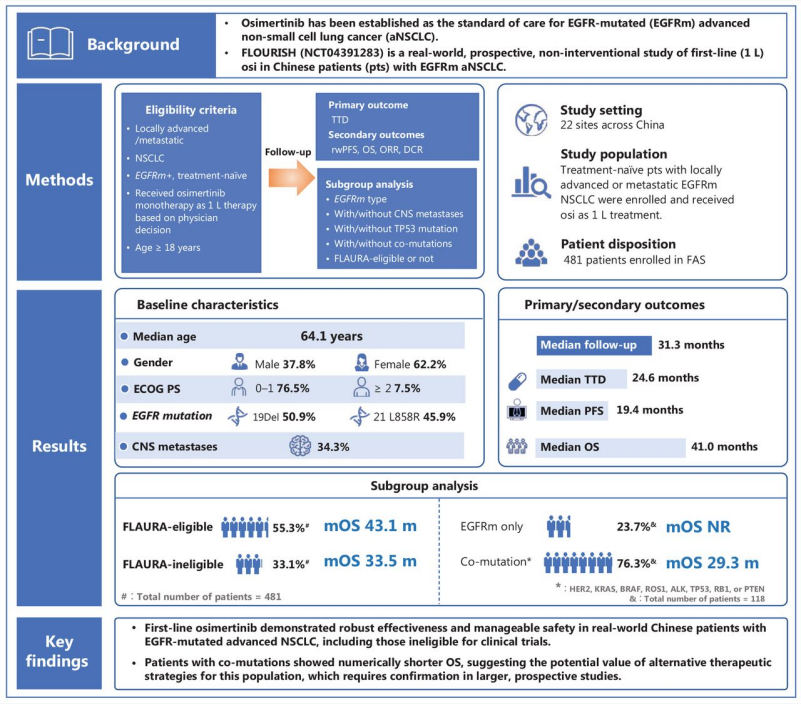
Real-world FLOURISH study confirms osimertinib benefit in Chinese NSCLC

GA, UNITED STATES, September 30, 2026 /EINPresswire.com/ -- A large prospective real-world study in China has confirmed that first-line osimertinib provides substantial clinical benefit to patients with EGFR-mutated advanced non-small cell lung cancer (NSCLC), including those who would have been excluded from pivotal clinical trials. The findings also reveal that patients carrying additional gene co-mutations experience significantly shorter survival, suggesting these individuals may require more intensive treatment approaches.



The FLOURISH study (NCT04391283) was a prospective, multicenter, non-interventional study evaluating first-line osimertinib in 481 treatment-naïve Chinese patients with EGFR-mutated advanced NSCLC across 22 sites. First, the study background and rationale

While the phase 3 FLAURA trial established osimertinib as a first-line standard for epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC), clinical trial populations often differ from real-world patients, who tend to be older and have more comorbidities. Previous real-world studies have been predominantly retrospective with limited sample sizes, leaving important questions unanswered—particularly regarding outcomes in patients with EGFR co-mutations or those who do not meet FLAURA eligibility criteria. These gaps underscore the need for large-scale prospective investigations that reflect routine clinical practice.

Now, researchers from 22 institutions across China, led by Zhejiang University School of Medicine, report findings from the FLOURISH study published in Cancer Biology & Medicine (August 2026, Volume 23, Issue 8). The prospective, multicenter, non-interventional study enrolled 481 treatment-naïve patients with locally advanced or metastatic EGFR-mutated NSCLC receiving first-line osimertinib, tracking outcomes over a median follow-up of 31.3 months.

The study found a median time to treatment discontinuation (TTD) of 24.6 months and a median real-world progression-free survival (rwPFS) of 19.4 months—figures closely aligned with the FLAURA trial's 18.9-month PFS, despite this real-world cohort having a higher proportion of patients with central nervous system (CNS) metastases (34.3% vs. 20.8%) and poorer performance status. Overall survival reached 41.0 months. Notably, 33.1% of patients were classified as FLAURA-ineligible—primarily due to comorbidities or ECOG performance status of 2 or higher—yet they still derived meaningful benefit, with a median overall survival (OS) of 33.5 months. Among the 118 patients who underwent baseline next-generation sequencing (NGS), 76.3% harbored additional gene co-mutations in genes such as TP53, HER2, KRAS, BRAF, ROS1, ALK, RB1, or PTEN. Patients with these co-mutations had a median OS of 29.3 months, compared with not reached in those with EGFR mutations alone. TP53 co-mutations, present in 67.8% of sequenced patients, were associated with particularly poor outcomes, with a median OS of 28.5 months versus not reached for those without TP53 alterations. The safety profile was manageable, with 71.7% of patients experiencing any adverse event and 11.4% experiencing grade 3 or higher events—consistent with previous reports and with no new safety signals identified.

"Our study confirms that first-line osimertinib works as well in the real world as it does in clinical trials—even for patients who wouldn't have qualified for the original FLAURA study," the authors said. "But the data also tell us something important: patients with additional gene mutations don't fare as well. That's a signal we need to take seriously. These patients may need combination approaches from the start, rather than single-agent therapy."

The findings have direct implications for clinical decision-making. For the majority of patients with EGFR-mutated NSCLC, first-line osimertinib remains a robust and well-tolerated standard of care. However, the substantial proportion of patients with co-mutations—particularly TP53—may benefit from closer monitoring and consideration of combination strategies. Recent trials such as FLAURA2 (osimertinib plus chemotherapy) and MARIPOSA (amivantamab plus lazertinib) have shown improved outcomes with combination regimens in patients with TP53 co-mutations, supporting this approach. The ongoing TOP study is now prospectively evaluating osimertinib plus chemotherapy specifically in this higher-risk population. For clinicians, these results reinforce the value of comprehensive genomic profiling at diagnosis to identify patients who might need more than monotherapy.

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References

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