



Nuove classi di farmaci

Terapie standard in continua evoluzione

Studi clinici interventistici IIT e sponsorizzati

Disponibilità ad uso nominale

HUMANITAS
GAVAZZENI



Ordine dei Medici Chirurghi
e Odontoiatri
della provincia di Bergamo

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Disponibilità ad uso nominale

Spesore	Conto/Spesore	Spesore
01/00000	01/00000/001	01/00000
02/00000	02/00000/001	02/00000
03/00000	03/00000/001	03/00000
04/00000	04/00000/001	04/00000
05/00000	05/00000/001	05/00000
06/00000	06/00000/001	06/00000
07/00000	07/00000/001	07/00000
08/00000	08/00000/001	08/00000
09/00000	09/00000/001	09/00000
10/00000	10/00000/001	10/00000

- Ricercatori clinici
- Servizi diagnostici dedicati



- Direzione scientifica e comitato scientifico
- Clinical trial office



- Struttura dedicata alla ricerca clinica
- Infermieri di ricerca

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Tumori rari

Nuove classi di farmaci

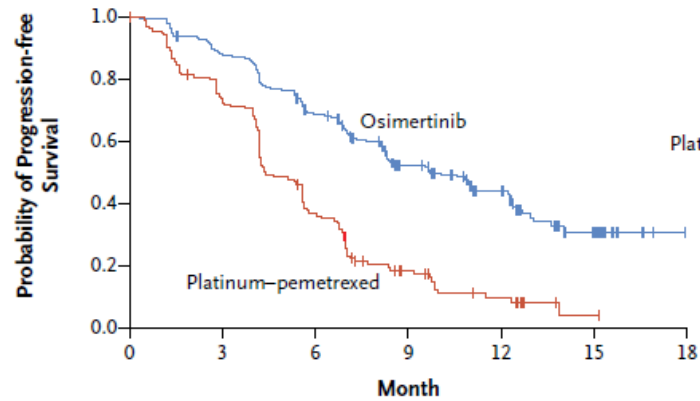


International Breast Cancer Study Group

Osimertinib or Platinum–Pemetrexed in EGFR T790M–Positive Lung Cancer

T.S. Mok, Y.-L. Wu, M.-J. Ahn, M.C. Garassino, H.R. Kim, S.S. Ramalingam, F.A. Shepherd, Y. He, H. Akamatsu, W.S.M.E. Theelen, C.K. Lee, M. Sebastian, A. Templeton, H. Mann, M. Marotti, S. Ghiorghiu, and V.A. Papadimitrakopoulou, for the AURA3 Investigators*

A Patients in Intention-to-Treat Population



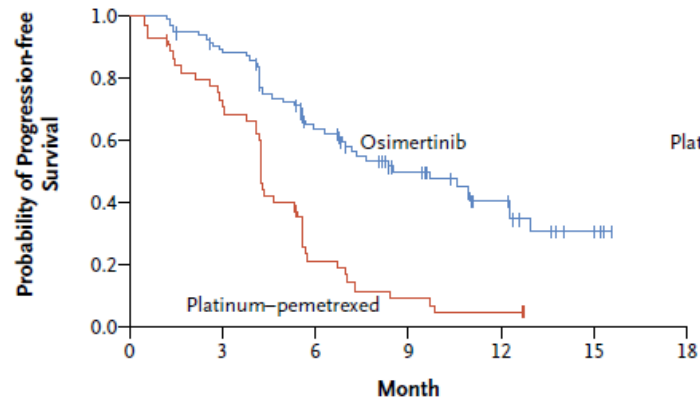
	No. of Patients	Median Progression-free Survival mo (95% CI)
Osimertinib	279	10.1 (8.3–12.3)
Platinum-pemetrexed	140	4.4 (4.2–5.6)

