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CNS Drugs Take 20% Longer to Develop and 38% Longer to Approve vs. Non-CNS Drugs, According to the Tufts Center for the Study of Drug Development

BOSTON – Sept. 11, 2018 – Developing drugs to treat central nervous system (CNS) disorders on average required 20% more time than other drugs that won marketing approval in the United States from 2000 through 2017, and took 38% longer to win that approval, according to a newly completed analysis by the Tufts Center for the Study of Drug Development.

"CNS drugs face greater development challenges compared to non-CNS drugs due, in large part, to a poor understanding of the underlying pathophysiology of many of the disorders they seek to treat, as well as difficulty identifying and measuring appropriate clinical endpoints," said Joseph A. DiMasi, director of economic analysis at Tufts CSDD.

Despite lengthier than average clinical development and approval phase times, the CNS share of new drug approvals in the U.S. since the 1980s has remained relatively steady, ranging from 10% to 12% on a decade-by-decade basis.

During 2000-17, the U.S. Food and Drug Administration approved 509 new drugs and biologics, of which 57 were CNS drugs.

DiMasi noted that demand for new CNS drugs will continue to remain strong, and likely grow, as CNS disorders are expected to constitute nearly 15% of the global disease burden by 2020.

"The principal challenge for drug developers is to decrease development time for CNS drugs and increase success rates without sacrificing safety, while simultaneously reigning in overall development costs," DiMasi said.

Other key study findings, summarized in the September/October Tufts CSDD Impact Report, released today, included the following:

- Mean total phase time (sum of clinical and approval phase lengths) for CNS drugs during 2000-17 ranged from 8.2 years for anti-psychotics to 12.6 years for multiple sclerosis treatments.
- The most prevalent disease areas among CNS drug approvals during 2000-17 were epilepsy and psychosis, each receiving 10 approvals.
- The share of CNS approvals that received a priority rating more than doubled over the study period, from 18.8% for 2000-05 to 39.1% for 2012-17.

ABOUT THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

Established in 1976, the Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) is a multidisciplinary, academic research group that provides data-driven analyses and strategic insight to help developers, regulators, and policy makers improve the efficiency and productivity of pharmaceutical R&D. Tufts CSDD also offers CME-accredited professional development courses, hosts workshops and public forums, and publishes the Tufts CSDD Impact Report, a bimonthly newsletter focusing on critical drug development issues.

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