Cardiovascular Drug Approval Rate in the U.S. Fell as Development Time Rose

BOSTON – Sept. 12, 2017 – Although the rate at which investigational drugs received marketing approval in the United States has declined in recent years, the cardiovascular approval rate trailed other drug approvals as a whole, while the time needed to develop cardiovascular drugs rose, according to a recently completed study conducted by the Tufts Center for the Study of Drug Development.

Approval success rates for cardiovascular compounds fell from about 5.2% for compounds that began clinical testing during 1995-00, to about 2.2% for those that started trials during 2001-07, a 58% decline, according to the study. That compares to a decline from 13.9% to 12.9% for non-cardiovascular compounds.

During the same period, mean clinical development time for cardiovascular drug approvals lengthened nearly two years from 1999-04 to 2005-10, and increased another 7% from 2005-10 to 2011-16.

Those trends together accounted for a drop of cardiovascular products as a share of new drug approvals in the U.S. According to Tufts CSDD, new cardiovascular drugs accounted for 27% of all U.S. new drug approvals in the 1980s, but only 13% during 2010-16.

The findings were reported in the September/October Tufts CSDD Impact Report, released today.

"Demand for new cardiovascular drugs will continue, but developers seem to be shifting investments to other therapeutic areas, in part, in response to lengthening development times and lower approval rates associated with cardiovascular products," noted Joseph A. DiMasi, director of economic analysis at Tufts CSDD and the study's author.

He said rising development costs and regulatory uncertainty are among the factors that have increased development challenges for cardiovascular drugs.

Other findings from the study include the following:

- The overall clinical approval success rate for cardiovascular drugs first tested in human subjects from 1995 to 2007 was 3.7%, or less than one-third the 12.9% rate for non-cardiovascular drugs.
- Fewer new cardiovascular drugs received a priority rating compared to other drugs approved during 1999-16 (38% vs. 50%).
During 1999-16, mean approval phase time for cardiovascular drug approvals was 17.5 months, or 22%, longer than the 14.3 months for non-cardiovascular approvals.

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