Hazard ratio for disease progression or death, 0.30 (95% CI, 0.23–0.41)
P<0.001

No. at Risk

Osimertinib	279	240	162	88	50	13	0
Platinum-pemetrexed	140	93	44	17	7	1	0

B Patients with CNS Metastases

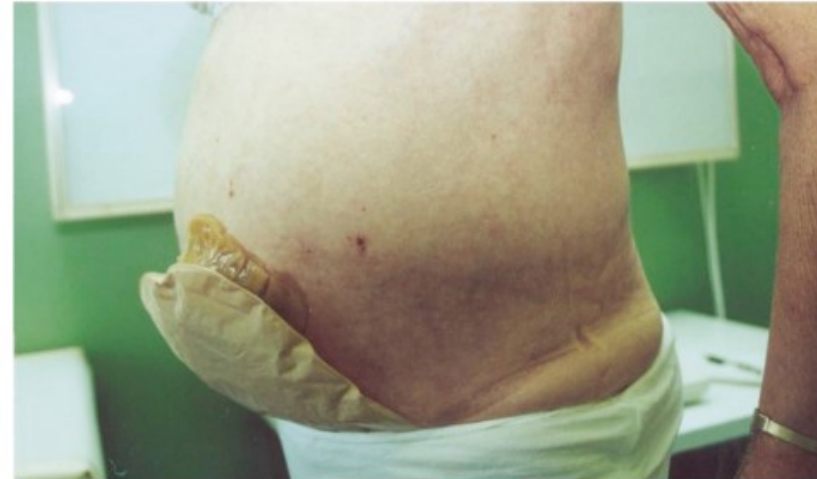
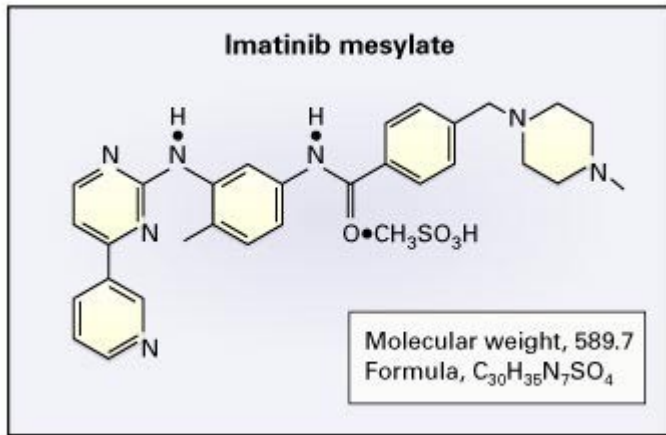


	No. of Patients	Median Progression-free Survival mo (95% CI)
Osimertinib	93	8.5 (6.8–12.3)
Platinum-pemetrexed	51	4.2 (4.1–5.4)

Hazard ratio for disease progression or death, 0.32 (95% CI, 0.21–0.49)

No. at Risk

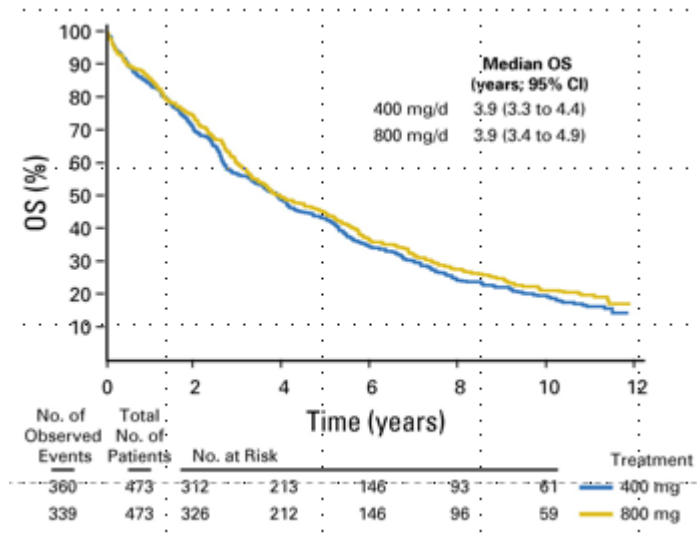
Osimertinib	93	80	46	27	14	4	0
Platinum-pemetrexed	51	32	9	4	2	0	0



September 14, 2000



September 27, 2000



Avapritinib in advanced PDGFRA D842V-mutant gastrointestinal stromal tumour (NAVIGATOR): a multicentre, open-label, phase 1 trial



Michael C Heinrich*, Robin L Jones*, Margaret von Mehren*, Patrick Schöffski, César Serrano, Yoon-Koo Kang, Philippe A Cassier, Olivier Mir, Ferry Eskens, William D Tap, Piotr Rutkowski, Sant P Chawla, Jonathan Trent, Meera Tugnait, Erica K Evans, Tamiaka Lauz, Teresa Zhou, Maria Roche, Beni B Wolf, Sebastian Bauer*, Suzanne George*

