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EDITORIAL

Updates to the 2024 CSCO advanced non-small cell lung cancer guidelines

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In the past year, several advancements have been achieved in the treatment of advanced non-small cell lung cancer (NSCLC), particularly in the areas of immunotherapy and targeted therapy. These achievements have provided additional options for improving patient outcomes. The 2024 Chinese Society of Clinical Oncology Guidelines for NSCLC (CSCO NSCLC), a key reference for clinical oncologists in China, have incorporated current global research and adapted recommendations for applicability in real-world scenarios in China. This update covers not only patient selection, efficacy, and safety, but also considers economics, and accessibility, with an aim to provide more precise and comprehensive treatment guidance for Chinese oncologists.

The targeted therapy guidelines have been revised for *EGFR*, *ALK*, *RET*, and *MET* mutations, to provide practical, future-oriented recommendations for oncogenic driver mutations. For patients with NSCLC without oncogenic driver mutations and with a performance status of 2, atezolizumab has been included as a grade II front-line recommendation, thereby highlighting the importance of immunotherapy in this cohort. Furthermore, novel treatment approaches such as antibody-drug conjugates (ADCs) are being actively investigated and have shown promising potential. This article describes key updates offering enhanced guidance for clinical practice and contributing to the advancement of lung cancer care quality.

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Advanced NSCLC with driver gene mutations

Common driver gene mutations

Numerous clinical studies and targeted therapies concerning *EGFR* mutations, the most prevalent driver mutations in NSCLC in China, have emerged in recent years. Third-generation *EGFR* inhibitors such as osimertinib, furmonertinib, and almonertinib have been successfully introduced. On the basis of the results from the IBIO-103 and IBIO-102 studies, the fourth third-generation *EGFR*-targeted therapy befotertinib has become available. Compared with icotinib, befotertinib significantly prolongs progression-free survival (PFS) as a first-line treatment [22.1 months *vs.* 13.8 months, Hazard Ratio (HR) = 0.49, $P < 0.0001$][1]. For patients with T790M mutations, befotertinib has also demonstrated a promising objective response rate (ORR) of 66.2%, with a median overall survival (OS) of 31.5 months[2]. On the basis of these data, the National Medical Products Administration (NMPA) approved befotertinib for both first- and second-line treatment of patients with *EGFR* mutations, and has included this grade I recommendation in the 2024 CSCO, thus further solidifying the role of third-generation *EGFR* inhibitors in the treatment of advanced NSCLC.

To address the limited efficacy of monotherapy, researchers have explored combinations of targeted therapies and other treatments. In the phase III FLAURA2 trial, osimertinib combined with chemotherapy significantly prolonged PFS (25.5 months *vs.* 16.7 months, HR = 0.62, $P < 0.001$) and showed a trend toward OS benefit, with no significant increase in adverse effects[3]. FLAURA2 established osimertinib-chemotherapy as a new first-line treatment for *EGFR* NSCLC; this treatment has been approved by both the NMPA and Food and Drug

Administration (FDA). Additionally, in the MARIPOSA study a combination of lazertinib and amivantamab (*EGFR-MET* bispecific antibody), compared with osimertinib, significantly extended the PFS (23.7 months *vs.* 16.6 months, HR = 0.70, $P < 0.001$)[4]. However, because neither drug has been introduced in China, this combination is included only in the descriptive section of the updated guidelines. In the MARIPOSA-2 trial, PFS was significantly longer for amivantamab–chemotherapy and amivantamab–lazertinib–chemotherapy *vs.* chemotherapy (6.3 and 8.3 *vs.* 4.2 months, respectively), and showed a higher ORR (64% and 63% *vs.* 36%, respectively).

