May 9, 2017

**Accelerating Pace of Approvals and a Strong Development Pipeline Indicate Vigorous Growth for New Biotech Products**

BOSTON – May 9, 2017 – Biopharmaceuticals accounted for 35% of all new drug approvals in the United States from 2006 through 2016, and a robust development pipeline suggests that the recent increased pace of biotech approvals will continue for the next decade, according to a newly completed assessment from the Tufts Center for the Study of Drug Development.

The annual pace of 13 new biotech products approvals by the U.S. Food and Drug Administration during the study period accelerated to more than 20 per year during 2014-16, while 220 major pharmaceutical and biotechnology firms worldwide were conducting 429 Phase III trials for biopharmaceuticals at the end of 2016, Tufts CSDD found.

"Given the historically high, 74% Phase III-to-approval success rate of biologicals in late stage development, and the extensive biotech product pipeline, the high pace of biotech product approvals will likely continue through the next decade," noted Ronald Evens, PharmD, FCCP, adjunct research professor at Tufts CSDD, who conducted the analysis.

Evens said the relative advantages of biotechnology product development over small-molecule drugs—higher approval numbers and success rates, more first-in-class products with high impact on disease mitigation and cures, and a high likelihood of obtaining favorable reimbursement—will help maintain the current pace of biotech approvals in the U.S.

Following are key findings from the analysis, reported in the May/June Tufts CSDD Impact Report, released today:

- The FDA approved 225 new biotech products during 2000-16, compared to 304 small-molecule drug approvals during the same time.
- Biotech products in Phase III clinical trials spanned a broad range of molecules, with monoclonal antibodies accounting for 34.5% of the total.
- Biotech products spanned a broad range of disease areas in Phase III trials at the end of 2016, with one-third focused on oncology.
- Biosimilars accounted for more than 60 products in Phase III trials in 2016.

"By any measure, the biotechnology revolution has had a significant impact – by fostering development of life saving and life extending treatments and promoting dramatic growth in the biotech sector, which promises still more product innovation," said Evens.
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About the Tufts Center for the Study of Drug Development

The Tufts Center for the Study of Drug Development 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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