New Concept

GOG 3021

A Phase II Trial of Doxorubicin Combined with Olaratumab in the Treatment of Recurrent or Persistent Carcinosarcoma of the Uterus or Ovary

Number of study subjects: 20-38
Estimated duration: 20-24 months if study goes to second stage

Primary objective: To assess the activity of doxorubicin plus olaratumab in patients with persistent or recurrent carcinosarcoma of the uterus or ovary as measured by the proportion of patients who survive progression-free for at least 6 months and the proportion of patients who have objective tumor response (complete or partial).

Key inclusion criteria: Carcinosarcoma of the ovary or uterus
Measureable disease
1-2 prior lines of treatment
No prior doxorubicin or liposomal doxorubicin
No prior olaratumab
Performance status 0-2
Adequate organ function

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Enroll patients with measurable, advanced carcinosarcoma of the uterus or ovary, who have received 1-2 prior lines of systemic therapy for carcinosarcoma

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Baseline CT CAP for RECIST measurements

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Doxorubicin 60 mg/m2 IV day 1, every 3 weeks for maximum 8 cycles

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Olaratumab 15 mg/kg IV day 1 and day 8, every 3 weeks, maximum 8 cycles

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CT CAP every 6 weeks (after every other cycle) to assess response by RECIST during cycles 1-8, then every 8 weeks until disease progression

Patients will remain on study treatment for a maximum of 8 cycles of doxorubicin + olaratumab provided CT imaging shows at least RECIST stable disease, and patient has not had unacceptable toxicity.