METHODS FOR TREATING OVARIAN CANCER

PRIORITY CLAIM

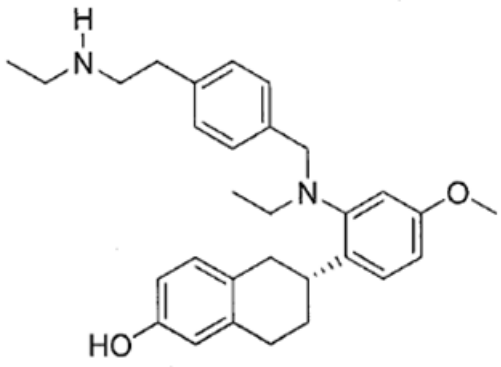
[0001] This application claims the benefit of U.S. Provisional Application No. 62/400,495, filed September 27, 2016, which is incorporated herein by reference in its entirety.

BACKGROUND

[0002] Ovarian tumors are known to often express estrogen receptor (ER) including ERα. ERs can be activated by estrogen and translocate into the nucleus to bind to DNA, thereby regulating the activity of various genes. See, e.g., Marino et al., "Estrogen Signaling Multiple Pathways to Impact Gene Transcription," *Curr. Genomics* 7(8): 497-508 (2006); and Heldring et al., "Estrogen Receptors: How Do They Signal and What Are Their Targets," *Physiol. Rev.* 87(3): 905-931 (2007). Ovarian cancers may be of different types including epithelial, stromal and sarcomas. Epithelial ovarian cancers are typically divided into serous, endometrioid, mucinous, clear cell and undifferentiated. Ovarian cancers may also be primary peritoneal, stromal and sarcomas. Regardless of origin or type, ovarian cancer is a serious and often fatal affliction with a great recognized need for new and effective treatment modalities.

BRIEF SUMMARY

[0003] In one aspect, the present disclosure relates to a use of a therapeutically effective amount of RAD1901 having the structure:



or a salt or solvate thereof in the manufacture of a medicament for inhibiting tumor growth or producing tumor regression in a subject having ovarian cancer or tumor selected from the group consisting of epithelial ovarian cancer, stromal ovarian cancer and ovarian sarcoma cancer.

[0003a] Certain examples of the methods disclosed herein relate to treating ovarian cancer and/or tumor in a subject comprising administering to the subject a therapeutically effective amount of RAD1901.

[0004] Certain examples of the methods disclosed herein relate to treating ovarian cancer and/or tumor in a subject comprising administering to the subject a therapeutically effective amount of RAD1901of RAD1901 and a therapeutically effective amount of one or more second therapeutic agents.

[0005] In certain examples of the methods disclosed herein, the ovarian cancer and/or tumor treated expresses ERα.

BRIEF DESCRIPTION OF DRAWINGS AND TABLES

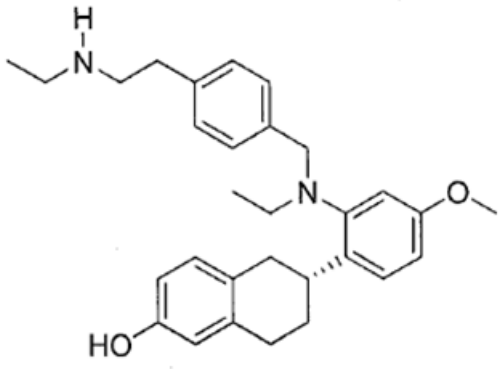
[0006] **Figure 1:** Tumor growth inhibition and regression effects of RAD1901 (p.o. daily at 30 mg/kg or 60 mg/kg) to PDX models (mice with established ovarian patient derived xenograft) tumors).

[0007] **Figure 2:** Individual tumor growth inhibition and regression effect at day 32 in PDX models treated with RAD1901 (p.o., daily at 30 mg/kg or 60 mg/kg).

CLAIMS

What is claimed is:

1. Use of a therapeutically effective amount of RAD1901 having the structure:



or a salt or solvate thereof in the manufacture of a medicament for inhibiting tumor growth or producing tumor regression in a subject having ovarian cancer or tumor selected from the group consisting of epithelial ovarian cancer, stromal ovarian cancer and ovarian sarcoma cancer.

2. The use of claim 1 wherein said ovarian cancer or tumor expresses ERα.

3. The use according to any one of claims 1-2, wherein the cancer or tumor is a metastatic cancer.

4. The use according to any one of claims 1-3 wherein the medicament is to be administered at a daily oral dose of between 100 and 1,000 mg.

5. The use according to claim 4 where the daily dose is 400 mg.

6. The use of any one of claims 1-3, wherein a 150 mg to 2,000 mg dose of RAD1901 is to be administered.

7. The use of claim 6, wherein a 200 mg, 400 mg, or 500 mg dose of RAD1901 is to be administered.

8. The use according to any one of claims 1-7 wherein the medicament is to be administered with a taxane.

9. The use of any one of claims 1 to 8, wherein the ovarian cancer or tumor is resistant to a drug selected from the group consisting of anti-estrogens, aromatase inhibitors, and combinations thereof.

10. The use of claim 9, wherein the anti-estrogen is tamoxifen or fulvestrant.

11. The use of claim 9, wherein the aromatase inhibitors is aromasin.

12. The use of any one of claims 1-11, wherein the medicament is to be administered with a therapeutically effective amount of one or more second therapeutic agents selected from the group consisting of CDK4 and/or CDK6 inhibitors to the subject.

13. The use of claim 12, wherein the CDK4 and/or CDK6 inhibitors are selected from the group consisting of ribociclib, abemaciclib and palbociclib.

14. The use of any one of claims 1 to 13, wherein one or more ovarian cancer or tumor of the subject has been surgically removed before the initiation of the administration of the medicament.