Protocol Title: A Phase I/II Clinical Study Evaluating the Safety and Effectiveness of BIO 300 Oral Suspension in Patients Receiving Chemoradiation Therapy for Non-Small Cell Lung Cancer (NSCLC)

Target Population: Adults with Non-Small Cell Lung Cancer (NSCLC)

Summary: The purpose of this study is to determine the safety and effectiveness of BIO 300 Oral Suspension when used in combination with standard dose radiation therapy and chemotherapy in patients with NSCLC.

Key Inclusion Criteria:
- Histological or cytological confirmation of NSCLC.
- Stage II, III, or IV NSCLC for whom RT of 60Gy & concurrent weekly paclitaxel/carboplatin is recommended.
- ≤ 3 small (≤ 3 cm) lung oligometastases will be allowed and/or 1 oligometastasis at any other site in the body.
- ECOG Performance Score of 0-1.
- Forced Expiratory Volume at 1 Second (FEV1): Best value obtained pre- or post-bronchodilator mus must be ≥ 1.0 liters/second or > 50% predicted value.
- Adequate bone marrow reserve, hepatic reserve, and renal function.
- Female subjects of childbearing potential must be a negative pregnancy test and must agree to use effective method of contraception.

Key Exclusion Criteria:
- Weight loss greater than 10% in prior 4 weeks.
- Prior malignancy in which they received any thoracic radiotherapy unless the treating physician considers it unlikely to impact the clinical outcome of the patients.
- Patients with concurrent invasive malignancy other than non-melanoma skin cancer or cervical intraepithelial neoplasia unless the treating physician considers it unlikely to impact the clinical outcome of patient.
- An active infection or with a fever ≥ 38.5°C or poorly controlled intercurrent illnesses.
- Patients with a prior thoracotomy within 1 week of study registration.
- COPD exacerbation or other respiratory illness requiring hospitalization or precluding study therapy within 30 days before registration.
- Patients must not have had a clinically significant cardiac event within 6 months before entry; or the presence of any other uncontrolled cardiovascular conditions that, in the opinion of the investigator, increases the risk of ventricular arrhythmia.
- Patients with a history of arrhythmia or asymptomatic sustained ventricular tachycardia are not eligible.
- Patients with atrial fibrillation with well-controlled ventricular rate on medication, are eligible.
- Psychiatric conditions, social situations or substance abuse that precludes the ability of the subject to cooperate with the requirements of the trial and protocol therapy.
- Grade 2 or higher peripheral neuropathy.
- Known history of HIV/AIDS, Hepatitis B or C.
- Pregnancy or women of childbearing potential and men who are sexually active that do not agree to use forms of contraception, and women who are breastfeeding.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02567799