FOR IMMEDIATE RELEASE

Drug Developers Are Implementing New Strategies for Use of Comparator Drugs in Clinical Trials, According to Tufts Center for the Study of Drug Development

BOSTON – Jan. 16, 2014 – Drug developers are aggressively implementing new strategies to improve their access to and use of comparator drugs, which are used in clinical trials to determine how development candidates compare to existing therapies, according to leaders from the research-based drug industry who recently participated in a roundtable discussion convened by the Tufts Center for the Study of Drug Development.

"The challenges obtaining the right drugs for clinical trials—in the right quantity at the right time, and at the right price—are formidable," said Tufts CSDD Director Kenneth I Kaitin. "The lack of fully robust supply chain management practices, growing emphasis on expensive biologics, changing regulatory requirements, and growth of counterfeit medicines are forcing drug sponsors to rethink and redesign their comparator drug supply chains to support drug development that, increasingly, crosses international borders."

Despite these hurdles, Kaitin said, the industry has embraced pro-active approaches, including improvements in communication between internal R&D and commercial operations, and a willingness to sell commercially available products to other developers, which are bearing fruit.

"Most importantly, sponsors of clinical trials, who understand that substantial benefits will accrue to those who are first to market with a new therapeutic, are investing in their comparator supply chains to improve in-house capabilities, and aligning with external service providers," Kaitin said.

Among other points discussed in the roundtable, summarized in the January *Tufts CSDD R&D Management Report*, released today:

- Up to half of the entire clinical supply budget is spent on comparators, although great variability exists from company to company.
- Planning, sourcing, logistics management and pricing need to be in balance to ensure that the right amount of comparator products is available where and when needed.
- The share of clinical studies using centrally and locally sourced comparators differs by region, with local sourcing requiring additional oversight to manage multiple country requests for the same product.

SCHEDULED TUFTS CSDD EXECUTIVE FORUM ROUNDTABLES

Upcoming Tufts CSDD Executive Forum Roundtable meetings:

Feb. 20, 2014: Predictors of Clinical Success: New Approaches to Boosting Success Rates
May 15, 2014: Risk-Sharing Partnerships and Alliances: Strategic and Operational Challenges
Sept. 18, 2014: New Directions in Outsourcing
Nov. 6, 2014: Managing the Changing Investigative Site Landscape

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.

--end--

Contacts:
Tufts Center for the Study of Drug Development
Sandra Peters – 617-636-2185
CSDDpublications@tufts.edu

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