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Oncology Drugs Get Faster Approvals than Non-Oncology Drugs in U.S., But the Opposite is True in the EU, According to Tufts Center for the Study of Drug Development

BOSTON – Sept. 5, 2012 –Approval times for new oncology drugs in the United States during the last decade were shorter than approval times for non-oncology products, while the reverse was the case in the European Union, according to a study recently completed by the Tufts Center for the Study of Drug Development.

For drugs approved by the U.S. Food and Drug Administration from 2002 through 2011, approval times were 10 months shorter for oncology vs. non-oncology drugs. In contrast, in Europe, approval times were almost two months shorter for non-oncology vs. oncology drugs.

During that period, oncology approvals accounted for 19% of all new drug approvals in the U.S. and 12% in the EU.

In addition, in both regions there was little difference in approval times between products that had a special designation—such as fast track, accelerated approval, and orphan designation—and those that did not.

“Oncology drug development continues to be challenging due to smaller patient populations for recruitment and longer periods for evaluation of treatment response,” said Christopher-Paul Milne, director of research at Tufts CSDD. “What’s encouraging is that while total development time for oncology and non-oncology drugs decreased by half a year during the 2002-11 period, for oncology drugs this was accomplished by process improvements that shortened regulatory review time.”

The study, reported in the September/October *Tufts CSDD Impact Report*, released today, also found that:

- Approval times for non-oncology drugs in the EU were 27% shorter than similar approvals in the U.S., but 54% longer for oncology therapeutics.
- Total development and approval time in the U.S. for fast track drugs dropped by 20% – from 8.3 years in 2002-06 to 6.6 years in 2007-11.
- In 2007-11, 39% of U.S. orphan approvals were for oncology drugs, up from 31% in 2002-06, while 37% of European orphan approvals were for oncology drugs in 2007-11, up from 28% in 2002-06.

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.

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