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 metastatsis (≥10mm in longest diameter) or multiples lesions that in aggregate are ≥10mm 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