

Clinical trial protocol

Title

A Randomized, Double Blind Phase III Study To Evaluate Adjuvant cG250 Treatment Versus Placebo In Patients With Clear Cell RCC And High Risk For Recurrence (ARISER)

Criteria

- Ages Eligible for Study: 18 Years and above, Genders Eligible for Study: Both

DISEASE CHARACTERISTICS:

- Histologically confirmed primary clear cell renal cell carcinoma
 - Meets 1 of the following high risk criteria:
 - T3a, N0/NX, M0 OR T3b, N0/NX, M0 OR T3c, N0/NX, M0 OR T4, N0/NX, M0
 - Any T stage and N + disease and M0
 - T1b, N0/NX, M0 OR T2, N0/NX, M0, each with grade ≥ 3 (Fuhrman or any other nuclear grading system with at least 3 grades)
- Prior nephrectomy (total or partial) of primary renal cell carcinoma with documented clear cell histology within the past 12 weeks
 - No evidence of macroscopic or microscopic residual disease
 - Enlarged lymph nodes should be removed

PATIENT CHARACTERISTICS:

Age 18 and over

Performance status ECOG 0-1

Life expectancy Not specified

Hematopoietic

- Platelet count $> 100,000/\text{mm}^3$
- WBC $> 3,000/\text{mm}^3$
- Hemoglobin $> 10 \text{ g/dL}$

Hepatic

- AST and ALT < 3 times upper limit of normal (ULN)
- Bilirubin < 1.5 times ULN
- Hepatitis B surface antigen (HbsAg) negative
- Hepatitis C antibody negative

Other

- Not pregnant or nursing

- Negative pregnancy test
- Fertile patients must use effective contraception
- HIV I and II negative
- No concurrent unrelated illness which can significantly jeopardize patients' clinical status
- No active infection
- No inflammation
- No medical condition or laboratory abnormalities that would preclude study participation
- No other malignancies within the past 5 years except surgically cured nonmelanoma skin cancer or carcinoma in situ of the cervix

PRIOR CONCURRENT THERAPY:

Biologic therapy

- More than 5 years since prior immunotherapy
- No prior murine or chimeric antibody therapy

Chemotherapy

- More than 5 years since prior chemotherapy

Endocrine therapy

- No concurrent corticosteroids for another disease
 - Physiologic corticosteroid replacement therapy allowed at discretion of the primary investigator

Radiotherapy

- More than 5 years since prior radiotherapy

Surgery

- See Disease Characteristics
- No prior organ transplantation

Other

- No concurrent immunosuppressive agents (e.g., cyclosporine or tacrolimus)

Start of the study

December 2006

Expected number of patients

856

Trial phase

Phase III

Drug

monoclonal antibody G250

International multicenter study