3.0 PATIENT ELIGIBILITY AND EXCLUSIONS

3.1 Eligible Patients

3.11 Patients with high risk uterine LMS, FIGO stage I (confined to corpus +/- cervix). Patients with known uterine serosa involvement are not eligible. Patients should have had, at least, a complete hysterectomy (including removal of the cervix). Bilateral salpingo-oophorectomy is not required.

3.111 Institutional pathology review calls the uterine leiomyosarcoma "high grade."

3.112 Additionally, if the pathology report indicates a mitotic rate, the mitotic rate should be greater than or equal to 5 mitoses/10 high power field.

All patients must be no longer than 12 weeks (3 months) from surgical resection of cancer at the time of enrollment on study. If a patient requires a second operation to complete her surgery, i.e. trachelectomy to remove the cervix and/or BSO, the 12 weeks may be counted from the time of the second operation.

Patients who had a "morcellation" hysterectomy procedure that involved morcellation within the peritoneal cavity are eligible IF a second operation is performed and biopsies from the second procedure show no evidence of leiomyosarcoma. **(10/28/2013)**

3.12 All patients must have no evidence of persistent or metastatic disease as documented by a post-resection CT of the chest/abdomen/pelvis or by CT chest + MRI abdomen/pelvis. The post-resection imaging studies should be performed within 4 weeks of registration on study.

3.13 Patients must have adequate:

3.131 Bone marrow function: Absolute neutrophil count (ANC) greater than or equal to 1,500/mcl (ANC 1.5 x 10^9/liter (L). Platelets greater than or equal to100,000/mcl (Platelets 100 x 10^9/L). Hemoglobin greater than 8.0 g/dl (= 80 g/L; or 4.9 mmol/L).

3.132 Renal function: creatinine less than or equal to 1.5 x institutional upper limit normal (ULN.)

3.133 Hepatic function: Bilirubin within normal range. SGOT (AST), SGPT (ALT), and alkaline phosphatase less than or equal to 2.5 x ULN.

Patients with a history of Gilbert's syndrome may be eligible provided total bilirubin is less than or equal to 1.5 x ULN and the AST, ALT, Alkaline phosphatase meet the criteria detailed.

3.134 Neurologic function: Neuropathy (sensory and motor) less than or equal to CTCAE grade 1.

3.14 Patients with GOG performance status of 0 or 1; ECOG performance status of 0 or,1; or KPS >= 80%.

3.15 Patients who have met the pre-entry requirements specified in Section 7.0.

3.16 Patients must have signed an approved informed consent.

3.17 Patients participating through U.S. sites must sign an approved and authorization permitting release of personal health information.

3.18 Patients must be a minimum of 18 years of age.

3.19 Patients should be free of active infection requiring antibiotics (with the exception of an uncomplicated UTI).

3.2 Ineligible Patients

3.21 Patients who have had prior therapy with docetaxel or gemcitabine or doxorubicin at any time in their history.

3.22 Patients with a history of other invasive malignancies, with the exception of non-melanoma skin cancer, are ineligible if there is any evidence of other malignancy being present within the last five years. Patients are also ineligible if their previous cancer treatment contraindicates this protocol therapy.

3.23 Patients with a history of severe hypersensitivity reaction to Taxotere® (docetaxel) or other drugs formulated with polysorbate 80.

3.24 Patients with GOG performance status of 2, 3 or 4; or ECOG performance status of 2, 3 or 4.

3.25 Patients who are breast-feeding.

3.26 Patients with a known history of congestive heart failure or cardiac ejection fraction < 50% (or less than institutional normal limits). ECHO or MUGA is not required prior to enrollment. For patients assigned to the chemotherapy arm, an ECHO or MUGA must have been done within 6 months of day 1 of gemcitabine-docetaxel treatment.

Patients who enroll on study and are randomized to Regimen I (chemotherapy) and then are found on baseline ECHO or MUGA to have cardiac ejection fraction <50% or below institutional normal will remain ON study. Such patients will receive gemcitabine + docetaxel for 4 cycles, as detailed in Section 5.2, but will NOT receive any doxorubicin treatment. They will continue treatment follow-up as outlined for all patients assigned to Regimen I. **(10/28/2013)**

3.27 Patients with a history of prior whole pelvic radiation.

3.28 Concurrent treatment with hormone replacement therapy is permitted at the discretion of the treating physician. Patients who have been taking hormonal/hormone blocking agents for breast cancer or breast cancer prevention or other indication are eligible. Use of anti-hormonal agents (tamoxifen, medroxyprogesterone, aromatase inhibitors) is permitted at the discretion of the treating physician. Documentation of concurrent medications is required.

3.29 Patients with recurrent uterine LMS.

3.210 Patients who are known to be HIV (human immunodeficiency virus) positive are not eligible due to the high risk for infectious complications of the myelosuppressive therapy used in the experimental arm of this study.

3.211 Patients with gross residual or metastatic tumor findings following complete surgical treatment for uterine LMS.