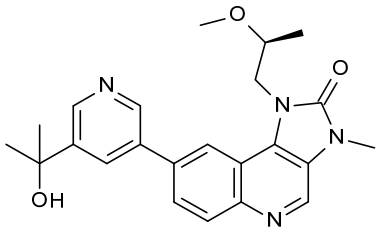
methoxyphenyl)-1H-pyrazol-3-ylamino) pyrazine-2-carbonitrile, or a pharmaceutically acceptable salt thereof, in squamous histology cancers, breast cancer, prostate cancer, endometrial cancer, ovarian cancer, and colorectal cancer patients as compared to the therapeutic effects provided by either agent alone. Furthermore, the present invention discloses methods of treating squamous histology cancers, breast cancer, prostate cancer, bladder cancer, cervical cancer, endometrial cancer, ovarian cancer, and colorectal cancer as part of a specific treatment regimen that provides enhanced and/or unexpected beneficial therapeutic effects from the combined activity of 8-[5-(1-hydroxy-1-methylethyl)pyridin-3-yl]-1-[(2S)-2-methoxypropyl]-3-methyl-1,3-dihydro-2H-imidazo[4,5-c]quinolin-2-one, or a pharmaceutically acceptable salt thereof, and 5-(5-(2-(3-aminopropoxy)-6-methoxyphenyl)-1H-pyrazol-3-ylamino) pyrazine-2-carbonitrile, or a pharmaceutically acceptable salt thereof, in squamous histology cancers, breast cancer, prostate cancer, bladder cancer, cervical cancer, endometrial cancer, ovarian cancer, and colorectal cancer patients as compared to the therapeutic effects provided by either agent alone.

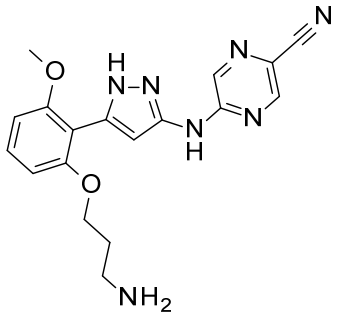
Summary

In one aspect of the present disclosure, there is provided a kit comprising a compound of the formula:



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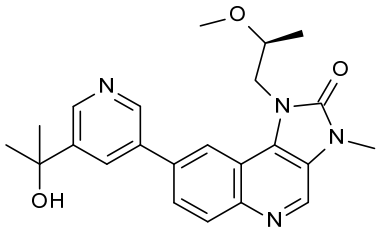
or a pharmaceutically acceptable salt thereof, and a compound of the formula:



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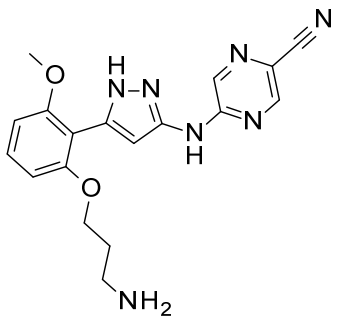
or a pharmaceutically acceptable salt thereof, for simultaneous, separate, or sequential use in the treatment of squamous histology cancers, breast cancer, prostate cancer, bladder cancer, cervical cancer, endometrial cancer, ovarian cancer, and colorectal cancer.

In another aspect of the present disclosure, there is provided a kit, comprising a pharmaceutical composition, comprising a compound of the formula:



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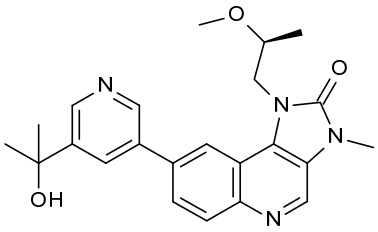
or a pharmaceutically acceptable salt thereof, with one or more pharmaceutically acceptable carriers, diluents, or excipients, and a pharmaceutical composition, comprising a compound of the formula:



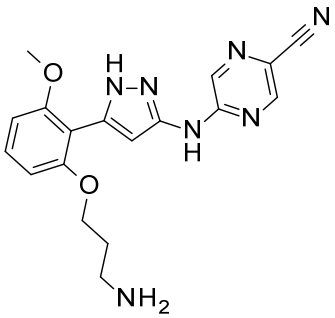
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or a pharmaceutically acceptable salt thereof, with one or more pharmaceutically acceptable carriers, diluents, or excipients for simultaneous, separate, or sequential use in the treatment of squamous histology cancers, breast cancer, prostate cancer, endometrial cancer, ovarian cancer, and colorectal cancer.