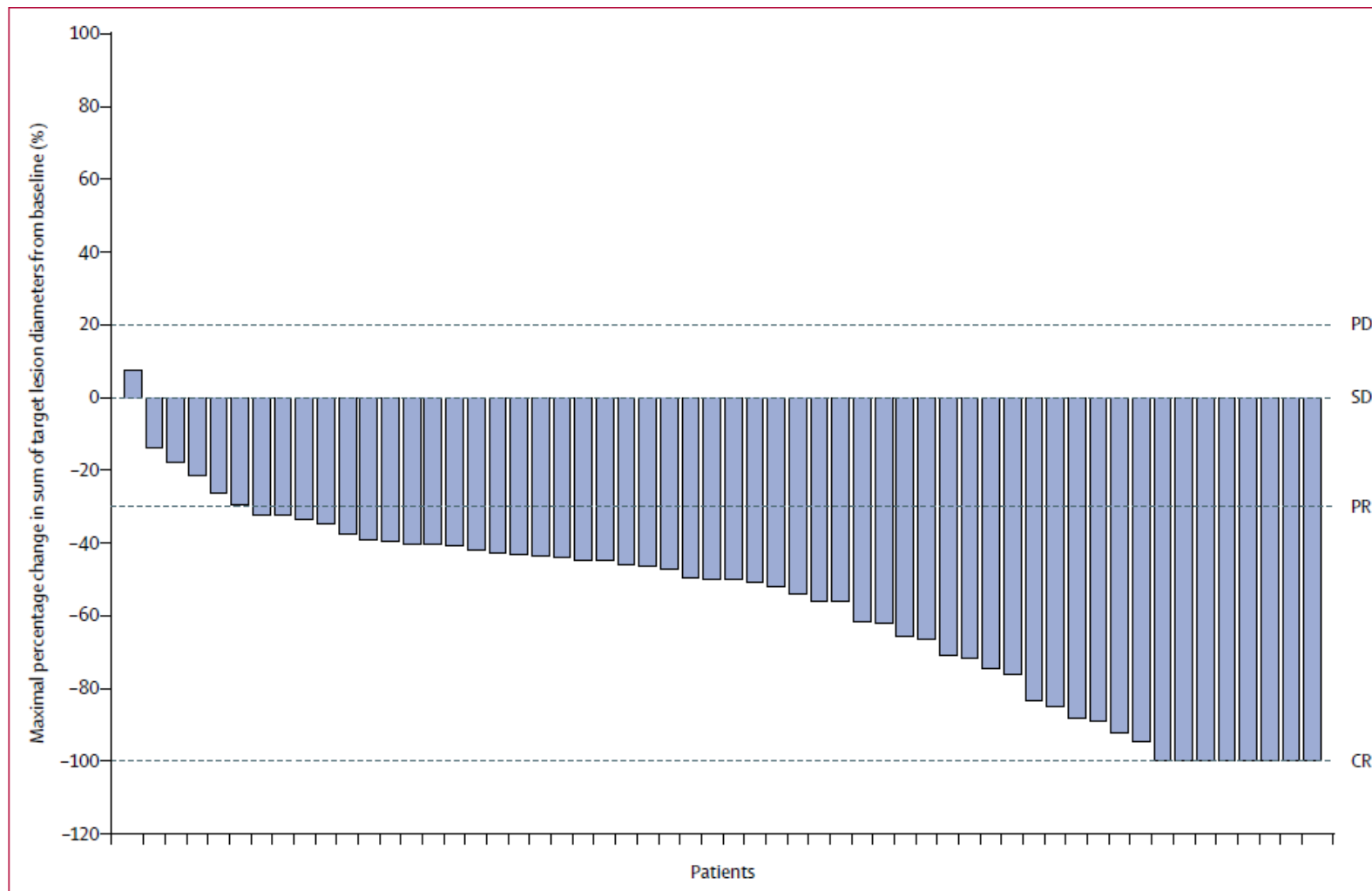
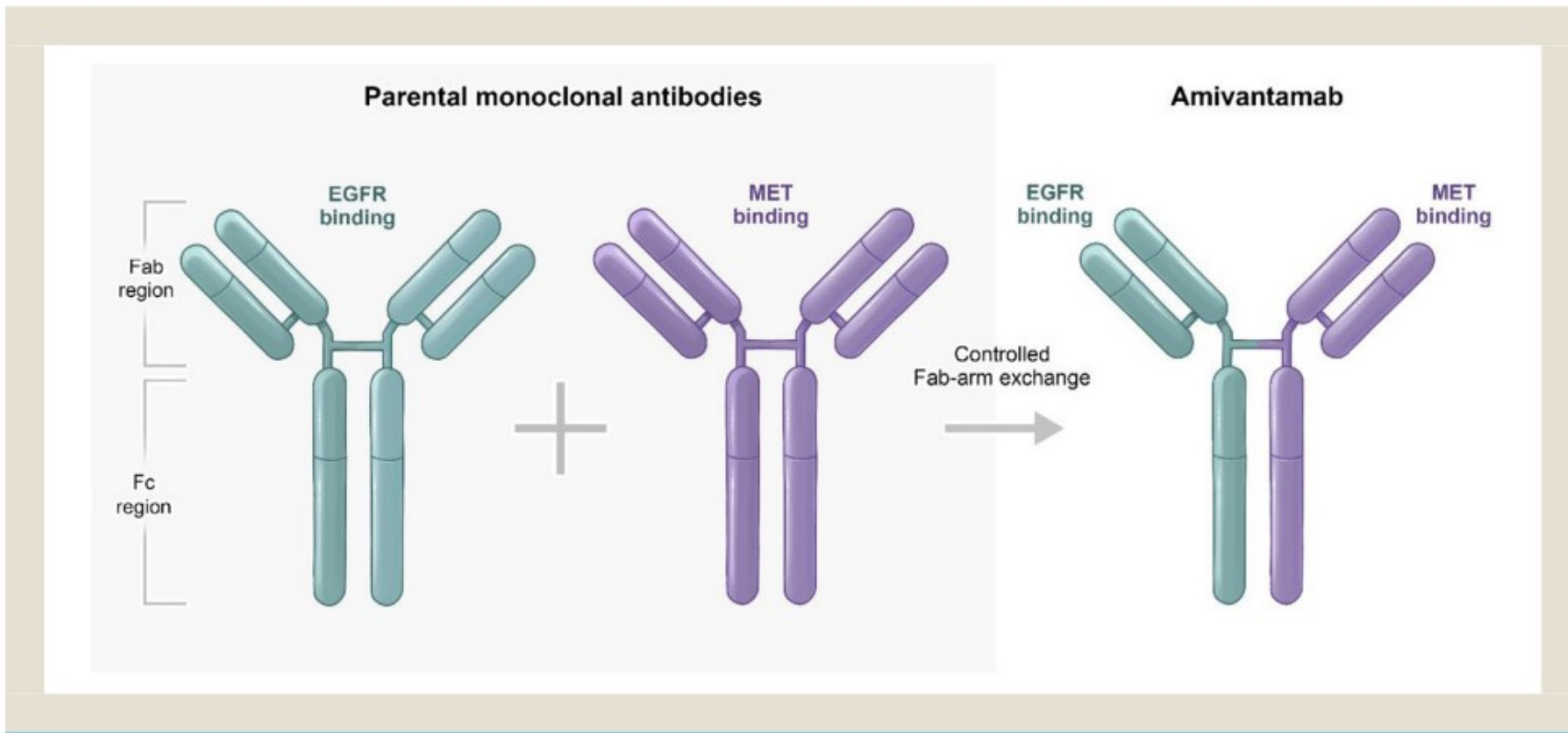


