

FDA Approvals in Lung Cancer in 2021

Compiled by Eugene Manley, Jr., PhD, Director, Scientific Programs



Date	Brand name	Generic name	Vendor	Indication	Target	Trial	FDA
2/3/2021	Tepmetko®	Tepotinib	Merck KGaA/ EMD Serono	mNSCLC, orally	MET Ex 14 skipping	Phase 2 VISION	link
2/22/2021	Libtayo®	Cemiplimab- rwlc	Regeneron and Sanofi	Advanced NSCLC (locally advanced who are not resection candidates or definitive chemoradiation or metastatic), i.v. mAB	high PD-L1 expression with no EGFR, ALK, or ROS1 aberrations	Phase 3 EMPOWER-Lung 1	link
3/3/2021	Lorbrena®	Lorlatinib	Pfizer	mNSCLC who had not received prior systemic therapy for metastatic disease, orally	ALK	Phase 3 Study B7461006	link
	Ventana ALK (D5F3) CDx Assay	n/a	Ventana Medical Systems	Companion diagnostic for Lorlatinib			
5/21/2021	Rybrevant®	Amivantamab -vmjw	Janssen Biotech	Locally advanced or mNSCLC that progressed on or after platinum-based therapy, bispecific EGFR and MET ab given i.v.	EGFR ex 20 insertion mutations	Phase 2 CHRYSALIS	link
	Guardant360® CDx	n/a	Guardant Health, Inc.	Companion diagnostic for amivantamab-vmjw			
5/28/2021	Lumakras®	Sotorasib	Amgen	Locally advanced or mNSCLC patients that have received at least one prior systemic therapy	KRAS G12C	Phase 2 CodeBreak 100	link
	therascreen® KRAS RGQ PCR kit (tissue)	n/a	QIAgen	Companion RT PCR diagnostic for KRAS			
	Guardant360® CDx (plasma)	n/a	Guardant Health, Inc.	Companion diagnostic liquid biopsy			
9/15/2021	Exkivity®	Mobocertinib	Takeda	Locally advanced or mNSCLC, progression on or after platinum-based chemo, orally	EGFR ex20 insertion	Phase 1/2 Study 101	link
	Oncomine Dx Target Test	n/a	Life Technologies Corporation	Companion diagnostic device to select patients for EGFR ex 20			
10/15/2021	Tecentriq®	Atezolizumab	Genentech, Inc.	Adjuvant treatment following resection and platinum-based chemo in patients with Stage II to IIIA NSCLC	PD-L1 >1% on tumor cells	Phase 3 IMpower010	link
	Ventana PD-L1- (SP263 Assay)	n/a	Ventana Medical Systems	Companion diagnostic to select patients for adjuvant Tecentriq			