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Fast Track Drugs Reach Market Sooner, According to Tufts Center for the Study of Drug Development

BOSTON – Sept. 3, 2008 – New drugs that receive fast track designation by the U.S. Food and Drug Administration (FDA) experience shorter clinical and approval times compared to drugs without the designation, according to a recently completed study of the first decade of the fast track program conducted by the Tufts Center for the Study of Drug Development.

Total average clinical and approval time for fast track drugs was 5% faster than for all drugs – 73.1 vs. 77.0 months – according to Tufts CSDD. The study looked at 344 drugs that received at least one FDA fast track designation since1998.

The fast track program was authorized by Congress in 1997 and implemented the following year.

"Since many drugs that receive fast track designation are being developed to treat serious or life-threatening conditions, such as AIDS, breast cancer, and leukemia, development hurdles are significant, resulting in longer clinical times than is the case for all drugs as a whole," said Janice M. Reichert, senior research fellow at Tufts CSDD and the author of the study. "Speedier FDA review, however, leads to shorter combined clinical and approval times for fast track drugs."

According to Tufts CSDD, clinical development time for fast track drugs was 6% longer than it was for all drugs (64.7 vs. 61.2 months). But average FDA approval review time for fast track drugs was considerably shorter than for drugs as a whole – an average of 8.4 vs. 15.8 months (for products that began clinical tests in 1992 or later and approved during 1998-07).

The Tufts CSDD analysis, reported in the September/October *Tufts CSDD Impact Report*, released today, also found that:

* Fast track designations for new drug candidates have grown substantially, from an average of 22 per year during 1998-02 to 49 per year during 2003-07.

* Anticancer candidates received the largest share of fast track designations since the program began.

* Fast track indications are more likely to be terminated during development than non-fast track indications, with efficacy being the primary reason for termination of fast track-designated candidates.

About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes the *Tufts CSDD Impact Report*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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