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Approval Success Rates Higher for Smaller Firms Among Top 50 Pharmaceutical Companies, According to Tufts Center for the Study of Drug Development

BOSTON – Sept. 9, 2010 – The top 10 pharmaceutical companies out of the world's top 50 have lower estimated overall clinical approval success rates than do smaller firms in that group, but nonetheless appeared to have some R&D productivity advantages, according to a new study completed by the Tufts Center for the Study of Drug Development.

Despite experiencing lower overall clinical success rates, the top 10 firms terminated a greater proportion of their failures in early stage clinical testing, compared to the other 40 companies in the group, the study found. Failing early lets developers redirect resources into other projects and avoid more costly later stage failures.

"While the very largest firms had lower approval success rates, they did make the decision to terminate earlier in the development process, which can help improve productivity of their new product pipelines," said Tufts CSDD Director of Economic Analysis Joseph A. DiMasi, who conducted the study.

He added, "The ultimate objective is to have higher success rates for drugs that are taken into clinical testing and earlier terminations of those that likely won't survive late clinical testing or regulatory review, or be successful in the marketplace."

The study was based on 1,734 compounds that entered clinical testing between 1993 and 2004, for the top 50 companies, which had 2006 revenues of more than $1 billion. The timeframe allowed for analysis of the full development cycle. Clinical approval success rate is the share of investigational new compounds entering clinical testing that eventually obtain FDA marketing approval.

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

* Small molecules accounted for 85% of the drugs that entered the clinical pipelines of top 50 pharmaceutical firms in the 1993-04 period.

* Large molecule clinical approval success rates outpaced small molecules by nearly 2:1 for each top-50 pharma size group examined.

* Across all top company size groups, transitioning compounds from Phase II to Phase III was a substantial hurdle.

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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