Figure 1 Engineered Fc mutations within EGFR and MET antibodies lead to bispecific amivantamab formation following controlled Fab-arm exchange process. EGFR = epidermal growth factor receptor; Fab = antigen-binding fragment; Fc = crystallizable fragment; MET = mesenchymal-epithelial transition factor

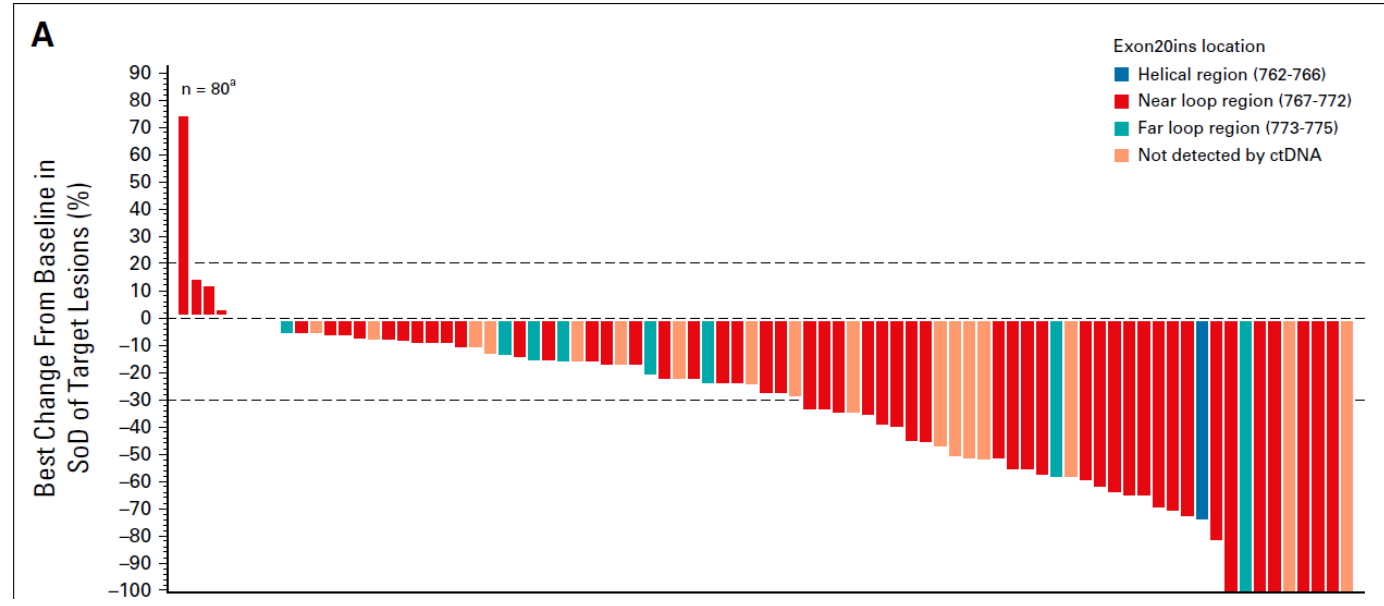


B. Chul Cho et al Clin Lung Cancer 2023

Amivantamab in EGFR Exon 20 Insertion–Mutated Non–Small-Cell Lung Cancer Progressing on Platinum Chemotherapy: Initial Results From the CHRYSALIS Phase I Study



