Cancer Immunotherapy Pilot Program/
Patents 4 Patients

USPTO BCP Customer Partnership Meeting
Alexandria, VA
August 2, 2017
Cancer Immunotherapy Pilot Program/ Patents 4 Patients

• The United States Patent and Trademark Office implemented Patents 4 Patients, also known as the Cancer Immunotherapy Pilot Program, to provide for fast-track review of patent applications pertaining to cancer immunotherapy in support of the White House national $1 billion initiative announced on February 1, 2016 to achieve ten years’ worth of cancer research in the next five years (“National Cancer Moonshot”).

• The objective of the pilot program was to complete the examination of the application within twelve months of special status being granted under the program.
Cancer Immunotherapy Pilot Program/ Patents 4 Patients

- **Patents 4 Patients**, implemented on June 29, 2016, was scheduled to end on June 28, 2017. In view of the continued interest in the pilot program and participation from various stakeholders from around the world— independent inventors, universities, research institutions, hospitals, medical centers, government agencies, and large and small companies—the USPTO is extending the pilot program until December 31, 2018. All pilot parameters will remain the same as the original pilot.
Petition Requirements

(1) Petition to make special under the pilot program may be filed in:
   - any application that has not received a first Office action,
   - any application where the petition is filed with a Request for Continued Examination (RCE), or
   - any application not under final rejection where the claimed cancer immunotherapy is the subject of an active Investigational New Drug (IND) application that has entered Phase II or Phase III (FDA) clinical trials.

(2) Three or fewer independent claims and twenty or fewer total claims.

(3) At least one method claim of treating a cancer using immunotherapy.

(4) File the petition electronically via EFS-Web. See Form PTO/SB/443
Eligibility Requirements

The application must contain a claim directed to a method of treating, ameliorating, or preventing a malignancy

• Steps must invoke (active) or achieve (passive) an immune response.
• Can include co-administration of biological adjuvants in combination with conventional therapies.
• Cancer vaccines (DNA, peptides, cells).
• Adoptive immunotherapies.
Prosecution

Requirement for Restriction:

- If multiple inventions are found in the application, the examiner may make a restriction requirement in accordance with current restriction practice.
  - Applicants must make a telephonic election without traverse to a method of treating cancer using immunotherapy that meets the eligibility requirements.
  - If Applicants cannot be reached after reasonable effort or applicant refuses to make a telephonic election, the examiner will treat the first group of claims to a method of treating a cancer using immunotherapy that meets the eligibility requirements as constructively elected without traverse for examination.
Prosecution

Amendments:

- Any amendment to a non-final Office action will be considered non-responsive if it attempts to:
  - Add claims which would result in more than three independent claims or more than twenty total claims.
  - Add any multiple dependent claim.
  - Present claims to a nonelected invention or an invention not previously claimed.
  - Cancel all method claims to treating a cancer using immunotherapy.
Petition History

TOTAL NUMBER OF APPLICATIONS PER MONTH AND DECISION

- **JUL**: 10
- **AUG**: 7
- **SEP**: 3 (UNDECIDED)
- **OCT**: 11
- **NOV**: 5
- **DEC**: 6
- **JAN**: 3 (GRANTED)
- **FEB**: 11
- **MAR**: 1 (DISMISSED)
- **APR**: 3
- **MAY**: 8 (DISMISSED)
- **JUN**: 20 (UNDECIDED)
- **JUL**: 4

Dates:
- JUL 2016
- AUG 2016
- SEP 2016
- OCT 2016
- NOV 2016
- DEC 2016
- JAN 2017
- FEB 2017
- MAR 2017
- APR 2017
- MAY 2017
- JUN 2017
- JUL 2017
### Status of Granted Petitions

#### Count of Applications Granted by Status

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The United States Patent
Grosvedt et al.

(45) Date of Patent: May 16, 2017

(10) Patent No.: US 9,650,441 B2

(60) Provisional Application No. 62/373,487; filed on Aug. 4, 2016; provisional application No. 62/221,446; filed on Sep. 21, 2015.

