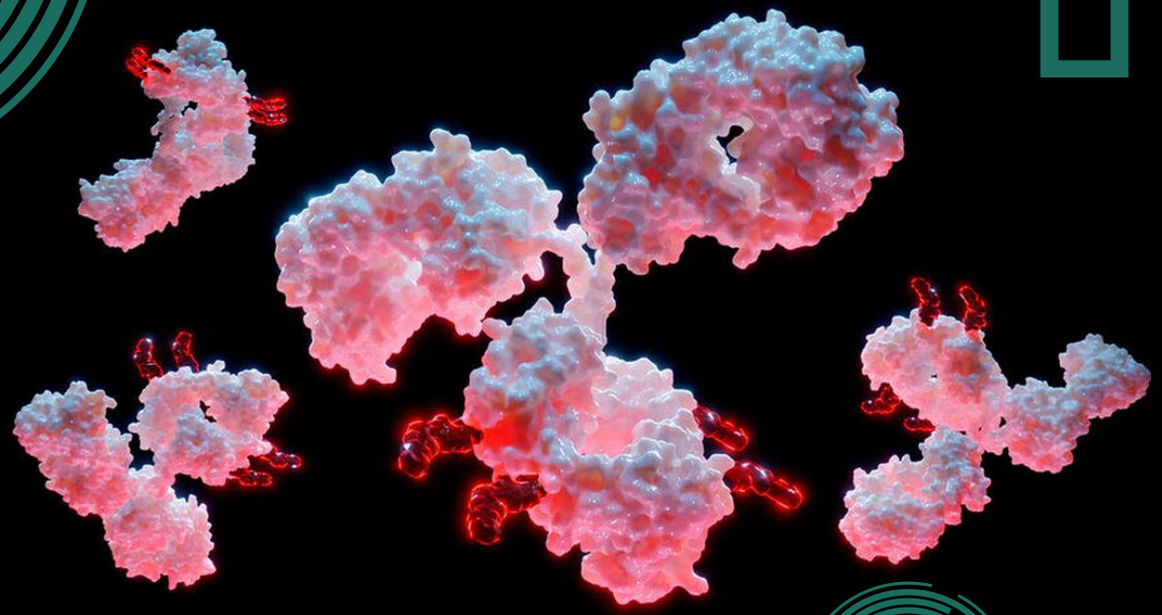
Inspiring Cancer Stories & Trusted Answers



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UNDERSTANDING ADC DATO-DXd CLINICAL TRIAL RESULTS IN NSCLC

By Patient Savvy

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Common Terms Used in Clinical Trial Results

Term	What it means	Simple example
Single-arm trial	A study with just one treatment group. Everyone enrolled gets the same new drug or therapy; there's no separate control or placebo arm to compare against	-
Randomized trial (RCT)	Participants are assigned by chance to different groups—usually the new treatment vs. standard care or placebo. This minimizes hidden bias and lets researchers make a fair, apples-to-apples comparison	-
Objective Response Rate (ORR)	The percentage of participants whose cancer shrinks (partial response, PR) or disappears (complete response, CR) for a pre-specified, confirmed period of time.	*30 of 100 patients had tumor shrinkage ⇒ ORR = 30 %.*
Disease Control Rate (DCR)	The percentage of participants whose cancer either shrink or at least stop growing for a pre-set amount of time. DCR = CR+PR+SD (stable disease)	*Suppose 100 patients are treated:10 have complete response (CR), 20 have partial response (PR), 30 have stable disease (SD), so DCR is 60%*
Duration of Response (DoR)	For people whose tumors shrank or disappeared, DoR is how long that good response lasts—measured from the first documented shrinkage until the cancer grows again or death	*A patient has a partial response after 2 months of treatment; the tumor stays smaller (still responding) until month 10, then starts to grow, so DoR is 8 months*
Overall Survival (OS)	The length of time from either the date of diagnosis or the start of treatment for a disease (like cancer) that patients are still alive	*"Median OS was 24 months" means half the study patients lived ≥24 months.*
Progression-Free Survival (PFS)	The length of time during and after treatment in which a patient lives with the disease but it does not get worse (i.e., no tumor growth or spread)	*If PFS is 8 months, patients went ~8 months before the cancer grew again.*
Adverse Event Grade	Side-effects are ranked 1 (mild) to 5 (death related to the drug) using the NCI CTCAE scale. Grade 3-4 = severe; Grade 5 = fatal.	-