In a further aspect of the present disclosure, there is provided a pharmaceutical composition comprising a compound of the formula:



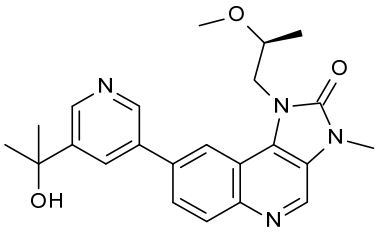
or a pharmaceutically acceptable salt thereof, and a compound of the formula:



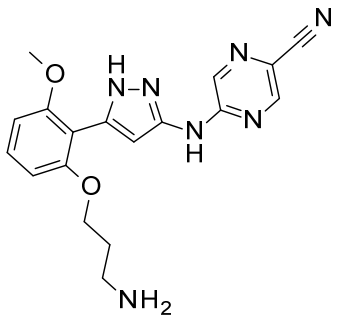
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or a pharmaceutically acceptable salt thereof, for use in the treatment of squamous histology cancers, breast cancer, prostate cancer, bladder cancer, cervical cancer, endometrial cancer, ovarian cancer, and colorectal cancer.

In another aspect of the present disclosure, there is provided a use of a compound of the formula:



or a pharmaceutically acceptable salt thereof, in combination with a compound of the formula:

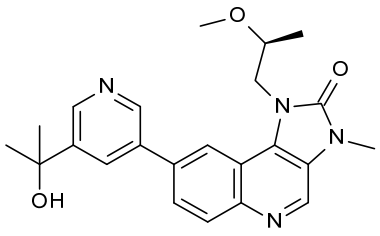


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or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the treatment of squamous histology cancers, breast cancer, prostate cancer, bladder cancer, cervical cancer, endometrial cancer, ovarian cancer, and colorectal cancer.

Description

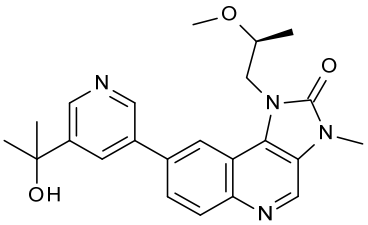
Accordingly, the present invention provides a method of treating squamous histology cancers, breast cancer, prostate cancer, bladder cancer, cervical cancer, endometrial cancer, ovarian cancer, and colorectal cancer in a patient, comprising administering to a patient in need of such treatment an effective amount of a compound of the formula:



, or a pharmaceutically acceptable salt thereof, in combination with an effective amount of a compound of the formula:

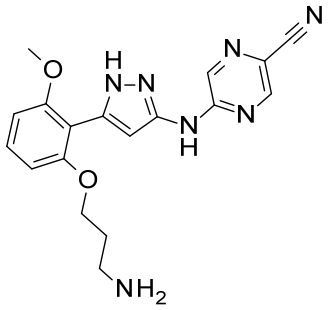
WE CLAIM:

1. A kit comprising a compound of the formula:



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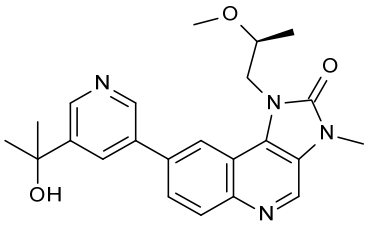
or a pharmaceutically acceptable salt thereof, and a compound of the formula:



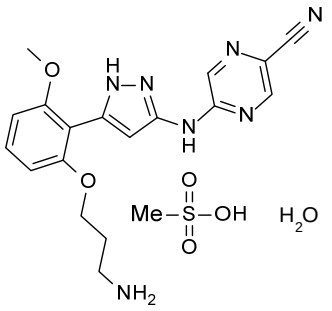
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or a pharmaceutically acceptable salt thereof, for simultaneous, separate, or sequential use in the treatment of squamous histology cancers, breast cancer, prostate cancer, bladder cancer, cervical cancer, endometrial cancer, ovarian cancer, and colorectal cancer.

