FOR IMMEDIATE RELEASE

New Approaches to R&D May Prove Best Path for Drug Developers, According to Tufts Center for the Study of Drug Development

BOSTON – April 6, 2010 – Innovative approaches to drug development, including alliances and partnerships, may prove the best way to increase the rate at which the research-based drug industry brings new products to market, according to a panel of pharmaceutical and biotech industry leaders recently convened by the Tufts Center for the Study of Drug Development.

Because patents on dozens of drugs are due to expire within the next few years—paving the way for generics to compete with those products—drug developers are in a race to develop and win market approval for new medicines.

"No one has yet figured out how to reliably identify early on which newly discovered compound will bear fruit," said Tufts CSDD Director Kenneth I Kaitin. "This is spurring companies across the industry to experiment with a growing range of new tools and approaches to weed out unpromising drug candidates earlier, speed development, and reduce development costs."

According to Tufts CSDD, drug development, which starts in discovery and may involve examining many thousands of compounds, takes an average of 15 years to produce a product approved for sale in the United States.

Industry executives, who convene several times a year at the Tufts CSDD Executive Forum Roundtable, noted that while a growing number of drug companies are developing alliances with external service providers, those approaches have not yet emerged into full-fledged partnerships, where both parties share development risks and rewards.

The executives also agreed that the following new approaches, among others, may help increase R&D efficiency:

* Reducing distinctions between phases — Traditional distinctions between clinical phases is a matter of practice and not a legal requirement. Starting human trials earlier may offer a way to save money and time.

* Engaging in collaborative relationships — Agreements between sponsors, similar to the formation of the Asian Cancer Research Group, Inc. announced by Eli Lilly, Merck, and Pfizer in February, may help accelerate research.

* Using exploratory INDs — This relatively new type of pre-Phase I clinical trial lets sponsors evaluate up to five chemical entities or formulations simultaneously to identify a lead compound.

SCHEDULED TUFTS CSDD EXECUTIVE FORUM ROUNDTABLES

Upcoming Tufts CSDD Executive Forum Roundtable meetings will focus on the following:

May 13, 2010 — Strategies for Managing Drug Development Risk: Maintaining Portfolio Diversity
Sept. 16, 2010 — Outsourcing Strategies Across the Value Chain
Nov. 4, 2010 — Strategies for Optimizing the Drug Development Process

To learn more, call 617-636-2170.

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 Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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