Keunchil Park, MD, PhD¹; Eric B. Haura, MD²; Natasha B. Leighl, MD³; Paul Mitchell, MD⁴; Catherine A. Shu, MD⁵; Nicolas Girard, MD, PhD⁶; Santiago Viteri, MD⁷; Ji-Youn Han, MD, PhD⁸; Sang-We Kim, MD, PhD⁹; Chee Khoo Lee, MD¹⁰; Joshua K. Sabari, MD¹¹; Alexander I. Spira, MD, PhD¹²; Tsung-Ying Yang, MD, PhD¹³; Dong-Wan Kim, MD, PhD¹⁴; Ki Hyeong Lee, MD, PhD¹⁵; Rachel E. Sanborn, MD¹⁶; José Trigo, MD¹⁷; Koichi Goto, MD, PhD¹⁸; Jong-Seok Lee, MD, PhD¹⁹; James Chih-Hsin Yang, MD, PhD²⁰; Ramaswamy Govindan, MD²¹; Joshua M. Bauml, MD²²; Pilar Garrido, MD, PhD²³; Matthew G. Krebs, MD, PhD²⁴; Karen L. Reckamp, MD²⁵; John Xie, PhD²⁶; Joshua C. Curtin, PhD²⁶; Nahor Haddish-Berhane, PhD²⁶; Amy Roshak, BS²⁶; Dawn Millington, MS²⁶; Patricia Lorenzini, MS²⁶; Meena Thayu, MD²⁶; Roland E. Knoblauch, MD, PhD²⁶; and Byoung Chul Cho, MD, PhD²⁷