2. The kit according to claim 1 wherein the compounds are

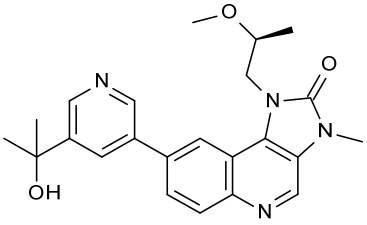


and

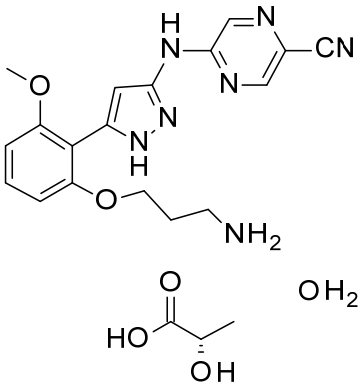


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3. The kit according to claim 1, wherein the compounds are



and

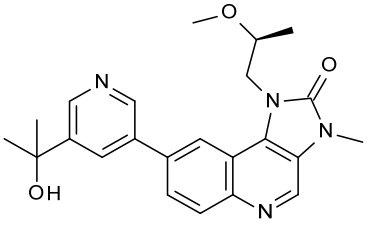


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4. The kit according to claim 1, wherein the squamous histology cancers and breast cancer are squamous NSCLC, HNSCC, esophageal cancer, anal cancer, and TNBC.

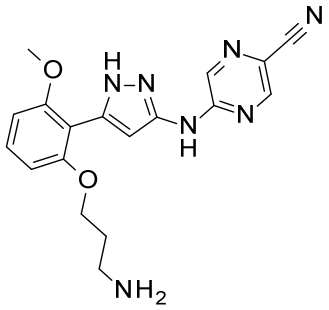
5. The kit according to claim 4, wherein the breast cancer is TNBC.

6. A kit, comprising a pharmaceutical composition, comprising a compound of the formula:



,

or a pharmaceutically acceptable salt thereof, with one or more pharmaceutically acceptable carriers, diluents, or excipients, and a pharmaceutical composition, comprising a compound of the formula:



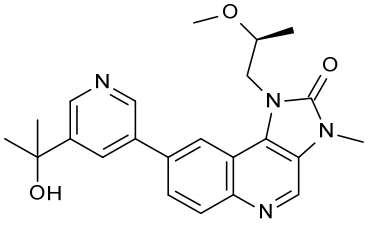
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or a pharmaceutically acceptable salt thereof, with one or more pharmaceutically acceptable carriers, diluents, or excipients for simultaneous, separate, or sequential use in the treatment of squamous histology cancers, breast cancer, prostate cancer, endometrial cancer, ovarian cancer, and colorectal cancer.

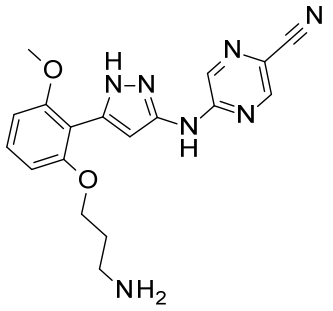
7. The kit according to claim 6, wherein the squamous histology cancers and breast cancer are squamous NSCLC, HNSCC, esophageal cancer, anal cancer, and TNBC.

8. The kit according to claim 7, wherein the breast cancer is TNBC.

9. A pharmaceutical composition comprising a compound of the formula:



or a pharmaceutically acceptable salt thereof, and a compound of the formula:



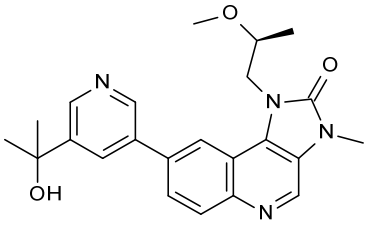
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or a pharmaceutically acceptable salt thereof, for use in the treatment of squamous histology cancers, breast cancer, prostate cancer, bladder cancer, cervical cancer, endometrial cancer, ovarian cancer, and colorectal cancer.

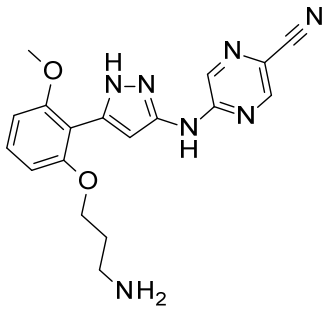
10. The pharmaceutical composition according to claim 9, wherein the squamous histology cancers and breast cancer are squamous NSCLC, HNSCC, esophageal cancer, anal cancer, and TNBC.

11. The pharmaceutical composition according to claim 10 wherein the breast cancer is TNBC.

12. Use of a compound of the formula:



or a pharmaceutically acceptable salt thereof, in combination with a compound of the formula:



,

or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the treatment of squamous histology cancers, breast cancer, prostate cancer, bladder cancer, cervical cancer, endometrial cancer, ovarian cancer, and colorectal cancer.

13. The use according to claim 12 wherein the squamous histology cancers and breast cancer are squamous NSCLC, HNSCC, esophageal cancer, anal cancer, and TNBC.

14. The use according to claim 12 wherein the breast cancer is TNBC.