specification

(11) NO/EP 3043816 B1

NORWAY

(19) NO  
(51) Int Cl.  
*A61K 39/395 (2006.01)*  
*A61P 35/00 (2006.01)*  
*C07K 16/28 (2006.01)*  
*C07K 16/30 (2006.01)*

Norwegian Industrial Property Office

---

|      |                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (21) | Translation Published                                                      | 2019.12.09                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| (80) | Date of The European<br>Patent Office Publication of<br>the Granted Patent | 2019.08.14                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| (86) | European Application Nr.                                                   | 14766962.6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| (86) | European Filing Date                                                       | 2014.09.11                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| (87) | The European Application's<br>Publication Date                             | 2016.07.20                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| (30) | Priority                                                                   | 2013.09.11, US, 201361876509 P<br>2014.03.27, US, 201461971212 P<br>2014.04.11, US, 201461978401 P<br>2014.05.27, US, 201462003349 P                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| (84) | Designated Contracting<br>States:                                          | AL ; AT ; BE ; BG ; CH ; CY ; CZ ; DE ; DK ; EE ; ES ; FI ; FR ; GB ; GR ; HR ; HU ;<br>IE ; IS ; IT ; LI ; LT ; LU ; LV ; MC ; MK ; MT ; NL ; NO ; PL ; PT ; RO ; RS ; SE ; SI ;<br>SK ; SM ; TR                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|      | Designated Extension<br>States:                                            | BA ; ME                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| (73) | Proprietor                                                                 | MedImmune Limited, Milstein Building Granta Park, CambridgeCambridgeshire<br>CB21 6GH, Storbritannia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| (72) | Inventor                                                                   | NARWAL, Rajesh, c/o MedImmune LLCOne MedImmune Way,<br>GaithersburgMaryland 20878, USA<br>FAIRMAN, David, c/o MedImmune LimitedMilstein BuildingGranta Park,<br>CambridgeCambridgeshire CB21 6GH, Storbritannia<br>ROBBINS, Paul, c/o MedImmune LLCOne MedImmune Way, GaithersburgMaryland<br>20878, USA<br>LIANG, Meina, c/o MedImmune LLCOne MedImmune Way, GaithersburgMaryland<br>20878, USA<br>SCHNEIDER, Amy, c/o MedImmune LLCOne MedImmune Way,<br>GaithersburgMaryland 20878, USA<br>CHAVEZ, Carlos, c/o MedImmune LLCOne MedImmune Way,<br>GaithersburgMaryland 20878, USA<br>HERL, Carina, c/o MedImmune LLCOne MedImmune Way, GaithersburgMaryland<br>20878, USA<br>PAK, Min, c/o MedImmune LLCOne MedImmune Way, GaithersburgMaryland<br>20878, USA<br>LU, Hong, c/o MedImmune LLCOne MedImmune Way, GaithersburgMaryland<br>20878, USA |

REBELATTO, Marlon, c/o MedImmune LLC One MedImmune Way,  
Gaithersburg Maryland 20878, USA  
 STEELE, Keith, c/o MedImmune LLC One MedImmune Way, Gaithersburg Maryland  
20878, USA  
 BOUTRIN, Anmarie, c/o MedImmune LLC One MedImmune Way,  
Gaithersburg Maryland 20878, USA  
 SHI, Li, c/o MedImmune LLC One MedImmune Way, Gaithersburg Maryland 20878,  
USA  
 HONG, Shengyan, c/o MedImmune LLC One MedImmune Way,  
Gaithersburg Maryland 20878, USA  
 HIGGS, Brandon, c/o MedImmune LLC One MedImmune Way,  
Gaithersburg Maryland 20878, USA  
 ROSKOS, Lorin, c/o MedImmune LLC One MedImmune Way, Gaithersburg Maryland  
20878, USA

(74) Agent or Attorney TANDBERG INNOVATION AS, Postboks 1570 Vika, 0118 OSLO, Norge

(54) Title **ANTI-B7-H1 ANTIBODIES FOR TREATING TUMORS**

(56) References  
Cited:

