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(54) COMBINATION THERAPY OF A TYPE II ANTI-CD20 ANTIBODY WITH A SELECTIVE **BCL-2 INHIBITOR**

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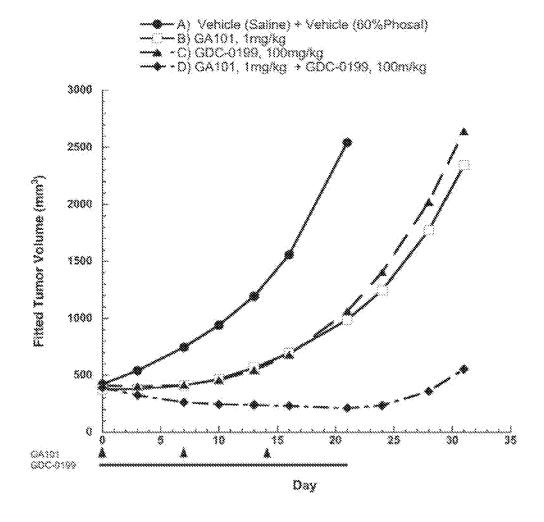
CPC A61K 31/496 (2013.01); A61K 2300/00 (2013.01)

(57)ABSTRACT

The present invention is directed to a combination therapy involving a type II anti-CD20 antibody and a selective BCL-2 inhibitor for the treatment of a patient suffering from cancer, particularly, a CD20-expressing cancer.



FIG 1/5



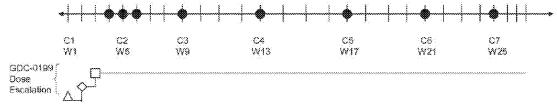


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FIG 2/5

Schedule A Dosing Schema: GDC-0199 Step-Up Dosing for

Three Weeks Before Starting Obinutuzumab



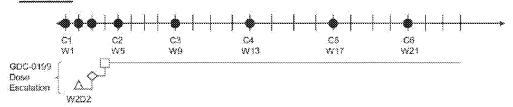
- Obinutuzumab administration: W4 (C1D22), W5 (C2D1), W6 (C2D8), W9 (C3D1), W13 (C4D1), W17 (C5D1), W21 (C6D1), and W25 (C7D1).
- △ GDC-0199 50 mg dose (starting dose): W1 (C1D1 through C1D7)
- ☐ GDC-0199 300 mg dose (ending dose); W3 (C1D16) through W28 (C7D28)

C=cycle; D=day; W=week.

FIG 3/5

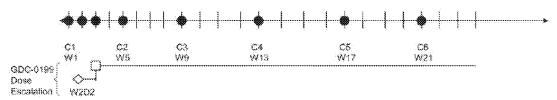
Schedule B Dosing Schema: Obinutuzumab Administered Before GDC-0199 Dose-Escalation

Cohort 1



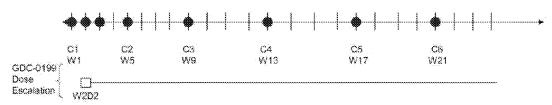
- Obinutuzumab administration: W1 (C1, split dose on D1 and D2), W2 (C1D8), W3 (C1D15), z
 W5 (C2D1), W9 (C3D1), W13 (C4D1), W17 (C5D1), and W21 (C6D1)
- △ GDC-0199 50 mg dose (starting dose): W2 (C1D9 through C1D14)
- OGDC-0199 100 mg dose: W3 (C1D15 through C1D21)
- ☐ GDC-0199 300 mg dose (ending dose): W4 (C1D22) through W24 (C6D28)

Cohort 2



- Obinutuzumab administration: W1 (C1, split dose on D1 and D2), W2 (C1D8), W3 (C1D15).
 W5 (C2D1), W9 (C3D1), W13 (C4D1), W17 (C5D1), and W21 (C6D1)
- ♦ GDC-0199 100 mg dose (starting dose): W2 (C1D9 through C1D14)
- ☐ GDC-0199 300 mg dose (ending dose): W3 (C1D15) through W24 (C6D28)

Cohort 3

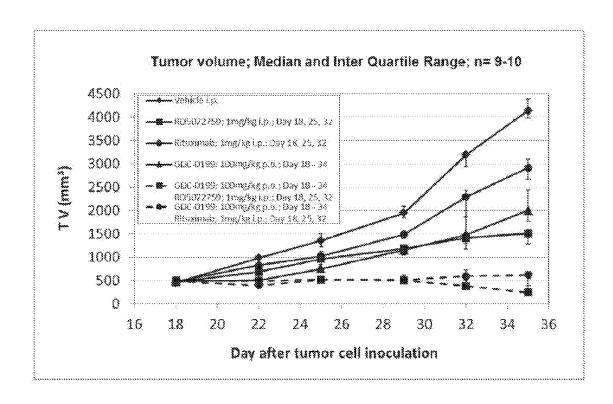


- Obinutuzumab administration: W1 (C1, split dose on D1 and D2), W2 (C1D8), W3 (C1D15), W5 (C2D1), W9 (C3D1), W13 (C4D1), W17 (C5D1), and W21 (C6D1)
- GDC-0199 300 mg dose: W2 (C1D9) through W24 (C6D28)

C=cycle; D=day; W=week.

Schedule B includes approximately three dosing cohorts to be enrolled sequentially.

FIG 4/5



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