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What you need to know about the new ADC Dato-DXd in lung cancer (1/3)

Key findings from the Dato-DXd TROPION-Lung05 clinical trial

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Key highlight

- **Tumor Response:** Among patients with EGFR mutations, approximately 44% experienced significant tumor shrinkage, and about 82% achieved disease control, meaning their cancer either shrank or remained stable.
- **The median progression-free survival** is approximately 5.5 months, with no significant differences observed across subgroups
- **Side effects were manageable**, but monitoring for serious conditions like ILD is essential

What this means for patients

- Dato-DXd may offer a new treatment avenue for patients with EGFR mutations, especially after other treatments have failed

Source: Paz-Ares, L., Ahn, M. J., Lisberg, A. E., Kitazono, S., Cho, B. C., Blumenschein, G., ... & Sands, J. (2023). 1314MO TROPION-Lung05: Datopotamab deruxtecan (Dato-DXd) in previously treated non-small cell lung cancer (NSCLC) with actionable genomic alterations (AGAs). Annals of Oncology, 34, S755-S756.

Further detailed information for reference

Data published in May 2024

Product	datopotamab deruxtecan (Dato-DXd)
Trial	**TROPION-Lung05**: Global, **single-arm**, open-label **Phase II trial**
Trial design	137 patients with advanced or metastatic NSCLC and AGAs (e.g., EGFR, ALK, ROS1, NTRK, BRAF, RET, MET). **Patients had received up to four prior lines of therapy**, including at least one TKI and platinum-based chemotherapy. Approximately 56% had EGFR mutations.
Efficacy	**Overall Population**: ▪ Confirmed objective response rate (ORR): 35.8% (95% CI: 27.8–44.4), including 4 complete responses and 45 partial responses. ▪ Disease control rate (DCR): 78.8% (95% CI: 71.0–85.3 ▪ Median progression-free-survival (PFS): 5.4 months. **EGFR-Mutated Subgroup**: ▪ ORR: 43.6% (95% CI: 32.4–55.3). ▪ DCR: 82.1%. ▪ Median PFS: 5.7 months. **ALK-Rearranged Subgroup**: ▪ ORR: 23.5% (95% CI: 10.7–41.2). ▪ DCR: 76.5%. ▪ Median PFS: 5.5 months.
Safety	Grade ≥3 treatment-related adverse events included stomatitis (10%), anemia (6%), decreased appetite (4%), and fatigue (4%). Interstitial lung disease (ILD) occurred in 4% of patients, with one Grade 5 (fatal) event.

What you need to know about the new ADC Dato-DXd in lung cancer (2/3)

Key findings from the Phase III TROPION-Lung01 clinical trial

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Key highlight

- **Modest delay in disease progression**: Dato-DXd kept cancer under control slightly longer than docetaxel and more patients had their tumors shrink
- **No proven survival advantage yet**: The drug did not extend overall survival in a statistically significant way at this analysis
- **Side-effect pattern differs from chemotherapy:** Severe low blood counts and hair loss are less common than with docetaxel, but mouth sores and eye irritation are more frequent

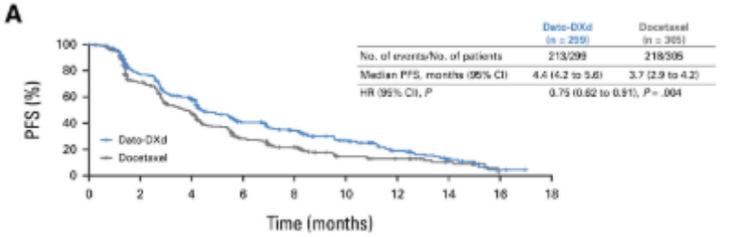
What this means for patients

- While Dato-DXd represents a promising option in 2L+, patients should maintain **realistic expectations** and be aware of different side effects vs. chemotherapy

Source: Ahn, M. J., Tanaka, K., Paz-Ares, L., Cornelissen, R., Girard, N., Pons-Tostivint, E., ... & TROPION-Lung01 Trial Investigators. (2025). Datopotamab deruxtecan versus docetaxel for previously treated advanced or metastatic non–small cell lung cancer: The randomized, open-label phase III TROPION-Lung01 study. *Journal of Clinical Oncology*, *43*(3), 260-272.

