

Crizotinib is being studied in clinical trials across multiple tumor types. Crizotinib is not approved in combination with other therapies, as a treatment for CNS tumors, anaplastic large cell lymphoma, or for use in children. Below are Pfizer-sponsored trials that are currently open and/or enrolling, as well as an independent study that is not sponsored by Pfizer, but for which Pfizer provides some support.

<p>NON-SMALL CELL LUNG CANCER (NSCLC)</p>	<p>Phase 3</p> <ul style="list-style-type: none"> • PROFILE 1014: Phase 3, Randomized, Open-Label Study Of The Efficacy And Safety Of Crizotinib Versus Pemetrexed/Cisplatin Or Pemetrexed/Carboplatin In Previously Untreated Patients With Non-squamous Carcinoma Of The Lung Harboring A Translocation Or Inversion Event Involving The Anaplastic Lymphoma Kinase (ALK) Gene Locus¹ <ul style="list-style-type: none"> ○ Primary objective: Progression free survival (PFS) versus Pemetrexed Plus Cisplatin Or Carboplatin ○ Number of patients: An estimated 334 patients will be enrolled in research sites in the United States (U.S.) and ex-U.S. • Phase 3, Randomized, Open-label, Efficacy and Safety Study Of Crizotinib Single Agent Versus Chemotherapy Regimens (Pemetrexed/Cisplatin Or Pemetrexed/Carboplatin) In First-Line Anaplastic Lymphoma Kinase (ALK) Positive East Asian Non-Small Cell Lung Cancer Patients² <ul style="list-style-type: none"> ○ Primary objective: PFS versus Pemetrexed/Cisplatin or Pemetrexed/Carboplatin ○ Number of patients: An estimated 200 patients will be enrolled from research sites across Asia <p>Phase 2</p> <ul style="list-style-type: none"> • PROFILE 1005: Phase 2, Open-Label Single Arm Study Of The Efficacy And Safety Of Crizotinib In Patients With NSCLC Harboring A Translocation Or Inversion Event Involving The Anaplastic Lymphoma Kinase (ALK) Gene³ <ul style="list-style-type: none"> ○ Primary objectives: Objective response rate (ORR); and the type, incidence, severity, seriousness and relationship to crizotinib of adverse events and laboratory test abnormalities ○ Number of patients: The study is ongoing with approximately 1,100 patients from research sites in the U.S. and ex-U.S. <p>Phase 1</p> <ul style="list-style-type: none"> • STUDY 1002: Phase 1/2, Open-Label, Randomized Study Of The Safety, Efficacy, And Pharmacokinetics Of Erlotinib With Or Without Crizotinib In Patients With Advanced Non-Small Cell Adenocarcinoma Of The Lung⁴ <ul style="list-style-type: none"> ○ Primary objectives: Phase 1: Determine the maximum tolerated dose (MTD) and recommended Phase 2 dose for crizotinib in combination with erlotinib; and Phase 2: PFS of single agent erlotinib vs erlotinib plus crizotinib ○ Number of patients: The study planned to enroll an estimated 175 patients from research sites in the United States. The study is fully accrued and enrollment is closed • STUDY 1006: A Phase 1, Open Label, Dose Escalation Study To Evaluate Safety, Pharmacokinetics And Pharmacodynamics Of Combined Oral C- MET/ALK Inhibitor Crizotinib And PAN-HER Inhibitor
--	---