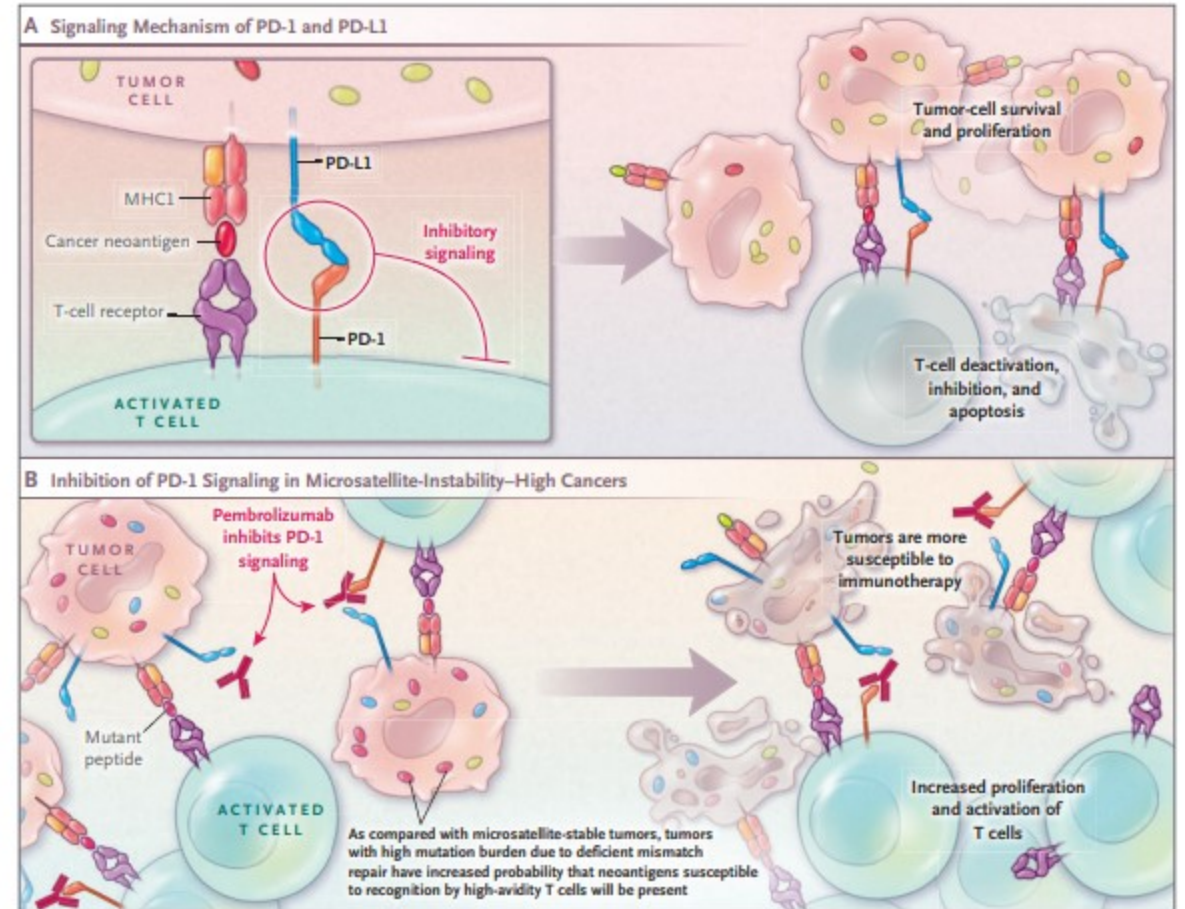




First FDA Approval Agnostic of Cancer Site — When a Biomarker Defines the Indication

Steven Lemery, M.D., M.H.S., Patricia Keegan, M.D., and Richard Pazdur, M.D.

Pembrolizumab Response Rate by Tumor Type.*			
Tumor Type	No. of Tumors	Patients with a Response no. (%)	Range of
			Response Duration mo
Colorectal cancer	90	32 (36)	1.6+ to 22.7+
Endometrial cancer	14	5 (36)	4.2+ to 17.3+
Biliary cancer	11	3 (27)	11.6+ to 19.6+
Gastric or gastroesophageal junction	9	5 (56)	5.8+ to 22.1+
Pancreatic cancer	6	5 (83)	2.6+ to 9.2+
Small-intestine cancer	8	3 (38)	1.9+ to 9.1+
Breast cancer	2	2 (100)	7.6 to 15.9
Prostate cancer	2	1 (50)	9.8+
Other cancers	7	3 (43)	7.5+ to 18.2+



Signaling Mechanism of PD-1 and PD-L1 and Inhibition of PD-1 Signaling in Microsatellite-Instability-High Cancers. MHC1 denotes major histocompatibility complex 1.

Entrectinib approval by EMA reinforces options for ROS1 and tumour agnostic *NTRK* targeted cancer therapies



