from 2 months (estimated from published clinical data in various types of patients with STS who were previously treated with one active agent and based on clinical assessment) to 3 months; in other words, per the Study design, a 4-week improvement is considered successful. The combination of olaratumab plus doxorubicin showed a 12-week improvement in PFS; the combination *tripled* the Study requirement under which the Study is considered successful. This illustrates an unexpected benefit over the anticipated Study outcome that is based on the standard of care, and the prior art when the Study was designed and initiated. When PFS and OS are compared to the currently available and recently investigated treatments referenced *supra*, the results are noteworthy and illustrate a clear unexpected benefit.

In one aspect of the present disclosure, there is provided a use of olaratumab in the manufacture of a medicament for the treatment of soft tissue sarcoma, wherein the medicament is to be administered in combination with doxorubicin, wherein following the fourth administration of doxorubicin to a patient, a cardioprotective agent is to be administered to the patient, wherein the cardioprotective agent is to be administered following administration of olaratumab to the patient and prior to administration of doxorubicin to the patient, and wherein the cardioprotective agent is dexrazoxane and is to be administered at a dose of about 600 mg/m^2 to about 750 mg/m^2, or wherein the dosage ratio of dexrazoxane to doxorubicin is 10:1.

In another aspect of the present disclosure, there is provided a use of olaratumab, doxorubicin and dexrazoxane in the manufacture of a medicament for the treatment of soft tissue sarcoma, wherein:

i) olaratumab is to be administered to a patient, wherein the patient has soft tissue sarcoma; and

ii) doxorubicin is to be administered to the patient,

wherein following a fourth administration of doxorubicin to the patient dexrazoxane is to be administered to the patient, wherein dexrazoxane is to be administered following administration of olaratumab to the patient and prior to administration of doxorubicin to the patient, and wherein dexrazoxane is to be administered at a dose of about 600 mg/m^2 to about 750 mg/m^2, or wherein the dosage ratio of dexrazoxane to doxorubicin is 10:1.

The present disclosure also provides a method of treating a patient having soft tissue sarcoma, comprising administering to the patient in need thereof olaratumab and doxorubicin. In a preferred embodiment of the present disclosure, the olaratumab is administered at a dose of about 15 mg/kg. In another embodiment of the present disclosure, the doxorubicin is administered at a dose of about 60 mg/m^2 or about 75 mg/m^2. In a preferred embodiment of the present disclosure, the doxorubicin is administered at a dose of about 75 mg/m^2. In yet another preferred embodiment of the present disclosure, the olaratumab is administered before the doxorubicin is administered. In a preferred embodiment of the present disclosure, the soft tissue sarcoma is leiomyosarcoma.

WE CLAIM:

1. Use of olaratumab in the manufacture of a medicament for the treatment of soft tissue sarcoma, wherein the medicament is to be administered in combination with doxorubicin, wherein following the fourth administration of doxorubicin to a

patient, a cardioprotective agent is to be administered to the patient, wherein the cardioprotective agent is to be administered following administration of olaratumab to the patient and prior to administration of doxorubicin to the patient, and wherein the cardioprotective agent is dexrazoxane and is to be administered at a dose of about 600 mg/m^2 to about 750 mg/m^2, or wherein the dosage ratio of dexrazoxane to doxorubicin is 10:1.

2. The use according to Claim 1 , wherein the olaratumab is to be administered at a dose of about 15 mg/kg.

3. The use according to Claim 1 or 2 wherein the doxorubicin is to be administered at a dose of about 60 mg/m^2 or about 75 mg/m^2.

4. The use according to Claim 3, wherein the doxorubicin is to be administered at a dose of about 75 mg/m^2.

5. The use according to any one of Claims 1 to 4, wherein the olaratumab is to be administered at a dose of about 15 mg/kg, wherein the doxorubicin is to be administered at a dose of about 75 mg/m^2, and wherein the cardioprotective agent is dexrazoxane and is to be administered at a dose of about 750 mg/m^2.

6. The use according to any one of Claims 1 to 5, wherein the soft tissue sarcoma is leiomyosarcoma.

7. Use of olaratumab, doxorubicin and dexrazoxane in the manufacture of a medicament for the treatment of soft tissue sarcoma, wherein:

i) olaratumab is to be administered to a patient, wherein the patient has soft tissue sarcoma; and

ii) doxorubicin is to be administered to the patient,

wherein following a fourth administration of doxorubicin to the patient dexrazoxane is to be administered to the patient, wherein dexrazoxane is to be administered following administration of olaratumab to the patient and prior to administration of doxorubicin to the patient, and wherein dexrazoxane is to be

administered at a dose of about 600 mg/m^2 to about 750 mg/m^2, or wherein the dosage ratio of dexrazoxane to doxorubicin is 10:1.

8. The use according to Claim 7, wherein the olaratumab is to be administered at a dose of about 15 mg/kg.

9. The use according to Claim 7 or 8, wherein the doxorubicin is to be administered at a dose of about 60 mg/m^2 or about 75 mg/m^2.

10. The use according to Claim 9, wherein the doxorubicin is to be administered at a dose of about 75 mg/m^2.

11. The use according to any one of Claims 7 to 10, wherein the olaratumab is to be administered at a dose of about 15 mg/kg, wherein the doxorubicin is to be administered at a dose of about 75 mg/m^2, and wherein the cardioprotective agent is dexrazoxane and is to be administered at a dose of about 750 mg/m^2.

12. The use according to any one of Claims 7 to 11, wherein the soft tissue sarcoma is leiomyosarcoma.