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New Anti-infective Drugs Had a 14% Speed Advantage vs. Other Drugs During 2000-19, According to Tufts Center for the Study of Drug Development

Anti-infectives were more likely than other drugs to receive expedited program designation, Tufts CSDD found

BOSTON – Sept. 15, 2020 – New anti-infective drugs that won marketing approval in the United States during the last two decades took 14% less time to undergo clinical trials and obtain regulatory approval compared to other drugs that came to market during the same period, a new analysis completed by the Tufts Center for the Study of Drug Development has found.

Combined clinical and approval phase timelines for anti-infective drugs was 7.1 years during 2000-19, compared to 8.3 years for all other drugs that were approved by the U.S. Food and Drug Administration (FDA) during the same period, according to Tufts CSDD.

From the first half to the second half of the two-decade period, mean total phase time (clinical plus approval phase times) for new anti-infective drugs declined by 3.0 months (3.4%), while that for all other drugs increased by 6.8 months (7.3%).

"Faster development times for anti-infective drugs is welcomed news, as the need for effective new medicines to treat novel pathogens and antibiotic-resistant infections continues to grow," said Joseph A. DiMasi, director of economic analysis and research associate professor at Tufts CSDD, principal investigator of the study.

The analysis was based on a study of 93 anti-infectives that received FDA approval from 2000 through 2019.

Other findings, summarized in the September/October *Tufts CSDD Impact Report*, released today, include the following:

- Mean clinical phase time for anti-infectives was 8.1% shorter, compared to all other drugs approved during 2000-09, and 14.8% shorter during 2010-19.
- Mean approval phase time for anti-infectives was 15.6% shorter, compared to all other drugs approved during 2009, and 23.1% shorter during 2010-19.
- Mean total phase time was 22% shorter for antivirals vs. other anti-infectives during 2000-19.
- 74.2% of anti-infective drug approvals received at least one facilitated regulatory pathway designation by the FDA, vs. 53.9% for all other drugs approved during 2000-19, with differences being notable only for fast track and priority review programs.

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 efficiency and productivity of pharmaceutical R&D. 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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