FOR IMMEDIATE RELEASE

Number of Monoclonal Antibody Products in Development Continues to Increase, According to Tufts Center for the Study of Drug Development

BOSTON – Nov. 8, 2011 – Developers are steadily increasing the number of monoclonal antibody products—known as mAbs—for which they are initiating clinical studies, extending a trend that began in the 1990s, according to the Tufts Center for the Study of Drug Development.

The number of novel mAbs entering clinical study worldwide annually rose from 19 in 1997 to 53 in 2010, peaking at 54 in 2008, continuing a trend dating back to the mid-1990s when about a dozen mAb candidates entered clinical study each year, a recently completed Tufts CSDD analysis found.

According to Tufts CSDD, from 1997 through 2010, clinical and FDA approval phases for mAb therapeutics averaged 7.2 and 1.0 years, respectively.

Total development and approval times for mAbs compare favorably with small molecule drugs, which require an average of 7.5 years in total to follow the same path, as well as with all biotech products, which require an average of 8 years.

“Advances in antibody engineering and design, improvement in cell lines and manufacturing, and better understanding of targets and mechanisms of action are some of the key reasons why more mAbs are entering clinical study,” said Janice M. Reichert, author of the study, research assistant professor and senior research fellow at Tufts CSDD.

Today, about 314 mAb products are in clinical study worldwide.

First developed in the 1980s, mAbs began enjoying commercial success in 1997 when the U.S. Food and Drug Administration (FDA) approved Rituximab®. Since then, the market for mAb products has grown rapidly. Global sales of these products reached $48 billion in 2010 and are projected to approach $80 billion by 2015.

The Tufts CSDD study, reported in the November/December Tufts CSDD Impact Report, released today, also found that:

* The cumulative success rate—mAbs that completed clinical trials and received FDA approval—was 17% for all humanized mAb candidates, with a lower rate (13%) for anticancer candidates and a higher rate (26%) for immunological candidates.

* FDA approvals dropped slightly, from 16 in the 1997-04 period to 13 in 2005-11.

* Of mAbs in clinical study, 51% are focused on anticancer therapies, 27% on immunological treatments, and the remaining 22% on various indications.

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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