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Personalized Medicines Are Shaping the Way R&D Is Done, According to Tufts Center for the Study of Drug Development

BOSTON – Nov. 16, 2010 – Personalized medicine development, occupying a growing role in the clinical pipelines of drug developers, is leading companies to change their R&D paradigms, including how they make go/no-go decisions, according to a recently completed study by the Tufts Center for the Study of Drug Development.

“Early indications show that development of personalized medicines is commanding more resources and fomenting more organizational change than is generally appreciated outside the industry,” said Christopher-Paul Milne, associate director at Tufts CSDD and author of the study.

He noted that the scientific, regulatory, commercial, and practical challenges confronting developers in creating personalized medicines are significant, and, as a result, approaches taken by individual companies in the pursuit of these new medicines vary greatly. In particular, developers are working with academic medical centers to better understand disease mechanisms and identify strata of target populations, and with diagnostics developers to augment in-house capabilities.

The analysis, the first of its kind to measure the pharma/biotech industry’s progress in developing personalized medicines, was based on interviews and a survey of nearly two dozen companies that are leading the way in this new field.

The study, reported in the November/December *Tufts CSDD Impact Report*, released today, also found that:

- * The magnitude of resources required to create personalized medicines means developers must team with multiple external partners, presenting challenges for project stewardship and intellectual property rights.
- * Biomarkers increasingly are used to better understand patient response, but companies still cannot use biomarker data to support approval until the regulators’ capacity to evaluate it catches up to the science.
- * Oncology leads other therapeutic areas in the number of personalized medicines on the market as well as in the pipeline with the expectation that within the decade all oncology drugs will have a related diagnostic.
- * Other key therapeutic areas in which personalized medicine is making headway include cardiovascular, central nervous system, and immunologic therapies, whereas personalized medicine development is just getting started for metabolic and respiratory therapies, as well as virology.

Milne will present results of his study on Nov. 18 at a conference, *Personalized Medicine: Impacting Healthcare*, being held at Harvard Medical School.

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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Contacts: Tufts Center for the Study of Drug Development
Robert Chung – 617-636-2187
robert.chung@tufts.edu

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