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Number of Therapeutic Peptides in Clinical Study Has Nearly Doubled Since the 1990s, According to Tufts Center for the Study of Drug Development

BOSTON – May 20, 2009 – Since 2000, the number of therapeutic peptides in clinical study have nearly doubled the 1990s rate, due in part to advances in synthesis, delivery, and formulation technologies, according to a study recently completed by the Tufts Center for the Study of Drug Development.

“Therapeutic peptides have emerged as a therapeutically and commercially important class of drugs and 48 are now on the market worldwide, with four having generated global sales of more than \$500 million each in 2007,” said Janice M. Reichert, senior research fellow at Tufts CSDD and author of the study.

The average annual number of therapeutic peptides entering clinical study worldwide in the 2000-07 period nearly doubled, to 16.9 from 9.7 during the 1990s, the study found.

Reichert said continued aggressive investing by the pharmaceutical industry in new therapeutic peptide product development is expected to continue at a strong pace for the foreseeable future.

While generally not as convenient to administer as traditional, small-molecule pharmaceuticals, peptides, such as ziconotide and degarelix, offer the advantage of providing greater specificity in targeting the cause of an ailment. Physicians and patients also are becoming more accepting of peptide-based medicines.

The Tufts CSDD study, aimed at eliciting a current picture of clinical development and approval trends for these products, done in cooperation with the Ferring Research Institute, examined data on 318 therapeutic peptide candidates that entered clinical study from the 1940s through October 2008.

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

- * During 2000-07, new peptides entering clinical development were most frequently studied as treatments for metabolic (26%) indications, one of 15 therapeutic areas in which peptides were being developed.
- * Average total clinical study and U.S. Food and Drug Administration review time for new therapeutic peptides was 10.8 years, 2.6 years longer than the combined average clinical study and review time for all drugs approved in the U.S. in 1993-07.
- * Efficacy issues and commercial considerations were most often cited as reasons for discontinuing clinical studies of new therapeutic peptides.

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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