



TUFTS CENTER FOR THE STUDY
OF DRUG DEVELOPMENT

PRESS RELEASE

Despite more Cancer Drugs in R&D, Overall U.S. Approval Rate is Eight Percent, According to the Tufts Center for the Study of Drug Development

BOSTON – Sept. 5, 2007 – Although the number of new cancer drugs entering clinical development more than doubled between the early 1990s and mid-2000s, only eight percent of candidates with known fates won marketing approval in the United States, according to a study recently completed by the Tufts Center for the Study of Drug Development.

This approval rate compares with an overall U.S. marketing approval rate of 20% for all new drugs that began human testing in 1993-97, according to Tufts CSDD.

In addition, the study found, U.S.-approved cancer therapeutics that entered clinical testing in 1990-06 took an average of seven years to complete the clinical development and approval process, compared with about six years for all new drugs approved by the FDA during the same period.

“While commercial development of cancer treatments has dramatically increased in the last dozen years or so, drug developers are still challenged to boost success rates in this area,” said Tufts CSDD Director Kenneth I Kaitin. “In today’s market, increased R&D efficiency is synonymous with long-term commercial viability, and improving success rates is key to enhanced R&D performance.”

The study assessed 1,111 cancer therapeutic or vaccine candidates that originated at biotechnology and pharmaceutical companies worldwide or were licensed by these companies from commercial, government, or academic sources, and included only candidates in which the active ingredient had not been approved previously for any indication.

Study results, reported in the September/October Tufts CSDD Impact Report, released today, also found that:

- * The rate of clinical entry for the therapeutics studied by Tufts CSDD more than doubled, from 33 in the early 1990s to 73 in the mid-2000s.
- * Overall U.S. success rates were low for compounds that have either been abandoned or approved to date: 8% for all candidates, 10% for small molecule drugs, 9% for monoclonal antibodies (mAbs) of all types, and 14% for humanized mAbs.
- * Compared to all candidates and the small molecules, mAbs had the lowest Phase 1-to-2 and Phase 2-to-3 phase transitions, but the highest Phase 3-to-FDA review and review-to-approval transitions.

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.

--end--

Contact: Tufts Center for the Study of Drug Development
Peg Hewitt – 617-636-2185
peg.hewitt@tufts.edu

Business Communication Strategies
Peter Lowy – 617-734-9980
lowy@bus-com.com