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[New Research Shows Breakthrough Therapy Designated Drugs Provide Maximum Benefit to Patients](#)

Washington, DC - May 26, 2022 - A new analysis conducted by Friends of Cancer Research (*Friends*) published today in *Clinical Cancer Research*, a journal of the American Association for Cancer Research, reveals that U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation (BTD) criteria select drugs that lead to better outcomes for patients with lung cancer.

The study titled “[Breakthrough Therapy Designation Criteria Identify Drugs that Improve Clinical Outcomes for Patients: A Case for More Streamlined Coverage of Promising Therapies](#),” shows that FDA-approved lung cancer [drugs that received a BTD resulted in improved overall survival for patients](#) when compared to lung cancer drugs that never received BTD. Additionally, the data show that drugs with BTD are more frequently categorized as preferred treatments in clinical guidelines developed and widely used by oncologists. These findings indicate that criteria for BTD accurately identifies drugs that improve patient outcomes and warrant coordinated efforts to ensure appropriate access.

Since its inception, FDA’s BTD has expedited clinical development timelines for drugs intended to treat serious conditions with preliminary clinical evidence indicating the drug may demonstrate substantial improvement over existing therapies on a clinically significant endpoint(s).

“Our findings show that the criteria for a breakthrough therapy designation are identifying products that provide maximum benefits for patients,” said Dr. Jeff Allen, President & CEO of Friends of Cancer Research. “Efforts to expedite development and review of breakthroughs are working to help address high unmet needs, and this data suggests that additional efforts to ensure timely access to these products are warranted.”

Friends continues to [monitor the effectiveness of BTD](#) and has [previously shown](#) that processes enabled by BTD can compress development timelines of new drugs by several years. These new results demonstrate that the additional efforts and resources applied to the collaborative development of drugs with BTD enable early access to highly beneficial products for patients. *Friends* supports efforts to ensure processes are in place for timely patient access to these valuable products following their approval, including enhanced coordination between FDA and Centers for Medicare and Medicaid Services (CMS).

[Click to read the full publication](#)

About Friends of Cancer Research

Friends of Cancer Research (*Friends*) is working to accelerate policy change, support groundbreaking science, and deliver new therapies to patients quickly and safely. We unite scientists, pharmaceutical companies, and policy makers with shared trust and guide them toward meaningful cooperation. This collaboration among partners from every healthcare sector ultimately drives advances in science, policy, and regulation that speed life-saving treatments to patients. For more information, please visit <https://friendsofcancerresearch.org/>.

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