

Article details



Title of article

Neo-DREAM study investigating Daromun for the treatment of clinical stage IIIB/C melanoma



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Trial registration number

NCT03567889

Primary objectives/rationale



Primary objective

Determine if neoadjuvant Daromun improves recurrence free survival versus surgery alone for patients with resectable stage IIIB/C melanoma



Secondary objectives

Assess if neoadjuvant Daromun improves overall survival, local recurrence free survival, and distant metastasis free survival. Safety and tolerability will also be evaluated

Study design and treatment including planned sample size, planned study period and study procedures



Global



Open-label



Multicenter



Phase III, 2-arm



Randomized patients:
248



Randomized 2:1

Neoadjuvant intratumoral Daromun (L19IL2 + L19TNF) followed by surgery versus surgery alone for patients with surgically resectable stage IIIB and IIIC metastatic melanoma

248 patients will be enrolled and randomized in a 1:1 ratio to one of two treatment arms: Neoadjuvant Daromun followed by surgery (Arm 1) versus surgery alone (Arm 2)

Arm 1 patients will receive intratumoral injections into injectable cutaneous, subcutaneous, and nodal tumors using Daromun once weekly, for up to 4 weeks and surgery within an additional 4 weeks

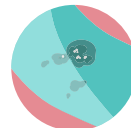
Arm 2 patients will proceed direct to surgery within within 4 weeks of randomization. Treatment response will occur every 3 months, for the first 36 months, and every 6 months from months 36 to 60, or until disease recurrence

Key eligibility criteria

Age ≥ 18 years



Clinical stage IIIB or IIIC cutaneous melanoma that is surgically resectable



Measurable disease and ≥ 1 cutaneous, subcutaneous, or nodal metastasis (≥ 10 mm in longest diameter) or multiples lesions that in aggregate are ≥ 10 mm in longest diameter that are amendable to intralesional injection

Eastern Cooperative Oncology Group (ECOG) performance status/WHO performance status of ≤ 1

Life expectancy of >24 months

Adequate renal, hematologic, and hepatic function; LDH ≤ 1.5 x upper limit of normal (ULN); documented negative test for HIV, hepatitis B/C

Outcome measures/end points

Primary end point

Recurrence free survival



Secondary end points

Overall survival, local recurrence free survival, distant metastasis free survival, toxicity