EGFR exon 20 insertion (*exon20ins*) mutations present a major challenge in the targeted treatment of NSCLC. Historically, platinum-based doublet chemotherapy or anti-angiogenesis therapies were the primary treatments for patients with this mutation. Mobocertinib, an *exon20ins*-targeting tyrosine kinase inhibitor (TKI), initially demonstrated moderate efficacy in the phase II EXCLAIM trial. However, because it did not show superiority as a front-line treatment in a phase III trial, the FDA withdrew its approval for this indication[5]. Sunvozertinib, a new target for *exon20ins*, has emerged as a promising option, demonstrating an ORR of 61% as a second-line treatment in the WONKONG-6 study[6]. Sunvozertinib addresses a major gap in the treatment of *exon20ins*; this treatment was granted "breakthrough therapy" designation by both the FDA and NMPA, and subsequently gained approval in China as a later-line treatment. Given sunvozertinib's exceptional performance, the 2024 CSCO guidelines list this drug as a grade I recommendation for second-line treatment of *EGFR exon20ins*. This update highlights the substantial progress in the treatment of *exon20ins*, particularly in targeted therapy. In the PAPILLON study, amivantamab combined with chemotherapy, compared with chemotherapy alone, significantly prolonged PFS in patients with advanced NSCLC with *EGFR ex20ins* mutation (16.7 months *vs.* 11.4 months, HR = 0.40, $P < 0.001$); this treatment has received a grade III recommendation for front-line treatment of *EGFR ex20ins* mutation. With the introduction of novel drugs and further accumulation of clinical data, treatment options for patients with *exon20ins* are expected to become increasingly diverse and personalized.

ALK fusions have been described as "diamond" mutations because of their low morbidity and favorable prognosis. With advancements in *ALK* inhibitors, advanced NSCLC with *ALK* fusion has gradually become a chronic disease. In first-line treatment, alectinib, brigatinib, and lorlatinib are preferred in the recommendations, because they have been found to achieve significantly longer PFS than crizotinib. Additionally, after the INSPIRE study, the NMPA approved iruplinalkib as a first-line treatment for *ALK*-fusion advanced NSCLC on January 16, 2024, on the basis of clinical data showing a median PFS of 27.7 months, compared with 14.6 months with crizotinib (HR = 0.34, $P < 0.0001$)[7]. Furthermore, iruplinalkib demonstrated high efficacy as a second-line treatment, with an ORR of 69.9% in the INTELLECT study, thus further confirming its clinical value[8]. Another promising medicine targeting c-Met/ALK/ROS1 is envonalkib. Compared with crizotinib, envonalkib significantly extends the median PFS in patients with *ALK* fusion (24.9 months *vs.* 11.6 months, HR = 0.47, $P < 0.0001$) and was approved by NMPA as a first-line treatment in June 2024[9]. With the approval of these therapies, the options for *ALK*-targeted medicine have become increasingly robust. Currently, 8 drugs have been approved in China for *ALK*-fusion NSCLC, including 6 international drugs and 2 domestic drugs.

Rare driver gene mutations

ROS1 fusion occurs primarily in lung adenocarcinoma without smoking. The current CSCO guidelines include updates for 2 TKIs targeting *ROS1*: repotrectinib and unecritinib. As the first approved second-generation *NTRK/ROS1* inhibitor, repotrectinib demonstrated high response rates and durability in patients with *ROS1*-fusion NSCLC, as shown in the TRIDENT-1 study, with an ORR of 79% and median PFS of 35.7 months as a first-line treatment. As a second-line treatment, repotrectinib achieved an ORR of 38%, a median PFS of 9.0 months, and median OS of 25.1 months[10]. On the basis of these results, repotrectinib has been granted a breakthrough therapy designation by the FDA and NMPA for both first- and second-line treatment of *ROS1*-fusion NSCLC. Additionally, unecritinib was approved by the NMPA in October, 2024, and has shown an ORR of 80.2% in second-line treatment and a median PFS of 16.5 months[11].

NSCLC with *BRAF V600* mutation has historically derived limited clinical benefits from conventional chemotherapy, and the main standard treatment involved a combination of dabrafenib and trametinib. However, the PHAROS study in 2023 has provided a new treatment option. The combination of encorafenib (BRAF inhibitor) and binimetinib (MEK inhibitor) as a first-line treatment for *BRAF V600* NSCLC achieved an ORR of 75%, with a good safety profile[12]. Only 15% of patients discontinued treatment because of intolerable

adverse events. On the basis of these results, encorafenib combined with binimetinib has been approved by the FDA for the treatment of *BRAF V600* advanced NSCLC. Therefore, the 2024 CSCO guidelines include encorafenib and binimetinib as a first-line treatment for *BRAF V600* advanced NSCLC as a grade III recommendation.

