FOR IMMEDIATE RELEASE

Pharma and Biotech Firms Are Rethinking Their Approach to Outsourcing, According to Tufts Center for the Study of Drug Development

BOSTON – Oct. 26, 2010 – The current business climate is challenging pharmaceutical and biotech companies to rethink their approach to outsourcing and how best to build alliances with external service providers as part of a long term drug development strategy, according to a panel of pharmaceutical and biotech industry leaders recently convened by the Tufts Center for the Study of Drug Development.

"The global economic downturn and operating pressures to launch new products faster and more efficiently have increased the need to leverage the benefits of outsourcing," said Tufts CSDD Senior Research Fellow Ken Getz. "But sponsors are rethinking how to best integrate CRO partners, given their unique corporate cultures, development and operating philosophies, and legacy processes and systems. That's why integrated partnerships are being supported through hybrid outsourcing relationship models."

According to Tufts CSDD research, annual growth in drug sponsor spending for contract clinical services over the last decade has outpaced annual increases in global spending on new drug development, 13.4% vs. 9.1%.

Reliance on CROs, however, has been rewarded, Getz said, citing research he has conducted which shows that greater use of CROs has been associated with faster development at comparable quality to projects with little to no CRO use.

The executives, who met as part of the Tufts CSDD Executive Forum Roundtable, agreed that good governance—critical to the success of alliances and partnerships—is supported by:

* Sharing definitions of the relationship, goals, and processes, to assure a standard and consistent approach to oversight.

* Instituting an audit plan that lets sponsors adopt a "trust but verify" approach to CROs, enabling sponsors to evaluate CRO methods and systems without co-monitoring trials.

* Keeping the joint executive committee focused on learning how problems get solved, not how to solve them.

SCHEDULED TUFTS CSDD EXECUTIVE FORUM ROUNDTABLES

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

Nov. 4, 2010 — Strategies for Optimizing the Drug Development Process
Feb. 24, 2011 — Managing Global Investigative Sites for Peak Operational Efficiency
May 19, 2011 — Management Implications of the Global Regulatory Environment
Sept. 15, 2011 — Designing and Maintaining Successful Innovation Partnerships

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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