

Marketed ALK Inhibitor – Xalkori (crizotinib)



LEERINK SWANN

Drug	Xalkori (crizotinib)
Structure	Amynopyridine
Mechanism of Action	Dual MET/ALK inhibitor
Indication	Locally advanced or metastatic ALK positive NSCLC with a companion diagnostic from ABT
Companion Diagnostic	Vysis ALK Break Apart FISH Probe Kit from Abbott - to detect chromosomal rearrangement of ALK
Note	EML4-ALK fusion occurs in 3-5% NSCLC pts, i.e. ~10k pts
Approval base on	2 single-arm studies 1) PROFILE (136 pts) - a Phase 2 study 2) Study 1001 (119 pts) - a part 2 expansion cohort of a Phase 1 study
Primary Endpoint	ORR based on investigators' assessment
Data	1) PROFILE - 50% with 41.9 wk median duration 2) Study 1001 - 61% with 48.1 wk median duration
Dosing	Oral 250mg twice daily
Pricing	\$115K
Future Development	Confirmatory, randomized, open-label Phase 3 trials 1) PROFILE 1007 - compare with SOC (P or D) in <u>previously treated</u> ALK positive NSCLC pts 2) PROFILE 1014 - compare with SOC (P/Cis or Carb) in <u>previously untreated</u> ALK positive NSCLC