Further detailed information for reference

Data published in Sep 2024

Product	datopotamab deruxtecan (Dato-DXd)
Design	**TROPION-Lung01**: Global, **open-label randomized 1:1 Phase III trial**
Trial design	**604 patients** (Dato-DXd = 299; docetaxel = 305) **with stage IIIB/IIIC/IV NSCLC after ≥1 prior systemic line;** both non-squamous (~75 %) and squamous tumors; patients with actionable genomic alterations allowed after targeted therapy failure
Efficacy	**Overall Population**: ▪ Median PFS **4.4 months** (Dato-DXd) vs 3.7 months (docetaxel)  ▪ Median OS **13 months** (Dato-DXd) vs 12 months (docetaxel) - not statistically significant ▪ Confirmed ORR **26.4 %** (Dato-DXd) vs 12.8 % (docetaxel) ▪ Median DoR **7.1 months** vs 5.6 months, respectively
Safety	▪ Grade ≥3 treatment-related Aes: 23% (Dato-DXd) vs. 30% (docetaxel) ▪ Common TRAEs: Stomatitis (47 %, mostly grade 1-2), ocular surface events; hematologic toxicities (e.g., neutropenia) less frequent than with docetaxel

What you need to know about the new ADC Dato-DXd in lung cancer (3/3)

Key findings specifically for EGFR-mutated patients from both trials

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Key highlight

Data specifically for EGFR-mutated NSCLC combined from both TROPION-Lung05 and TROPION-Lung01

- Objective response rate: **43%**
- Median duration of response: **7.0 months**
- Median PFS: **5.8 months**
- Median OS: **15.6 months**

Latest Update:

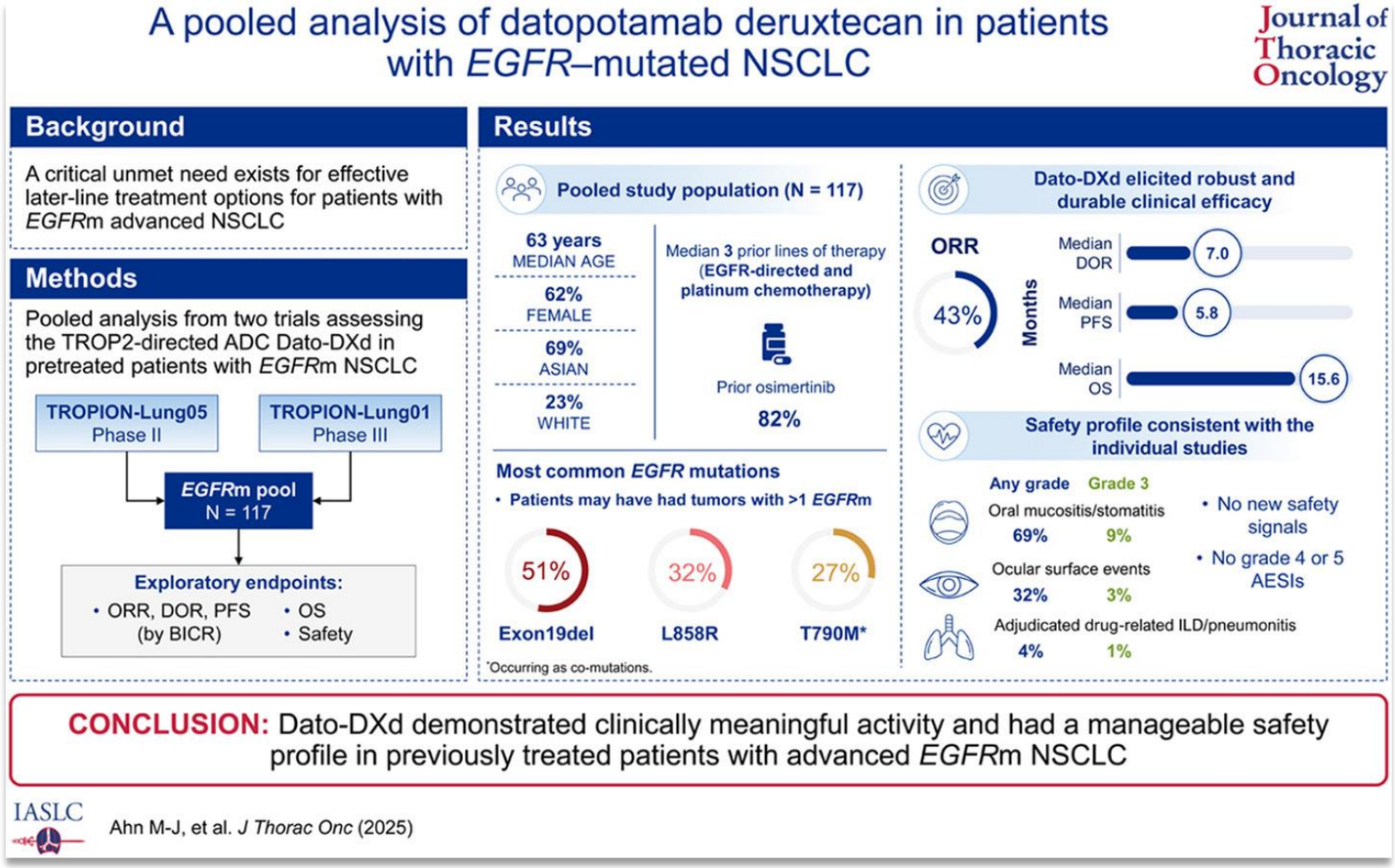
- Currently, Dato-DXd is under FDA review for the treatment of previously treated advanced EGFR-mutated NSCLC, with a decision anticipated by mid-July 2025*. There is no approved product for NSCLC at this time.

