

Daraxonrasib significantly improves survival in metastatic pancreatic ductal adenocarcinoma (PDAC)

Market Event Summary

Pivotal RASolute-302 trial met both primary endpoints

Background

- **PDAC** remains **chemotherapy-dominated**, with only modest survival gains and a poor patient prognosis.
- **Most targeted therapies and immunotherapies** have largely **failed** in Phase 3 trials, underscoring the **urgent need** for effective targeted treatments.
- **Daraxonrasib** is a **first-in-class, oral multi-selective RAS(ON) inhibitor** targeting **broad RAS variants**; it has been granted **Breakthrough Therapy and Orphan Drug designations and a Commissioner's National Priority Voucher (CNPV) in the US.**

Event

- The **registrational Phase 3 RASolute-302** trial evaluated daraxonrasib versus chemotherapy in previously treated metastatic PDAC with documented *RAS* mutation status.
- Daraxonrasib showed an impressive survival benefit in ITT, **doubling median OS to 13.2 months vs. 6.7** months in the chemotherapy arm, corresponding to a 60% reduction in mortality risk (HR 0.40, $P < 0.0001$).
- **Revolution Medicines plans to submit** these final data to **global regulatory authorities**, including the **FDA under CNPV**, with full results to be presented at the **ASCO 2026** Annual Meeting.

Clarivate's takeaways



Medical practice changing

Daraxonrasib's landmark survival benefit vs. chemotherapy in previously treated metastatic PDAC positions the drug as a potential new SOC and could reshape treatment practices.



Broad applicability with strong commercial opportunity

PDAC is driven by *RAS* alterations, with mutations in over 90% of cases. As per the topline results, daraxonrasib has shown promising OS benefit across broader PDAC population, creating a wide target base and lucrative commercial opportunity.



Growth potential

Daraxonrasib is advancing beyond its second-line role, with registrational trials in first-line (RASolute-303) and adjuvant (RASolute-304) PDAC. These late-phase programs position it for meaningful expansion across treatment settings, potentially reshaping its long-term role in this disease.

About the author



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Prior to joining Clarivate, Ms. Tripathi was a senior research associate in the intellectual property and research division at Evalueserve in Gurgaon. She conducted secondary research and delivered technology landscape reports in the domain of pharmaceutical sciences and healthcare. She obtained her master's degree in pharmaceutical chemistry from the Birla Institute of Technology and Science in Pilani.

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