WO-A1-2011/066389  
 WO-A1-2013/079174  
 EP-A1- 2 172 219  
 Villaruz L et al.: "Immunotherapy in lung cancer", Transl lung Cancer Res , vol. 3, no. 1 1  
 February 2014 (2014-02-01), pages 2-14, XP002733500, Retrieved from the Internet:  
 URL: <http://www.tlcr.org/article/view/1772/2722> [retrieved on 2014-12-08]  
 Medimmune LLC: "A Phase 1/2 Study to Evaluate MEDI4736", Clinical trials , 14 September  
 2012 (2012-09-14), XP002733502, Retrieved from the Internet:  
 URL: <http://clinicaltrials.gov/ct2/show/NCT01693562> [retrieved on 2014-12-05]  
 Lutky J et al.: "A phase 1 study of MEDI4736, an anti-PD-L1 antibody, in patients with advanced  
 solid tumors", Journal of clinical oncology , vol. 32, no. 15 Suppl. 20 May 2014 (2014-05-20),  
 page 3001, XP002733501, Retrieved from the Internet:  
 URL: [http://meeting.ascopubs.org/cgi/content/abstract/32/15\\_suppl/3001](http://meeting.ascopubs.org/cgi/content/abstract/32/15_suppl/3001) [retrieved on 2014-12-08]  
 AstraZeneca Glogal: "AstraZeneca initiates phase III immunotherapy study for MEDI4736 in  
 patients with lung cancer", , 8 May 2014 (2014-05-08), XP002733499, Retrieved from the  
 Internet: URL: <http://www.astrazeneca.com/Media/Press-releases/Article/20140508--astrazeneca-initiates-phase-iii-immunotherapy-study-MEDI4736> [retrieved on 2014-12-08]  
 SHENG YAO ET AL: "Advances in targeting cell surface signalling molecules for immune  
 modulation", NATURE REVIEWS DRUG DISCOVERY, vol. 12, no. 2, 1 February 2013 (2013-02-01),  
 pages 130-146, XP055157248, ISSN: 1474-1776, DOI: 10.1038/nrd3877

Enclosed is a translation of the patent claims in Norwegian. Please note that as per the Norwegian Patents Acts, section 66i the patent will receive protection in Norway only as far as there is agreement between the translation and the language of the application/patent granted at the EPO. In matters concerning the validity of the patent, language of the application/patent granted at the EPO will be used as the basis for the decision. The patent documents published by the EPO are available through Espacenet (<http://worldwide.espacenet.com>) or via the search engine on our website here: <https://search.patentstyret.no/>

**Patentkrav**

1. MEDI4736 eller et antigenbindende fragment derav for anvendelse i behandling av en pasient identifisert som å ha et PD-L1-positivt ikke-småcellet lungekarsinom (NSCLC),  
5 hvori pasienten administreres 10 mg/kg MEDI4736 eller et antigenbindende fragment derav annenhver uke eller hver tredje uke.
2. MEDI4736 eller et antigenbindende fragment derav for anvendelse ifølge krav 1, hvori  
10 MEDI4736 administreres annenhver uke.
3. MEDI4736 eller et antigenbindende fragment derav for anvendelse ifølge krav 1 eller  
2, hvori PD-L1-statusen detekteres ved anvendelse av immunhistokjemi.
4. MEDI4736 eller et antigenbindende fragment derav for anvendelse ifølge krav 1 eller  
15 2, hvori minst 25 % av tumorcellene er PD-L1-positivt fargende.
5. MEDI4736 eller et antigenbindende fragment derav for anvendelse ifølge et hvilket  
som helst av kravene 1 til 4, hvori svulsten er en ikke-småcellet lungekreft som er et  
plateepitelkarsinom eller et ikke-plateepitelkarsinom.  
20
6. MEDI4736 eller et antigenbindende fragment derav for anvendelse ifølge et hvilket  
som helst av kravene 1 til 5, hvori det administreres minst to doser.