

## **FOR IMMEDIATE RELEASE**

### **Drugs to Treat CNS Diseases Take 35% Longer to Develop than Other Drugs, According to Tufts Center for the Study of Drug Development**

BOSTON – March 6, 2012 – Drugs developed to treat central nervous system (CNS) diseases take 35% longer to complete clinical trials and receive regulatory approval compared to other new prescription medicines, according to an analysis recently completed by the Tufts Center for the Study of Drug Development.

Between 1996 and 2010, mean clinical-plus-approval phase time for U.S.-approved CNS drugs was 32 months – or 35% longer than that for non-CNS drugs approved during the same period.

“Despite the longer and more costly development associated with CNS drugs, the CNS new product pipeline is among the richest in the R&D-based drug industry,” noted Joseph DiMasi, director of economic analysis at the Tufts, who conducted the study.

According to DiMasi, the CNS drug pipeline grew six-percent annually during the past decade and currently accounts for 11% of all drug development projects worldwide.

Still, CNS drug development poses a challenge for developers. The estimated clinical approval success rate for self-originated CNS drugs entering clinical trials between 1993 and 2004 was about one in 10, compared to one in six for all self-originated drugs, according to Tufts CSDD.

Self-originated drugs are products developed entirely by one drug company, in contrast to compounds that a company may obtain through licensing, purchase, or other means. Clinical approval success rate is the share of new chemical entities in clinical development that eventually obtains FDA marketing approval.

The Tufts CSDD study, reported in the March/April *Tufts CSDD Impact Report* and released today, also found that:

- The clinical approval success rate for self-originated CNS drugs varied from a low of 7.1% for drugs that entered clinical testing during 1995-2000 to more than double, at 14.8%, for drugs entering clinical testing during 1998-2003.
- Mean clinical time for CNS drugs during 1996-2010 was 102.1 months (40% longer than for non-CNS drugs).
- Mean approval time for CNS drugs during 1996-2010 was 20.3 months (13% longer than for non-CNS drugs).

CNS diseases include neurological diseases, such as Alzheimer’s, epilepsy, migraine headaches, and stroke, and mental health diseases, such as addictions, autism, depression, panic, and schizophrenia.

#### **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  
[sandra.peters@tufts.edu](mailto:sandra.peters@tufts.edu)

Business Communication Strategies  
Peter Lowy – 617-734-9980  
[lowy@bus-com.com](mailto:lowy@bus-com.com)