FOR IMMEDIATE RELEASE

Number of Monoclonal Antibody Products in Development Nearly Tripled in Last Decade, According to Tufts Center for the Study of Drug Development

BOSTON – March 11, 2008 – The number of monoclonal antibody products—known as mAbs—entering clinical study nearly tripled in the last decade and now require 7.6 years on average to complete the clinical development process and receive marketing approval, according to a new study completed by the Tufts Center for the Study of Drug Development.

Total development and approval times for mAbs, one of today's premier biotech tools, compare favorably with small molecule drugs, which require an average of 7.5 years to follow the same path, and with all biotech products, which require an average of 8 years.

"Historically the province of biotechnology companies, mAbs are now just as likely to be developed and marketed by major pharmaceutical firms as they are by biotechs," said Janice M. Reichert, senior research fellow at Tufts CSDD and author of the study.

She noted that mAbs have also become big business. In 2006, the global market for these products exceeded $17 billion, with sales forecasted to grow an average of 14% per year through 2012.

Currently, 21 such products have been approved for sale in the United States and abroad, and more than 200 are in clinical study.

Research results of the Tufts CSDD study, reported in the March/April *Tufts CSDD Impact Report*, released today, also found that:

* The average number of all mAb candidates entering clinical study nearly tripled from 12 in the mid-1990s to 34.5 in the mid-2000s.

* The share of human mAbs entering clinical study grew from 11% in the 1990s to more than 40% in 2000-06.

* Overall success rate was 17% for all humanized candidates, with a slightly lower rate (15%) for anticancer candidates and a slightly higher rate (21%) for immunological candidates.

* Transition probabilities for humanized mAbs that entered clinical study during 1988-06 were 83%, 44%, and 81%, respectively, for the three phase transitions.

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 the *Tufts CSDD Impact Report*, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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