Elena Ardini,¹ Salvatore Siena ²

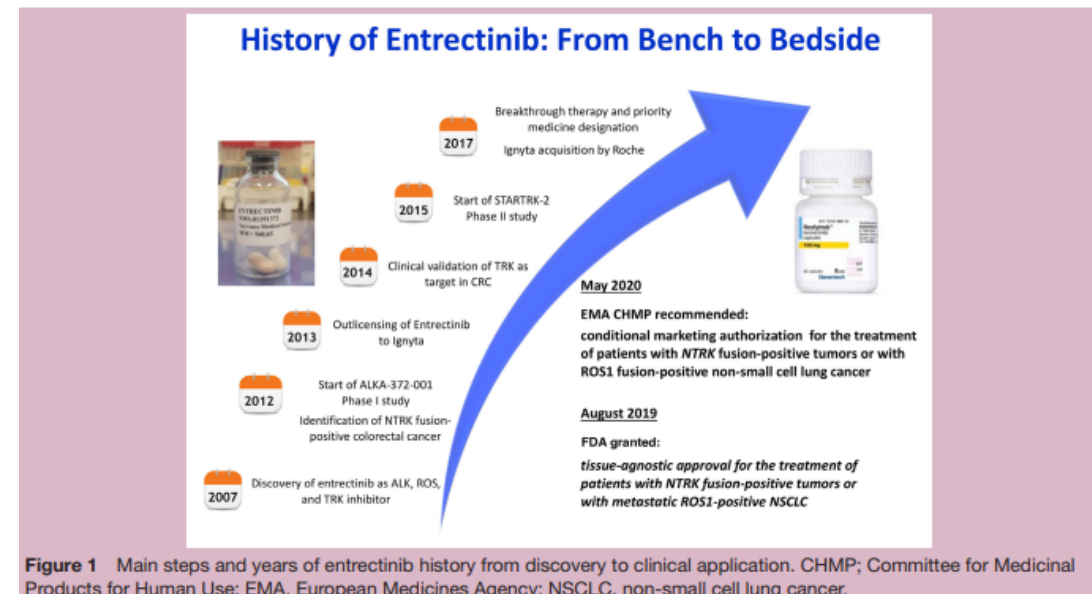
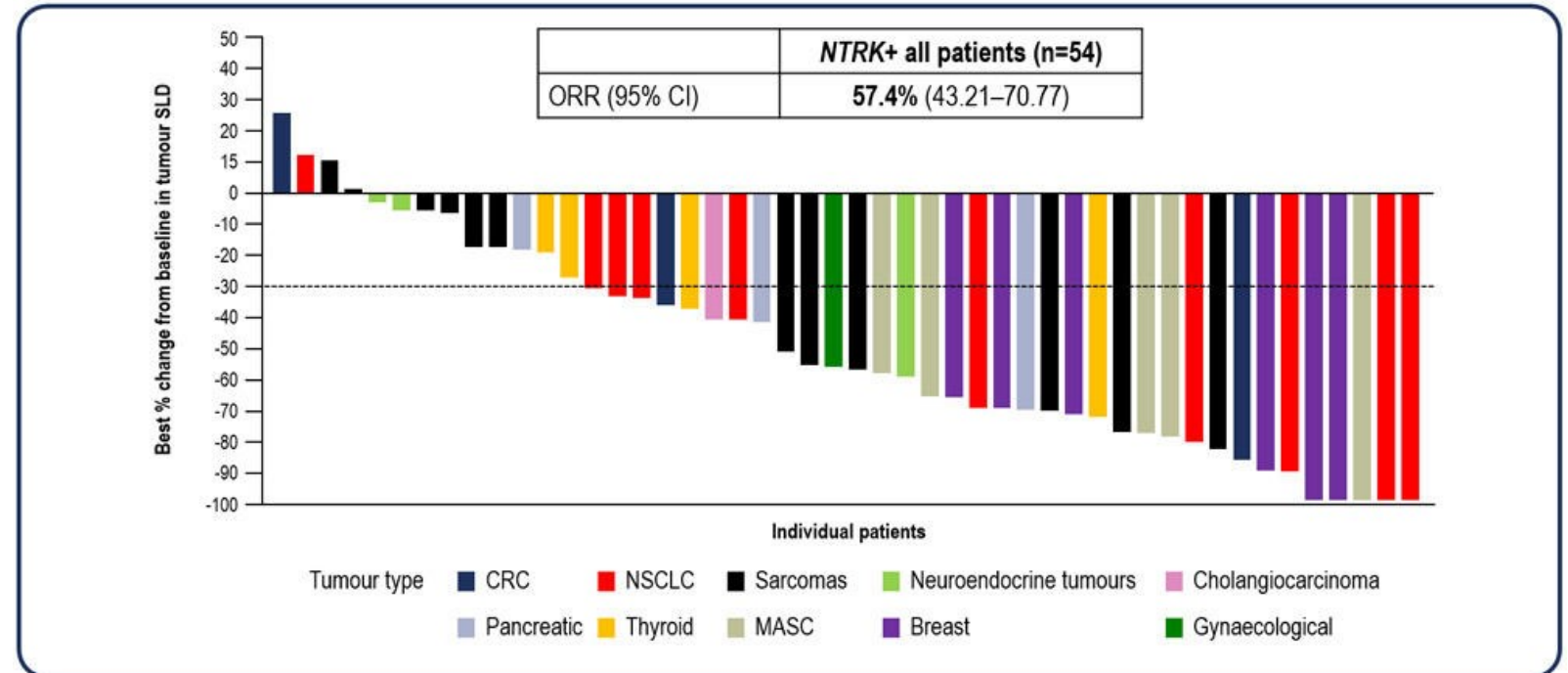


Figure 1 Main steps and years of entrectinib history from discovery to clinical application. CHMP; Committee for Medicinal Products for Human Use; EMA, European Medicines Agency; NSCLC, non-small cell lung cancer.

4.1 Indicazioni terapeutiche

Rozlytrek in monoterapia è indicato per il trattamento di pazienti adulti e pediatrici di età pari o superiore a 12 anni con tumori solidi che esprimono una fusione dei geni del recettore tirosin-chinasico neurotrofico (*NTRK*),

- che sono affetti da malattia localmente avanzata, metastatica o la cui resezione chirurgica potrebbe comportare una severa morbidità, e
- che non sono stati trattati in precedenza con un inibitore di NTRK
- che non dispongono di opzioni terapeutiche soddisfacenti (vedere paragrafi 4.4 e 5.1).

