CNS Drugs Take Longer to Develop and Have Lower Success Rates than Other Drugs

BOSTON – Nov. 4, 2014 – Drugs that treat central nervous system (CNS) diseases take more than a year longer to develop and are less than half as likely to obtain marketing approval than other drugs, according to a newly completed study by the Tufts Center for the Study of Drug Development.

Mean clinical development time for CNS drugs approved for marketing in the United States from 1999 through 2013 was 12.8 months, or 18%, longer than for non-CNS compounds, according to Tufts CSDD.

In addition, the overall clinical approval success rate (share of compounds entering clinical testing that obtain marketing approval) for CNS compounds first tested in human subjects from 1995 to 2007 (and followed through 2013) was 6.2%, or less than half the 13.3% rate for non-CNS drugs.

“CNS drugs are more challenging to develop than other medicines, because the conditions they aim to treat are typically chronic and complex, and clinical endpoints are often difficult to measure,” said Joseph A. DiMasi, director of economic analysis at Tufts CSDD and author of the study. “That’s why CNS drug development takes longer and has a lower likelihood of overall clinical success than non-CNS drug development.”

CNS drugs treat a wide array of psychiatric and neurodegenerative disorders, including depression, psychosis, epilepsy, and Alzheimer’s disease.

The success rate analysis was based on development and approval histories of 274 CNS and 1,168 non-CNS investigational compounds, and the approval phase time analysis was based on 42 CNS and 345 non-CNS therapeutic compounds approved by the U.S. Food and Drug Administration (FDA).

Other findings from the study, reported in the November/December Tufts CSDD Impact Report, released today, include the following:

- During 1999-13, mean approval phase time for CNS compounds approved for marketing in the U.S. was 19.3 months, or 31% longer than the 14.7 months for non-CNS approvals.
- From 1999 to 2013, about one in six CNS compounds received a priority review rating from the FDA, compared to nearly half of all non-CNS compounds.
- Despite longer clinical and approval phase times, and lower clinical success rates, CNS approvals have held steady, accounting for about one in 10 of all U.S. approvals since the 1980s.
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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