MET exon 14 skipping (*METex14*) mutations are rare but aggressive in advanced NSCLC. Traditional chemotherapy and immunotherapy have demonstrated limited efficacy in this population, with a median OS of only 6.7 months for chemotherapy and a median PFS of 1.9 months for immunotherapy. These data highlight the urgent need for more effective strategies. In the past year, rapid advancements in targeted therapies for *METex14* have provided new hope for these patients. Tepotinib, gumarontinib, and vebreltinib have all demonstrated ORR exceeding 50% as a first-line treatment, and achieve significantly longer PFS and OS than chemotherapy[13-15]. Second-line treatments have also yielded positive results. All these drugs have been approved by the NMPA and are grade I recommendations in the 2024 CSCO guidelines, thus marking a notable change in the treatment landscape for *METex14* NSCLC. Additionally, the 2023 WCLC presented data on savolitinib, showing an ORR of 59.5% and a median PFS of 12.6 months in first-line treatment[16]. Because it has not yet received NMPA approval, savolitinib is currently listed as a grade II recommendation in the guidelines. These targeted therapies offer significantly improved outcomes for patients with *METex14* and enable precision medicine for this subset of NSCLC.

RET fusions occur in approximately 2% of patients with NSCLC, and traditional platinum-based chemotherapy treatments have provided limited benefits. In recent years, the introduction of the new *RET* inhibitors pralsetinib and selpercatinib has markedly advanced the treatment of *RET* fusion NSCLC. In the LIBRETTO-001 study, selpercatinib achieved an ORR of 84% as a first-line treatment and 61% as a second-line treatment[17]. The LIBRETTO-431 study, presented at the 2023 European Society for Medical Oncology (ESMO) Congress, demonstrated remarkable enhancements in PFS (24.8 months *vs.* 11.2 months, HR = 0.46, $P < 0.001$), duration of response (24.2 months *vs.* 11.5 months), and intracranial disease control (response rate: 82% *vs.* 58%; progression rate: 6% *vs.* 20%). On the basis of these results, the 2024 CSCO guidelines have elevated the recommendation for selpercatinib from grade III to grade I, reflecting its potential as a superior therapeutic option. Additionally, updated data from the ARROW study in Chinese patients with *RET* fusion-positive NSCLC indicated an ORR of 83% and a median PFS of 12.7 months. Consequently, pralsetinib was approved by the NMPA for first-line treatment of *RET* fusion NSCLC, and its recommendation has been upgraded to grade I.

In advanced NSCLC with *KRAS G12C* mutations, multiple small molecule inhibitor treatment has progressed. Garsorasib has achieved in an ORR and disease control rate of 40.5% and 91.9%, respectively, with a median PFS of 8.2 months and a median duration of response of 7.1 months. The ORR for JDQ443 was 45% in the all of doses and 57.1% in the 200 mg group. In postline treatment of advanced NSCLC with KRAS G12C mutation, fosfomycin achieved an ORR of 61.2% and a disease control rate of 92.5%. *HER2*, *EGFR* exon 20ins, and *TROP2*-targeting ADCs have all shown promising results. *HER2* mutations are identified in approximately 2% to 4% of patients with NSCLC in China, and these mutations or amplifications are a major mechanism underlying acquired resistance to *EGFR*-TKIs in NSCLC. The DESTINY-Lung02 study has revealed the outstanding efficacy of trastuzumab deruxtecan (T-DXd) in previously treated patients with *HER2*-positive NSCLC, achieving ORRs of 50.8% and 73.3% at doses of 5.4 mg/kg and 6.4 mg/kg, respectively. Furthermore, the median PFS was 10.8 months for the 5.4 mg/kg dose and an impressive 15.4 months for the 6.4 mg/kg dose.[18]. On the basis of these results, T-DXd received accelerated approval from the FDA for *HER2* NSCLC and was designated a "breakthrough therapy" by the CDE in January 2024. The drug is already available for clinical use in China and has recently been approved by NMPA for second-line treatment of *HER2* NSCLC. The phase III PAPILLON study has shown that amivantamab combined with platinum-based chemotherapy significantly prolongs PFS (11.4 months *vs.* 6.7 months, HR = 0.395, $P < 0.0001$) and ORR (73% *vs.* 47%) in patients with *EGFR* exon 20ins, thus leading to FDA approval as a first-line treatment[19]. However, because of the current unavailability and lack of approval of this ADC in China, it has been categorized as a grade III recommendation in the guidelines.

