FOR IMMEDIATE RELEASE

Drug Companies Are Looking to Shorten Time to Early Clinical Development, According to Tufts Center for the Study of Drug Development

BOSTON – April 26, 2012 – Drug companies looking to increase the efficiency and productivity of their R&D pipelines are turning to a host of techniques and approaches aimed at shortening the time from nonclinical to early clinical development—with promising results—according to a panel of leaders from the research-based drug industry recently convened by the Tufts Center for the Study of Drug Development.

"New paradigms for the exploratory phase of drug development offer encouragement," noted Tufts CSDD Professor and Director Kenneth I Kaitin. "A growing number of companies, for example, are utilizing biomarkers, modeling and simulation, and advanced statistical methodology. And rapid drug prototype creation combined with novel scientific and formulation approaches are creating more predictable outcomes of early stage human testing."

He cautioned, however, that key to managing the transition from nonclinical to early clinical development will be a project management ethos that shuns existing silos and encourages rapid handoffs between teams within the same company, as well as between companies and development partners.

Nonclinical drug development focuses on identifying potential drug candidates. Early clinical development refers to Phase I studies, usually involving small groups of healthy volunteers, to determine how the drug is absorbed, distributed, and eliminated by the body, assess the drug's safety, and possibly detect early evidence of effectiveness.

Key points made by the industry leaders, summarized in the April *Tufts CSDD R&D Management Report*, released today, include the following:

- There is no single approach to setting development priorities. Some companies set milestones and publicize ranking criteria internally, while others do not share ranking criteria to avoid a premature decision to terminate a project at the discovery stage when much is still in flux.

- While new information may make previously terminated projects worthy candidates for further development, most drug developers said they lack a formal process to re-examine rejected compounds; some companies outsource those compounds for others to re-assess.

SCHEDULED TUFTS CSDD EXECUTIVE FORUM ROUNDTABLES

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

May 17, 2012 — Academic-Industry Partnerships: Opportunities and Pitfalls
Sept. 13, 2012 —The Changing Landscape for Technical Services Outsourcing
Nov. 1, 2012 — Development Strategies for Companion Diagnostics

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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