

## CLINICAL TRIAL INFORMATION SUITABLE FOR POSTING ON WEB APPLICATIONS

**Protocol Number:** CBA-TP0301

**Official Title:** Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of CBT-1™ and Paclitaxel/Carboplatin in Patients with Inoperable Non-Small Cell Lung Cancer

**Brief Title:** CBT-1™ plus paclitaxel and carboplatin for NSCLC

**Study Sponsor:** CBA Research, Inc.

**Sponsor's Address:** 670 Perimeter Dr.  
Lexington, KY 40517

**Web Site of Sponsor:** <http://CBAPharma.com>

**Brief Summary (in lay language):** Paclitaxel and carboplatin are common chemotherapeutic drugs used to treat advanced stage (cancer that has spread) non-small cell lung cancer (NSCLC). However, tumors develop resistance to chemotherapeutic drugs. CBT-1™ is a new investigational drug that reduces tumor cell resistance to chemotherapy. This study seeks to determine if the combination of paclitaxel and carboplatin chemotherapy with the investigational drug CBT-1 is a more effective treatment than paclitaxel and carboplatin chemotherapy alone.

### **Detailed Description:**

#### *Objectives*

The primary objective of this study is to determine if CBT-1™ in combination with paclitaxel and carboplatin will increase the overall survival of patients with inoperable NSCLC.

Additional objectives include, determining the safety of CBT-1™ in combination with paclitaxel and carboplatin in the study population, and assessing the efficacy of CBT-1™ in combination with paclitaxel and carboplatin in improving overall tumor response, time-to-progression, progression-free survival, and quality of life.

#### *Study Design*

This is a double-blind (neither the physician nor the patient knows the treatment group), placebo-controlled, study in which, patients will be randomly assigned in a 1:1 ratio to one of two treatment groups, CBT-1™ or placebo. Both groups will receive identical paclitaxel/carboplatin chemotherapy.

Each cycle of therapy will consist of CBT-1™ 500 mg/m<sup>2</sup> or placebo split and delivered three times a day by oral injection for seven consecutive days with paclitaxel 135 mg/m<sup>2</sup> i.v. 3 hr infusion plus carboplatin AUC 6 mg/mL/min. i.v. given on day 6. Two cycles of treatment given as one week of treatment with two weeks off followed by another week

of treatment will be considered as one course of therapy. Patients who do not experience any grade 2 or higher toxicities after the first cycle of therapy will receive 175 mg/m<sup>2</sup> of paclitaxel during subsequent cycles. Patients will be assessed for tumor response 3-weeks after the completion of each course of therapy and a quality of life questionnaire after each cycle. Patients will continue to receive treatment as long as their disease does not progress for a total of 4 courses (8 cycles) of therapy and assessments. Thereafter, patients will be followed for disease progression and survival.

**Intervention Name:** CBT-1™ plus paclitaxel and carboplatin

**Study Phase:** Phase 3

**Study Status:** Recruiting

**Eligibility Criteria:**

*Patients must:*

Have a diagnosis of advanced inoperable NSCLC and adequate kidney and liver function and bone marrow reserve. If the patient is female and of child-bearing potential, she must agree to use an acceptable method of birth control.

*Patients must not:*

Be eligible for curative surgery or radiotherapy, have previously received taxanes, platinum, vinca alkaloids, anthracyclines, podophyllotoxins, or CBT-1, have a medical condition that would adversely affect their participation in the study, or be pregnant or nursing. In addition, patients cannot take omeprazole (Prilosec, Losec) or ranitidine hydrochloride (Zantac) while participating in the study as these reduce the effectiveness of CBT-1™.

**Gender:** Both

**Age Limits:** At least 18 years-of-age

**Expected Total Enrollment:** 400