SODIUM STIBOGLUCONATE IRB 7059

Full Title
Phase I Evaluation of Sodium Stibogluconate in Combination with Interferon alpha-2b for Solid Tumors, Lymphoma, or Myeloma

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Eligibility
Inclusion

1. Histologically confirmed malignancy. Patients with malignancy potentially responsive to SSG and/or IFNs including, but not limited to renal cell carcinoma, melanoma, Kaposi's sarcoma; breast, prostate, colorectal and lung adenocarcinoma, bone and soft tissue sarcomas; lymphoma, myeloma, and tumors of neuroendocrine and endothelial cell origin. Clinical staging required to establish as AJCC Stage IV.
2. Patients must be refractory or resistant to established treatments or metastatic tumor settings for which no effective therapy has been established.
3. Stage IV Patients must have measurable or evaluable disease: Evaluable disease can include clinically or radiographically non-measurable tumor or specific tumor markers.
4. Patients with controlled CNS metastases may be entered. A CT or MRI must confirm stable brain metastases within 30 days of on-study. Patients with primary CNS malignancies refractory to other therapies are eligible.
5. Required initial laboratory data:
    - Granulocytes: > 1,500/µl
    - Platelets: > 100,000/µl
    - Creatinine: < 1.5 x ULN
    - Bilirubin: < 1.5 x ULN
    - AST: < 1.5 x ULN
    - ALT: < 1.5 x ULN
6. The patient must have adequate renal reserve as evidenced by a calculated creatinine clearance of $\geq$ 60 cc/min.
7. Prior IFN therapy is allowed if:
    - $\geq$ 4 months since IFN therapy
    - $\geq$ 3 weeks since major surgery
    - $\geq$ 3 weeks since prior radiation therapy or chemotherapy

8. Measurable or evaluable disease by RECIST criteria
9. Performance Status: ECOG 0-2
10. Must have a normal ejection fraction, $\geq$ 50%

Exclusions

1. Patients with a history of atrial fibrillation, flutter or other serious arrhythmia (excluding asymptomatic atrial and ventricular premature complexes), in the prior 24 months history of congestive heart failure currently requiring treatment, angina pectoris, or other severe cardiovascular disease, i.e. New York Heart Association Class III or IV.
2. Patients who have baseline ECG abnormalities suggestive of cardiac conduction delay, i.e., 1^{0} or greater atrio-ventricular block and/or complete or incomplete (QRS > 120 ms) bundle branch block, or patients who have baseline ECG abnormalities suggestive of repolarization abnormalities, i.e., QTc $\geq$ 0.48 sec, are not eligible for this study.
3. Patients with culture positive acute infections requiring antibiotics within the past 14 days. Patients on long term suppressive antibiotic therapies are eligible.
4. All female patients of childbearing potential or less than 1 year postmenopausal must have a negative beta-HCG pregnancy test at baseline and be practicing a medically acceptable method of birth control (oral contraceptives for at least 3 months, implantation of an intrauterine device at least 2 months, or barrier methods (e.g. vaginal diaphragm, vaginal sponge, or condom with spermicidal jelly). These must be continued for 3 months after study initiation.
5. Pregnant or lactating women, and fertile women or men unless surgically sterile or using effective contraception.
6. Use of daily glucocorticoids except for physiological replacement.
7. Patients who are known to be positive for $HB_{S}Ag$.
8. Patients with prior history of solid organ allografts or allogeneic bone marrow transplant.
9. Patients under the age of 18.
10. Patients judged to not be psychologically prepared to understand informed consent or compliance to an investigational study.
11. Patients taking the following medications will not be eligible:
    - Amiodarone (Cordarone)
    - Disopyramide (Norpace)

- Dofetilide (Tikosyn)
- Procainamide (Procanbid, Pronestyl)
- Quinidine (Quinaglute)
- Sotalol (Betapace)
- Erythromycin
- Azithromycin (Z-pack)
- Clarithromycin (Biaxin)
- Pentamidine (Pentacarinat)
- Trimethoprim-sulfamethoxazole (Bactrim)
- Bepridil (Vascor)
- Phenothiazines -- prochlorperazine (Compazine), promethazine (Phenergan), chlorpromazine (Thorazine) or any antipsychotic medication
- Butryophenones - Haloperidol (Haldol)
- Riperidone (Risperdal)
- Tricyclic or tetracyclic antidepressants - imipramine (Tofranil), amitriptyline (Elavil), desipramine (Norpramin), nortriptyline (Pamelor) **(Although tricyclic antidepressants have been associated with QT prolongation, a possible toxicity of stibogluconate, SSRI's have not)**
- Monoamine oxidase inhibitors
- High dose methodone
- Arsenic trioxide
- Dolasetron (Anzemet)
- Any herbal preparations

Note: A patient will be eligible if stopping any of the noted medications provided there has been a one week wash out period.