(51) Int. Cl.
A61K 5/00 (2006.01)
C07K 1/50 (2006.01)

(54) ANTI-CD47 ANTIBODIES AND METODS OF USE

(71) Applicants: Eurusam University Medical Center, Rotterdam, NL; Surface Oncology, Inc., Cambridge, MA, US; Adalat M. Holland, Betheman, MA, US; Allison Paterson, Orkney, UK; Jonathan Hill, Samson, MA, US

(73) Assignee: Eurusam University Medical Center, Rotterdam, NL; Surface Oncology, Inc., Cambridge, MA, US

(8) International Patent Classification:
A61K 5/00 (2006.01)
C07K 1/50 (2006.01)

(9) Other Classes:
C07K 23/765 (2013.01); C07K 23/765/1 (2013.01); C07K 23/765/7 (2013.01)

(22) Filing Date: Sep. 21, 2015

(21) Appl. No.: 15/271,861

(50) Reference Information:

What is claimed is:

1. A method of treating cancer in a subject in need thereof, wherein the cancer comprises cells that express CD47, the method comprising administering to the subject an effective amount of an isolated anti-CD47 antibody molecule comprising a heavy chain complementarity determining region 1 (HCDR1) of the amino acid sequence set forth in SEQ ID NO: 7, a heavy chain complementarity determining region 2 (HCDR2) of the amino acid sequence set forth in SEQ ID NO: 8, a heavy chain complementarity determining region 3 (HCDR3) of the amino acid sequence set forth in SEQ ID NO: 9, a light chain complementarity determining region 1 (LCDR1) of the amino acid sequence set forth in SEQ ID NO: 10, a light chain complementarity determining region 2 (LCDR2) of the amino acid sequence set forth in SEQ ID NO: 11, and a light chain complementarity determining region 3 (LCDR3) of the amino acid sequence set forth in SEQ ID NO: 12.

2. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with a chemotherapy agent or therapeutic antibody molecule.

3. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with an agonizing antibody molecule.

4. The method of claim 3, wherein the agonizing antibody molecule is an anti-CD9 antibody molecule, an anti-CD20 antibody molecule, or an anti-CD38 antibody molecule.

5. The method of claim 4, wherein the agonizing antibody molecule is an anti-CD20 antibody molecule.

6. The method of claim 4, wherein the antibody molecule is rituximab.

7. The method of claim 1, wherein the cancer is hematological.

8. The method of claim 7, wherein the hematological cancer is selected from the group consisting of acute lymphoblastic leukemia (ALL), T-ALL, B-ALL, acute myelogenous leukemia (AML), Non-Hodgkin lymphoma, B-lymphoblastic leukemia/lymphoma, B-cell chronic lymphocytic leukemia/small lymphocytic lymphoma, chronic lymphocytic leukemia (CLL), chronic myeloid leukemia (CML), Burkitt's lymphoma, follicular lymphoma, SLL.

9. The method of claim 1, wherein the anti-CD47 antibody molecule further comprises a wild type or mutant IgG1 heavy chain constant region.

10. The method of claim 14, wherein the IgG4 heavy chain constant region comprises one or both of the substitutions S228P and L253E.

11. The method of claim 1, wherein the anti-CD47 antibody molecule comprises a heavy chain of the amino acid sequence set forth in SEQ ID NO: 15, SEQ ID NO: 23, SEQ ID NO: 24, or SEQ ID NO: 25, and a light chain of the amino acid sequence set forth in SEQ ID NO: 16 or SEQ ID NO: 26.

12. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with a pharmacologically acceptable carrier or diluent.

13. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with a pharmacologically acceptable carrier or diluent.

14. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with a pharmacologically acceptable carrier or diluent.

15. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with a pharmacologically acceptable carrier or diluent.

16. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with a pharmacologically acceptable carrier or diluent.

17. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with a pharmacologically acceptable carrier or diluent.
Resources

• Federal Register notice on extending Patents 4 Patients to December 31, 2018 (Extension of the Cancer Immunotherapy Pilot Program, 82 FR 28645 (June 23, 2017))

• Federal Register notice on Patents 4 Patients (Cancer Immunotherapy Pilot Program, 81 FR 42328 (June 29, 2016))
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