<p>NON-SMALL CELL LUNG CANCER (NSCLC) (continued)</p>	<p>(PF-00299804) In Patients With Advanced NSCLC⁵</p> <ul style="list-style-type: none"> ○ Primary objective: To define the recommended Phase 2 dose of combined crizotinib plus PF-00299804 in patients with advanced NSCLC ○ Number of patients: An estimated 70 patients will be enrolled from research sites in the United States and ex-U.S.
<p>PEDIATRIC PATIENTS WITH RELAPSED OR REFRACTORY SOLID TUMORS OR ANAPLASTIC LARGE CELL LYMPHOMA (ALCL)</p>	<p>Phase 1/2</p> <ul style="list-style-type: none"> ● ADVL0912*: A Phase I/II Study of Crizotinib, an Oral Small Molecule Inhibitor of Anaplastic Lymphoma Kinase (ALK) and c-Met, in Children With Relapsed/Refractory Solid Tumors, Primary CNS Tumors, and Anaplastic Large Cell Lymphoma⁶ <ul style="list-style-type: none"> ○ Primary objectives: Maximum tolerated dose and recommended Phase 2 dose of crizotinib; toxicities of crizotinib; and pharmacokinetics of crizotinib ○ Number of patients: An estimated 196 patients will be enrolled from research sites in the U.S. and Canada
<p>ALK-POSITIVE TUMORS EXCEPT NSCLC</p>	<p>Phase 1</p> <ul style="list-style-type: none"> ● PROFILE 1013: Phase 1B Open-Label Study Of The Safety And Clinical Activity Of Crizotinib In Tumors With Genetic Events Involving The Anaplastic Lymphoma (ALK) Gene Locus⁷ <ul style="list-style-type: none"> ○ Primary objectives: Type, incidence, severity, seriousness and relationship to crizotinib of adverse events and any laboratory abnormalities; and ORR in patients with ALK-positive tumors except NSCLC, including lymphoma and neuroblastoma ○ Number of patients: An estimated 40 patients will be enrolled from research sites in the U.S. and ex-U.S.
<p>ADVANCED CANCER</p>	<p>Phase 1</p> <ul style="list-style-type: none"> ● STUDY 1001: Phase 1 Safety, Pharmacokinetic And Pharmacodynamic Study Of Crizotinib, A c-Met/HGFR Selective Tyrosine Kinase Inhibitor, Administered Orally To Patients With Advanced Cancer⁸ <ul style="list-style-type: none"> ○ Primary objective: To assess the safety of crizotinib and MTD in NSCLC and non-NSCLC patients ○ There are also subsets of the Phase 1 study evaluating crizotinib in patients with MET or ROS-1 positive advanced NSCLC

*This is an independent study that is sponsored by the Children's Oncology Group. While not sponsored by Pfizer, Pfizer does provide some support for the ADVL0912 trial.

For more information about crizotinib trials currently open and enrolling, please visit www.clinicaltrials.gov, www.pfizeroncology.com or call Pfizer Oncology's toll-free number at 1-877.369.9753 (U.S.).

-
- ¹ ClinicalTrials.gov. A Clinical Trial Testing The Efficacy Of Crizotinib Versus Standard Chemotherapy Pemetrexed Plus Cisplatin Or Carboplatin In Patients With ALK Positive Non Squamous Cancer Of The Lung (PROFILE 1014). Available at: <http://clinicaltrials.gov/ct2/show/NCT01154140?term=1014&rank=1>. Accessed April 22, 2013.
- ² ClinicalTrials.gov. A Study Of Crizotinib Versus Chemotherapy In Previously Untreated ALK Positive East Asian Non-Small Cell Lung Cancer Patients. Available at: <http://www.clinicaltrials.gov/ct2/show/NCT01639001?term=crizotinib&phase=2&rank=1>. Accessed on May 9, 2013.
- ³ ClinicalTrials.gov. An Investigational Drug, PF-02341066, Is Being Studied In Patients With Advanced Non-Small Cell Lung Cancer With A Specific Gene Profile Involving The Anaplastic Lymphoma Kinase (ALK) Gene. Available at: <http://clinicaltrials.gov/ct2/show/NCT00932451?term=crizotinib+AND+Anaplastic+Lymphoma+Kinase&rank=5>. Accessed April 22, 2013.
- ⁴ Clinicaltrials.gov. Erlotinib Is Being Studied With Or Without An Investigational Drug, PF-02341066, In Patients With Lung Cancer. Available at: <http://clinicaltrials.gov/ct2/show/NCT00965731?term=erlotinib+AND+crizotinib&rank=1>. Accessed April 22, 2013.
- ⁵ ClinicalTrials.gov. A Study Of Combined C- MET Inhibitor And PAN-HER Inhibitor (PF-02341066 And PF-00299804) In Patients With Non- Small Cell Lung Cancer. Available at: <http://clinicaltrials.gov/ct2/show/NCT01121575?term=crizotinib&rank=14>. Accessed April 22, 2013.
- ⁶ Clinicaltrials.gov. PF-02341066 in Treating Young Patients with Relapsed or Refractory Solid Tumors or Anaplastic Large Cell Lymphoma. Available at: <http://www.clinicaltrials.gov/ct2/show/study/NCT00939770?term=crizotinib+ADVL0912&rank=1#locn>. Accessed April 22, 2013.
- ⁷ ClinicalTrials.gov. An Investigational Drug, Crizotinib (PF-02341066), Is Being Studied In Tumors, Except Non-Small Cell Lung Cancer, That Are Positive For Anaplastic Lymphoma Kinase (ALK). Available at: <http://clinicaltrials.gov/ct2/show/NCT01121588?term=A8081013&rank=1>. Accessed April 22, 2013.
- ⁸ Clinicaltrials.gov. A Study Of Oral PF-02341066, A c-Met/Hepatocyte Growth Factor Tyrosine Kinase Inhibitor, In Patients With Advanced Cancer. Available at: <http://clinicaltrials.gov/ct2/show/NCT00585195>. Accessed April 22, 2013.