In one example, the present disclosure refers to a combination of 4,4,4-trifluoro-N-[(1S)-2-[[(7S)-5-(2-hydroxyethyl)-6-oxo-7H-pyrido[2,3-d][3]benzazepin-7-yl]amino]-1-methyl-2-oxo-ethyl]butanamide, or a pharmaceutically acceptable salt or hydrate thereof; and a PD-1 or PD-L1 inhibitor selected from the group consisting of pembrolizumab, nivolumab, atezolizumab, durvalumab, and avelumab for use in combination therapy for the treatment of colorectal cancer.

Disclosed is a compound 4,4,4-trifluoro-N-[(1S)-2-[[(7S)-5-(2-hydroxyethyl)-6-oxo-7H-pyrido[2,3-d][3]benzazepin-7-yl]amino]-1-methyl-2-oxo-ethyl]butanamide, or a pharmaceutically acceptable salt or hydrate thereof; and a PD-1 or PD-L1 inhibitor selected from pembrolizumab, nivolumab, atezolizumab,

WE CLAIM:

1. Use of 4,4,4-trifluoro-N-[(1S)-2-[[(7S)-5-(2-hydroxyethyl)-6-oxo-7H-pyrido[2,3-d][3]benzazepin-7-yl]amino]-1-methyl-2-oxo-ethyl]butanamide, or a pharmaceutically acceptable salt or hydrate thereof in the manufacture of a first medicament; and use of a PD-1 or PD-L1 inhibitor selected from the group consisting of pembrolizumab, nivolumab, atezolizumab, durvalumab, and avelumab in the independent manufacture of a second medicament; for the treatment of colorectal cancer, wherein the first medicament and the second medicament are to be administered in combination.

2. The use of claim 1, wherein the 4,4,4-trifluoro-N-[(1S)-2-[[(7S)-5-(2-hydroxyethyl)-6-oxo-7H-pyrido[2,3-d][3]benzazepin-7-yl]amino]-1-methyl-2-oxo-ethyl]butanamide, or the pharmaceutically acceptable salt or hydrate thereof, and the PD-1 or PD-L1 inhibitor are to be administered simultaneously, separately, or sequentially.

3. The use of claim 1 or claim 2, wherein the first medicament comprises between 2.5 mg and 75 mg of 4,4,4-trifluoro-N-[(1S)-2-[[(7S)-5-(2-hydroxyethyl)-6-oxo-7H-pyrido[2,3-d][3]benzazepin-7-yl]amino]-1-methyl-2-oxo-ethyl]butanamide, or a pharmaceutically acceptable salt or hydrate thereof.

4. The use of claim 3, wherein the first medicament comprises between 10 mg and 50 mg of 4,4,4-trifluoro-N-[(1S)-2-[[(7S)-5-(2-hydroxyethyl)-6-oxo-7H-pyrido[2,3-d][3]benzazepin-7-yl]amino]-1-methyl-2-oxo-ethyl]butanamide, or a pharmaceutically acceptable salt or hydrate thereof.

5. The use of any of claims 1-3, wherein the first medicament is to be administered in an amount between 2.5 mg and 75 mg once per day every other day over a five day period followed by two days without dosing (T.I.W.).

6. The use of any of claims 1-4, wherein the first medicament is to be administered in an amount between 10 mg and 50 mg T.I.W.

7. The use of any of claims 1-6, wherein the first medicament is to be administered orally.

8. The use of any of claims 1-7, wherein the second medicament is to be administered in an amount between 1 mg/kg and 3 mg/kg once every 14 to 21 days.

9. The use of any of claims 1-8, wherein the second medicament is to be administered parenterally.

10. The use of claim 9, wherein the parenteral administration is intravenous infusion.