RECLAP Schema - cohort 1

Course 1

C1 W1 dl 1 → C1 W2 → C1 W3 dl 1 → C1 W4 rest (Tox eval) → DLT

If DLT = yes, then Dose de-escalation → Escalate to next dose level → C2 W1 dl 2 → C2 W2 rest → C2 W3 dl 2 → C2 W4 rest (Tox eval)

If DLT = no, then Escalate to next dose level → C2 W1 dl 2 → C2 W2 rest → C2 W3 dl 2 → C2 W4 rest (Tox eval)

C2 W4 Evaluation of response

PD by RECIST or by clinical exam → Off treatment

If PR, SD, CR by RECIST = yes, then Off Study Treatment Surgical Resection

Resectable

no → DLT

If DLT = no, then Escalate to next dose level → C2 W1 dl 2 → C2 W2 rest → C2 W3 dl 2 → C2 W4 rest (Tox eval)

If DLT = yes, then Treat at prior dose level → C2 W1 dl 2 → C2 W2 rest → C2 W3 dl 2 → C2 W4 rest (Tox eval)

Course 2 and 3

C1 W1 dl 3 → C1 W2 → C1 W3 dl 3 → C1 W4 rest (Tox eval) → DLT

If DLT = yes, then Dose de-escalation → Escalate to next dose level → C2 W1 dl 3 → C2 W2 rest → C2 W3 dl 3 → C2 W4 rest (Tox eval)

If DLT = no, then Escalate to next dose level → C2 W1 dl 3 → C2 W2 rest → C2 W3 dl 3 → C2 W4 rest (Tox eval)

C2 W4 Evaluation of response

PD by RECIST or by clinical exam → Off treatment

If PR, SD, CR by RECIST = yes, then Off Study Treatment Surgical Resection

Resectable

no → DLT

If DLT = no, then Escalate to next dose level → C2 W1 dl 3 → C2 W2 rest → C2 W3 dl 3 → C2 W4 rest (Tox eval)

If DLT = yes, then Treat at prior dose level → C2 W1 dl 3 → C2 W2 rest → C2 W3 dl 3 → C2 W4 rest (Tox eval)