

Clinical trials of ALK inhibitors for lung cancer (metastatic) in ALK positive patients

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1 ALK inhibitors

Trial	Treatments	Patients	Trials design and methods
alectinib vs chemotherapy			
ALUR , 2018 [NCT02604342] n=NA follow-up:	oral alectinib at a dose of 600 milligrams (mg) twice daily versus chemotherapy with either pemetrexed (500 milligrams per square meter [mg/m ²] <i>of body surface area</i>) or docetaxel (75mg/m ²) intravenously.	ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) Participants Previously Treated With Platinum-Based Chemotherapy and Crizotinib	Parallel groups
ceritinib vs chemotherapy			
ASCEND-4 , 2017 [NCT01828099] n=189/187 follow-up:	oral ceritinib 750 mg/day versus platinum-based chemotherapy ([cisplatin 75 mg/m ² or carboplatin AUC 5-6 plus pemetrexed 500 mg/m ²] every 3 weeks for four cycles followed by maintenance pemetrexed	untreated patients with stage IIIB/IV ALK-rearranged non-squamous NSCLC	open-label
crizotinib vs chemotherapy			
Shaw , 2013 [NCT00932893] n=NA follow-up:	crizotinib (250 mg) twice daily versus intravenous chemotherapy with either pemetrexed (500 mg per square meter of body-surface area) or docetaxel (75 mg per square meter) every 3 weeks	patients with locally advanced or metastatic ALK-positive lung cancer who had received one prior platinum-based regimen	Parallel groups open-label
PROFILE 1014 , 2014 [NCT01154140] n=172/171 follow-up: 16.7 months	oral crizotinib, at a dose of 250 mg twice daily versus Standard Chemotherapy Pemetrexed Plus Cisplatin Or Carboplatin	patients with advanced ALK-positive nonsquamous NSCLC who had received no previous systemic treatment for advanced disease	open-label
A8081029 ongoing [NCT01639001] n=NA follow-up:	Crizotinib versus Chemotherapy	Previously Untreated ALK Positive East Asian Non-Small Cell Lung Cancer Patients	China
alectinib vs crizotinib			
ALEX , 2017 [NCT02075840] n=152/151 follow-up:	alectinib 600 mg orally (four 150 mg capsules) BID versus Crizotinib	patients with stage IIIB or IV, ALK-positive NSCLC who had not received prior systemic therapy	Parallel groups open label USA

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Trial	Treatments	Patients	Trials design and methods
J-ALEX <i>ongoing</i> [JapicCTI-132316] n=NA follow-up:	-	-	
YO29449 <i>ongoing</i> [NCT02838420] n=NA follow-up:	alectinib capsules orally at a dose of 600 mg BID versus crizotinib capsules orally at a dose of 250 mg BID	asian participants with treatment-naive ALK-positive advanced NSCLC	China
brigatinib vs crizotinib			
ALTA-1L <i>ongoing</i> [NCT02737501] n=NA follow-up:	Brigatinib 90 mg QD for 7 days, then 180 mg QD, continuously versus Crizotinib 250 mg orally BID	ALK-positive Advanced Lung Cancer Patients	USA
ensartinib vs crizotinib			
X396-CLI-301 <i>ongoing</i> [NCT02767804] n=NA follow-up:	ensartinib 225mg QD versus oral crizotinib at 250mg BID	patients with ALK-positive non-small cell lung cancer that have received up to 1 prior chemotherapy regimen and no prior ALK inhibitor	USA
lorlatinib vs crizotinib			
B7461006 <i>ongoing</i> [NCT03052608] n=NA follow-up:	Lorlatinib single agent, 100 mg (4 x 25 mg) oral tables, QD, continuously versus Crizotinib single agent, 250 mg (1 x 250) oral capsules, BID, continuously	advanced ALK-positive NSCLC patients who are treatment nave	
ceritinib vs pemetrexed or docetaxel			
ASCEND 5 , 2017 [NCT01828112] n=NA follow-up:	Oral LDK378 750 mg once daily versus pemetrexed or docetaxel	patients previously treated with chemotherapy (platinum doublet) and crizotinib	USA
crizotinib vs placebo			
E4512 <i>ongoing</i> [NCT02201992] n=NA follow-up:	-	Patients With Stage IB-IIIA Non-small Cell Lung Cancer That Has Been Removed by Surgery and ALK Fusion Mutations	double-blind
alectinib vs premetrexed or docetaxel			
MO29750 <i>ongoing</i> [NCT02604342] n=NA follow-up:	oral alectinib at a dosage of 600 mg BID versus either pemetrexed (500 mg per square meter of body-surface area) or docetaxel (75 mg per square meter)	participants with ALK-positive advanced NSCLC who were previously treated with chemotherapy and crizotinib	Belgium

References

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ASCEND-4, 2017:

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Shaw, 2013:

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PROFILE 1014, 2014:

Solomon BJ, Mok T, Kim DW, Wu YL, Nakagawa K, Mekhail T, Felip E, Cappuzzo F, Paolini J, Usari T, Iyer S, Reisman A, Wilner KD, Tursi J, Blackhall F First-line crizotinib versus chemotherapy in ALK-positive lung cancer. *N Engl J Med* 2014;371:2167-77 [25470694]

Solomon BJ, Kim DW, Wu YL, Nakagawa K, Mekhail T, Felip E, Cappuzzo F, Paolini J, Usari T, Tang Y, Wilner KD, Blackhall F, Mok TS Final Overall Survival Analysis From a Study Comparing First-Line Crizotinib With Chemotherapy: Results From PROFILE 1014. *J Clin Oncol* 2018;:JCO2017774794 [29768118]

A8081029, 0:

ALEX, 2017:

Peters S, Camidge DR, Shaw AT, Gadgeel S, Ahn JS, Kim DW, Ou SI, Prol M, Dziadziuszko R, Rosell R, Zeaiter A, Mitry E, Golding S, Balas B, Noe J, Morcos PN, Mok T Alectinib versus Crizotinib in Untreated ALK-Positive Non-Small-Cell Lung Cancer. *N Engl J Med* 2017 Aug 31;377:829-838 [28586279] [10.1056/NEJMoa1704795](https://doi.org/10.1056/NEJMoa1704795)

J-ALEX, :

YO29449, 0:

ALTA-1L, 0:

X396-CLI-301, 0:

B7461006, 0:

ASCEND 5, 2017:

Shaw AT Ceritinib versus chemotherapy in patients with ALK-rearranged non-small-cell lung cancer previously given chemotherapy and crizotinib (ASCEND-5): a randomised, controlled, open-label, phase 3 trial. *Lancet Oncol* 2017;18:874-886 [28602779] [10.1016/S1470-2045\(17\)30339-X](https://doi.org/10.1016/S1470-2045(17)30339-X)

E4512, 0:

MO29750, 0:

2 About TrialResults-center.org

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