Advanced NSCLC without driver gene mutations

Immunotherapy

Immunotherapy has become a treatment mainstay for patients with driver gene-negative advanced NSCLC; pembolizumab

Table 1 Summary of updated drugs in the 2024 CSCO guidelines and relevant clinical issues

Drugs	Trials	Mutation	Administration	Indication	Objective response rate (%)	Progression free survival (months)	Overall survival (months)	Treatment-related adverse events (%)	NMPA/FDA approval	Medical insurance
Osimertinib with chemotherapy	FLAURA2	*EGFR*	Osimertinib with chemotherapy *vs.* osimertinib monotherapy	First line	92 *vs.* 83***	29.4 *vs.* 19.9***	Immature	Anemia (46.4); diarrhea (43.4); nausea (43.1)	FDA/NMPA	Yes
Befotertinib	IBIO-103	*EGFR*	Befotertinib or icotinib	First line	67 *vs.* 64	22.1 *vs.* 13.8***	Immature	Thrombocytopenia (57.7); headache (34.1); elevated ALT (33.3)	NMPA	Yes
	IBIO-102		Befotertinib 50 mg or 75 to 100 mg once daily	Post line	54 (50 mg); 68 (75–100 mg)	16.5 (50 mg); 16.6 (75–100 mg)	23.9 (50 mg); 31.5 (75–100 mg)	Thrombocytopenia (52.8; 63.1); leukopenia (19.3; 25.5); anemia (18.8; 24.1)[#]	NMPA	Yes
Amivantamab	PAPILLON	*EGFR* 20ins	Amivantamab–chemotherapy or chemotherapy alone	First line	73 *vs.* 47***	11.4 *vs.* 6.7***	Immature	Neutropenia (59.0); paronychia (56.0); rash (54.0)	FDA	No
Sunvozertinib	WU-KONG6	*EGFR* 20ins	Sunvozertinib 300 mg once daily	Post line	61	Immature	Immature	CPK increased (17.0); diarrhea (8.0); anemia (6.0) (grade ≥ 3)	NMPA	Yes
Iruplinalkib	INSPIRE	*ALK*	Iruplinalkib 180 mg once daily or crizotinib 250 mg twice daily	First line	93 *vs.* 89	27.7 *vs.* 14.6***	Immature	AST increased (60.1); CPK increased (58.0); ALT increased (50.3)	NMPA	Yes
	INTELLECT		Iruplinalkib 180 mg orally once daily for a 21-day cycle	Post line	70	19.8		AST increased (43.2); ALT increased (37.0); CPK increased (34.9)	NMPA	Yes
Vebreltinib	KUNPENG	*METex14*	Vebreltinib at 200 mg twice daily in 28-day cycles	First line	77	14.5	20.3	Peripheral edema (82.7); Qt prolongation (30.8); elevated serum creatinine (28.8)	NMPA	Yes
				Post line	71	7.7	20.7		NMPA	Yes
Repotrectinib	TRIDENT-1	ROS1	160 mg daily for 14 days, followed by 160 mg twice daily	First line	79	35.7	Immature	Dizziness (58.0); dysgeusia (50.0); paresthesia (30.0)	FDA/NMPA	Yes
				Post line	38	9	25.1		FDA/NMPA	Yes
Encorafenib + Binimetinib	PHAROS	BRAF V600	Encorafenib 450 mg once daily plus binimetinib 45 mg twice daily	First line	75	Immature	Immature	Nausea (50.0); diarrhea (43.0); fatigue (32.0)	FDA	No
				Post line	46	9.3	Immature		FDA	No