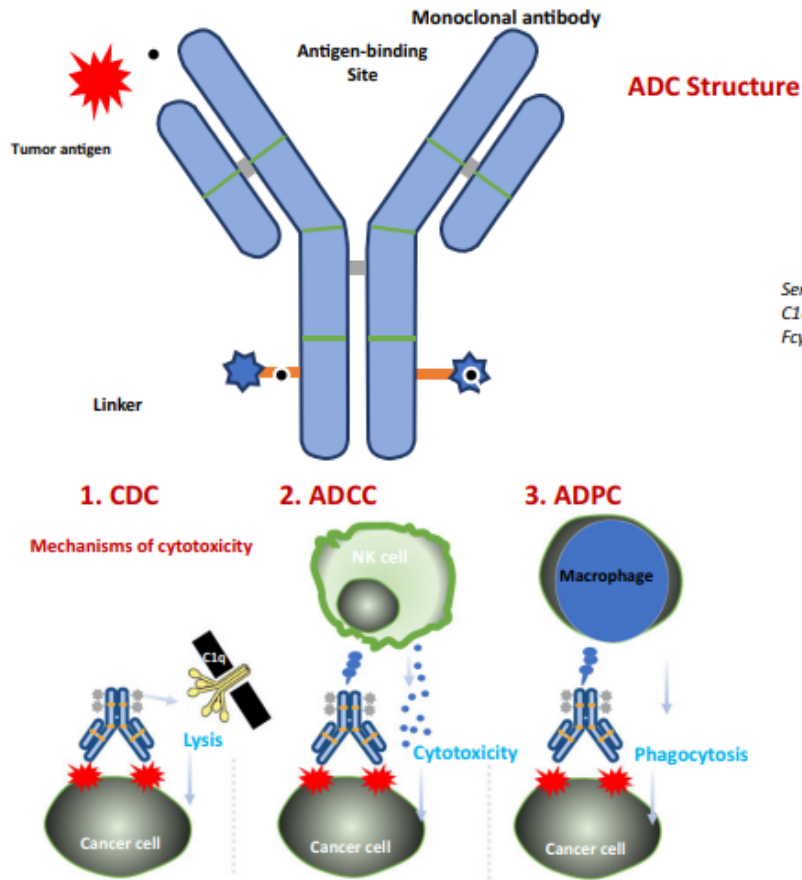


CI, confidence interval; MASC, mammary analogue secretory carcinoma; SLD, sum of longest diameter

Cut-off date: 31 May 2018
*Patients with missing SLD percent change (n=6) were excluded from the plot

Antibody-drug conjugates in lung cancer: dawn of a new era?

Niamh Coleman¹, Timothy A. Yap^{1,2,3,4}, John V. Heymach^{1,2}, Funda Meric-Bernstam^{1,4,5} and Xiuning Le²✉



	IgG1	IgG2	IgG3	IgG4
Serum half-life	21 days	21 days	7-21 days	21 days
C1q binding	Yes	Yes	Yes	No
Fcy avidity	High	Low	High	Moderate
	Cleavable			Noncleavable
	Hydrazone (acid cleavable)	Disulfide (reducible)	Dipeptide (protease cleavable)	MC or MCC
	Auristatins (MoA: antimicrotubule)	Maytansinoids (MoA: antimicrotubule)	Calicheamicins (MoA: DNA cleavage)	Camptothecins (MoA: Topoisomerase 1 inhibition)

antibody-dependent cell phagocytosis
antibody-dependent cell cytotoxicity
complement-dependent cytotoxicity


A review of recent advances on single use of antibody-drug conjugates or combination with tumor immunology therapy for gynecologic cancer

An-Jin Wang^{1,2,3}, Yang Gao^{1,2,3}, Yu-Ying Shi^{1,2,3},
Meng-Yuan Dai^{1,2,3*} and Hong-Bing Cai^{1,2,3*1}

Antibody-drug conjugates in breast cancer: Marching from HER2-overexpression into HER2-low

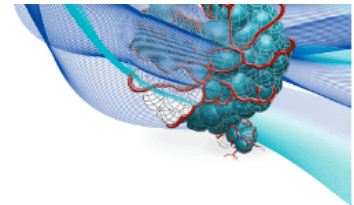
Pinchao Fan^a, Kun Xu^{b,*}

Discovery and development of trastuzumab deruxtecan and safety management for patients with HER2-positive gastric cancer

Kohei Shitara¹  · Eishi Baba² · Kazumasa Fujitani³ · Eiji Oki⁴ · Satoshi Fujii⁵ · Kensei Yamaguchi⁶

Clinical Trial Protocol

Multicenter phase II trial of trastuzumab deruxtecan for HER2-positive unresectable or recurrent biliary tract cancer: HERB trial



Tommaso De pas	Tommaso.depas@gavazzeni.it	
Chiara Catania	chiara.catania@gavazzeni.it	Responsabile Oncologia toracica
Emilia Cocorocchio	emilia.cocorocchio@gavazzeni.it	Responsabile Oncologia urogenitale
Fabio Conforti	fabio.conforti@gavazzeni.it	Responsabile Oncologia mammaria
Nunzio Digiacomo	nunzio.digiacomogavazzeni.it	Oncologia toracica Oncologia urogenitale
Laura Pala	laura.pala@gavazzeni.it	Responsabile Oncologia gastrointestinale Tumori cutanei
Daniele Laszlo	daniele.laszlo@gavazzeni.it	Responsabile emato-oncologia
Giovanna Rossi	giovanna.rossi@gavazzeni.it	Oncologia toracica Oncologia gastrointestinale
Emma Zattarin	emma.zattarini@gavazzeni.it	Oncologia mammaria