*The Prescription Drug User Fee Act (PDUFA) target action date is set for July 12, 2025

Further detailed information for reference

Data published in May 2025

This is a recently published analysis, pooled from two trials TROPION-Lung05 (Phase II) and TROPION-Lung01 (Phase III) in pre-treated patients with EGFR-mutated NSCLC. ***The full study can be found HERE***



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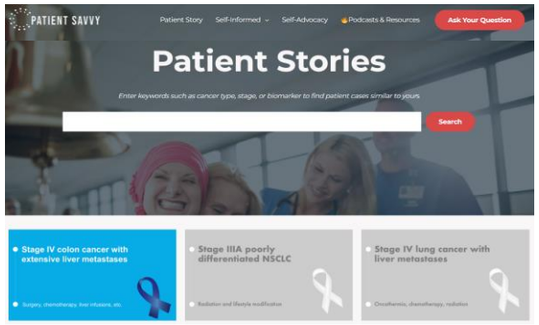

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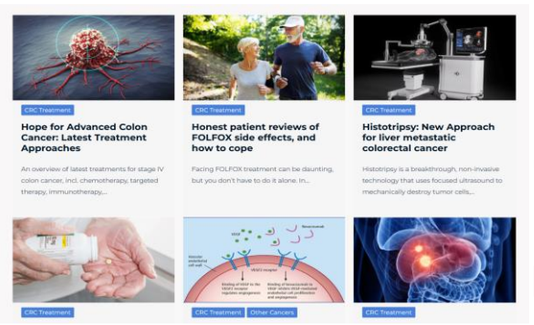

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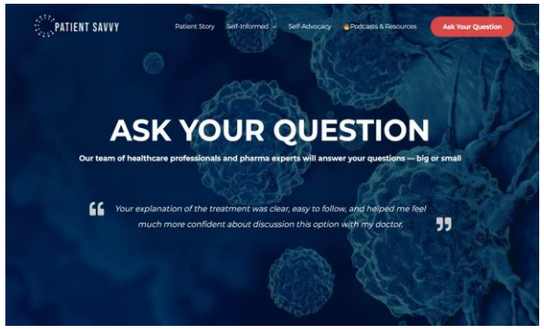

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