***$P < 0.001$; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CPK, creatine phosphokinase; NMPA, National Medical Products Administration; FDA, Food and Drug Administration. [#]The two values in parentheses represent the proportion of adverse events for 50 mg and 75–100 mg, respectively.

or atezolizumab monotherapy in the PD-L1 positive population; or combination treatment with chemotherapy (pembrolizumab, camrelizumab, sindilimab, tirelizumab, atezolizumab, sugemalimab, and torelizumab) in the all-comer population. However, a portion of patients with advanced NSCLC are ineligible for combination therapy because of poor performance status (PS ≥ 2) and multiple comorbidities. Therefore, monotherapies, such as immunotherapy or chemotherapy, are typically used. The IPSOS study has provided promising data for patients with PS = 2, in which atezolizumab, compared with chemotherapy, significantly improved OS (10.3 months *vs.* 9.2 months, HR = 0.78, P = 0.028), doubling the 2-year survival rate (24.3% *vs.* 12.4%). The ORR was 16.9% *vs.* 7.9%, and the safety profile was favorable, with a lower incidence of grade 3 or higher treatment-associated adverse events (16% *vs.* 33%). Consequently, the 2024 CSCO guidelines have updated the recommendation to grade II for atezolizumab in patients with driver gene-negative advanced NSCLC with PS = 2. Atezolizumab monotherapy is now a viable option for patients with poor PS (≥ 2) or contraindications to chemotherapy.

ADCs

ADCs have shown promising results as a later-line treatment for patients with advanced NSCLC with wildtype driver genes. Dato-DXd, a *TROP2*-targeting ADC, has shown positive results. That study included patients who had progressed after targeted or immunotherapy, to explore the benefits of post-treatment Dato-DXd administration. Dato-DXd effectively overcame resistance to prior targeted or immunotherapy. In non-squamous NSCLC, the Dato-DXd treatment group achieved a longer PFS compared with docetaxel (5.6 months *vs.* 3.7 months), with ORRs of 26.4% and 12.8%, and a 37% decrease in the risk of disease progression or death[20]. Because Dato-DXd has not been approved by the NMPA, it is currently a descriptive recommendation in the guidelines. We look forward to its approval, which would enable patients to benefit from this new therapy. We also anticipate more clinical studies to enrich the treatment options available for these patients. The 2024 edition of the CSCO NSCLC guidelines reflects a period of rapid advancement in both targeted and immunotherapy for late-stage NSCLC, underscoring explosive growth in clinical research. Patients now have a broader array of treatment options, owing to the continued development of novel targeted therapies and the rising prominence of bispecific antibodies and ADCs. These innovative therapies have garnered substantial attention and are becoming increasingly integral to NSCLC treatment, as highlighted by their notable inclusion in the current guidelines.

The recommendations in the updated guidelines consider not only efficacy and safety data, but also applicability to a wide patient population, the maturity of clinical evidence, and pharmacoeconomic considerations. This comprehensive approach ensures that the guidelines provide practical, evidence-based, patient-centered treatment strategies that are tailored to the unique needs of Chinese patients with NSCLC. The efficacy and accessibility of the drugs associated with this guideline update are summarized in **Table 1**. As targeted therapies and immunotherapies continue to evolve, the integration of emerging modalities, such as ADCs and combination treatments, is likely to redefine the therapeutic landscape for advanced NSCLC in the years to come. Future directions emphasize the importance of ongoing research and the need for continual updates to ensure optimal patient outcomes.

Author contributions

Jiale Wang: collected the data and drafted the manuscript; Tianyu Qiu: drafted the manuscript; Shengxiang Ren: designed the concept, provided critical suggestions, and revised the manuscript. All authors have read and approved the article.

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Conflict of interest statement

No potential conflicts of interest are disclosed.

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