

ADVIGO 1018: Figitumumab (CP-751,871) (an IGF-1R inhibitor) plus Erlotinib vs. Erlotinib in Refractory Advanced Non-adenocarcinoma Non-Small Cell Lung Cancer (NSCLC)

<p>INTRODUCTION</p>	<ul style="list-style-type: none"> • Non-small cell lung cancer (NSCLC) is a difficult disease to treat, particularly in the metastatic setting. In these patients the five-year survival rate is only two percent.¹ Despite decades of research and testing of numerous chemotherapy regimens, the prognosis for most patients with metastatic NSCLC remains poor. • Figitumumab is a selective fully human monoclonal antibody against the insulin-like growth factor-1 receptor (IGF-1R) pathway. It is believed that through this inhibition, figitumumab may block one of the key signaling pathways in cancer cells that leads to uncontrolled growth and survival of tumor cells. • The Insulin-like Growth Factor (IGF) pathway is a fundamental mechanism of cell survival. Activation of this pathway, by the binding of the growth factor IGF-1 to the receptor IGF-1R, triggers a complex signaling cascade that stimulates cell growth, proliferation, differentiation and drives survival. • IGF-1R is increasingly recognized by the medical community as a relevant target for investigation in cancer research. Several other companies are pursuing this target with either monoclonal antibody or tyrosine kinase inhibitors. Figitumumab is the first IGF-1R compound to initiate a Phase III clinical trial. To date, more than 1,000 patients have participated in figitumumab clinical trials in multiple tumor types.
<p>RATIONALE</p>	<ul style="list-style-type: none"> • Based on the results of a Phase II study, Pfizer has initiated a Phase III clinical trial program for figitumumab in NSCLC, a disease with a significant unmet medical need.
<p>OBJECTIVES</p>	<ul style="list-style-type: none"> • Primary: <ul style="list-style-type: none"> ○ Determine whether the addition of figitumumab in combination with erlotinib, an epidermal growth factor receptor (EGFR) inhibitor, prolongs survival (overall survival) in patients with locally advanced (Stage IIIB with pleural effusion) or metastatic (Stage IV or recurrent) NSCLC of non-adenocarcinoma histology versus erlotinib alone. • Secondary: <ul style="list-style-type: none"> ○ Assess progression-free survival (PFS) in each arm ○ Evaluate the safety and tolerability of figitumumab in combination with erlotinib ○ Assess the overall response rate (ORR) in each arm ○ Assess health status (EQ-5D) in both treatment arms
<p>STUDY DESIGN</p>	<ul style="list-style-type: none"> • Phase III, open-label, randomized (1:1), two-arm study <ul style="list-style-type: none"> ○ Arm A: Patients will receive figitumumab by intravenous infusion on Cycle 1 Days 1 and 2 (loading dose for Cycle 1 only), and every three weeks (from Cycle 1 Day 1) thereafter, in combination with erlotinib by mouth daily for up to one year. ○ Arm B: Patients will receive erlotinib by mouth daily for up to one year.
<p>SELECTED ELIGIBILITY CRITERIA</p>	<ul style="list-style-type: none"> • Selected Inclusion Criteria <ul style="list-style-type: none"> ○ Histologically/cytologically confirmed squamous, large-cell, or adenosquamous carcinoma with metastases (stage IV or recurrent disease), or locally advanced (stage IIIB) with malignant pleural effusion ○ Previous treatment for advanced disease consisting of ≥ 1 platinum-based combination regimen(s); patients aged ≥ 70 years may have received ≥ 1

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	<ul style="list-style-type: none"> ○ single-agent therapy ○ EGOG performance status score 0, 1 or 2 ○ Enrollment ≥ 2 weeks since last systemic therapy or ≥ 1 week since last radiotherapy ○ At least 1 measurable lesion as defined by Response Evaluation Criteria in Solid Tumor (RECIST) • Selected Exclusion Criteria <ul style="list-style-type: none"> ○ Primary adenocarcinoma NSCLC and its subtypes: acinar, papillary, bronchioalveolar, solid, fetal, mucinous, signet ring, clear cell, or mixed histologies of these types ○ Prior erlotinib or IGF-1R-based therapy ○ Symptomatic brain metastases ○ Major surgery ≤ 3 weeks prior to study enrollment ○ Uncontrolled diabetes (HbA1c > 8 percent), hypertension, unstable angina, deep venous thrombosis, pulmonary embolism, cerebrovascular attack, valvular disease, congestive heart failure, myocardial infarction within the previous 6 months, or serious cardiac arrhythmias
NUMBER OF PATIENTS	<ul style="list-style-type: none"> • An estimated 600 patients will be enrolled from approximately 60 research sites in the United States and 110 ex-U.S. sites.
PATIENT ENROLLMENT INFORMATION	<p>For more information, contact the Pfizer Oncology Clinical Trial Information Services.</p> <ul style="list-style-type: none"> • Physicians interested in participating or referring a patient: www.pfizeroncology.com/clinicaltrials Please call toll-free (US) 1-800-528-6628 Outside the US: + 1-646-307-8070 E-mail: PfizerHPTrials@emergingmed.com • Patients interested in participating: www.pfizercancertrials.com Please call toll-free (US): 1-877-369-9753 Outside the US: +1-646-277-4066 E-mail: PfizerCancerTrials@emergingmed.com

¹ American Cancer Society. How is Non-Small Cell Lung Cancer Staged? Available at www.cancer.org. Accessed April 8, 2008.