Diabetes Drug Development Is Riskier Compared to All Drug Development

BOSTON – Sept. 20, 2016 – Whereas scores of new diabetes and non-diabetes endocrine drugs have been launched since the mid-1990s, and the demand for new therapies continues to grow, the development process for new diabetes and non-diabetes endocrine drugs is riskier compared to all drug development, according to results of a new study conducted by the Tufts Center for the Study of Drug Development.

Only one in 13 investigational diabetes drugs that entered clinical testing from 1995 to 2007 ultimately received U.S. marketing approval, compared to one in eight of all investigational drugs, the study found.

Although diabetes drugs that enter the clinical pipeline are less likely to enter Phase III testing, compared to all drugs, once in Phase III, diabetes drugs enjoy slightly higher approval rates, according to Tufts CSDD.

"Creating new drugs to treat diabetes poses special development challenges, as reflected in part by Food and Drug Administration (FDA) regulatory guidelines promulgated in 2008 that require developers to demonstrate cardiovascular safety in large trials that include high-risk patients," said Joseph A. DiMasi, director of economic analysis and research associate professor at the Tufts Center for the Study of Drug Development, who conducted the analysis.

He added, "Diabetes is a major cause of morbidity and mortality, and its incidence in the U.S., according to the Centers for Disease Control and Prevention, has tripled since 1980. Although there are numerous hypoglycemic agents on the market, there remains a strong need for new drugs that will reduce the human suffering and economic costs associated with this highly prevalent disease.”

The study examined the development pathways and characteristics for 27 diabetes and 34 non-diabetes endocrine drugs, which accounted for 10% of all FDA new therapeutic drug approvals during the 21-year period ending in 2015.

Key findings, reported in the September/October Tufts CSDD Impact Report, released today, include the following:

- Mean clinical development time for diabetes drugs increased by 1.3 years from 2002-08 to 2009-15.
- Of the new diabetes drugs approved from 1995-15, 15% received a priority review designation from the FDA, compared to 50% for non-diabetes endocrine drugs and 46% for all non-endocrine drugs.
- The likelihood that a diabetes drug entering clinical testing would transition to Phase III testing was 12.8%, vs. 21.1% for all drugs.
- The likelihood of approval for a diabetes drug entering Phase III was 60%, compared to 56% for all drugs.

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About the Tufts Center for the Study of Drug Development

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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