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Personalized Medicine Is Gaining Traction, but Faces Multiple Challenges

BOSTON – May 14, 2015 – While development of personalized medicines has grown since the human genome was first sequenced in 2001, biopharmaceutical sponsors face a number of hurdles that are impeding more rapid market uptake, according to a recently completed study by the Tufts Center for the Study of Drug Development.

Fourteen years after the human genome was initially sequenced, paving the way for development of personalized medicine, 13% of drugs marketed in the United States today post pharmacogenomic information on the label, but developers continue to encounter challenges relating to basic science, regulatory and reimbursement policies, and, equally critical, clinical adoption, according to Tufts CSDD.

“The biopharmaceutical industry is increasingly committed to translating genomic discoveries into personalized medicines, but it needs to overcome scientific, regulatory, and economic challenges,” said Joshua Cohen, associate professor at Tufts CSDD. “In particular, the continued development of personalized medicine depends on identifying biomarkers and developing clinically useful diagnostic tests.”

He noted, however, that higher R&D success rates alone may not lead translate into commercial success without physicians increasing the rate at which they prescribe personalized medicines, supported by payer willingness to reimburse users.

These assessments, based on a survey of major drug manufacturers and interviews with leading drug and diagnostics companies, were reported in the May/June Tufts CSDD Impact Report, released today. Other highlights include the following:

- Biopharmaceutical firms said they expect investment in personalized medicine to increase 33%, and medicines in development to increase 69%, over the next five years.
- Biomarker identification and diagnostic test development rank highest in terms of scientific challenges, followed by regulatory and reimbursement issues.
- Oncology products continue to rank highest in terms of average share of personalized medicines in development across all phases, followed by neurology and cardiovascular drugs.

To date, the U.S. Food and Drug Administration (FDA) has approved 137 drugs with pharmacogenomics information in their labeling, with 20% of all FDA approvals in 2014 for personalized medicines, according to Tufts CSDD.

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The Tufts Center for the Study of Drug Development 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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