BIO Supports Timely Reauthorization of PDUFA to Promote the Development of Innovative Therapies and Speed New Medicines to Patients

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Washington, D.C. (September 1, 2011) – Biotechnology Industry Organization (BIO) President and CEO Jim Greenwood released the following statement on the Prescription Drug User Fee Act (PDUFA) V recommendations as published today* by the U.S. Food and Drug Administration (FDA):

"BIO supports the PDUFA V recommendations as they will enhance the drug development and review process through increased transparency and scientific dialogue, advance regulatory science, and strengthen post-market surveillance. Most importantly, PDUFA V will provide patients and doctors with earlier access to breakthrough therapies.

"Since PDUFA was enacted in 1992, it has contributed to the approval of more than 1,200 new medicines and initially reduced review times for the newest, most innovative drugs by more than a year. However, the human drug review program has been under considerable stresses in recent years as new regulatory requirements have been layered on the review process and the scientific complexity of applications has increased. As a result, overall approval times lengthened in the early years of PDUFA IV and patients were forced to wait longer for new therapies.

"Unpredictability in the review process, suboptimal communication with sponsors, and decreased FDA performance not only hinders patient access to new treatments, but also negatively impacts the ability of biotechnology companies to raise funding to support clinical development and ongoing innovation. This undermines economic growth in the biotechnology sector as well as biomedical research into key public health priorities.

"In PDUFA V, industry and FDA have agreed upon a set of enhancements that seek to restore FDA's review performance and get back-to-basics for patients by strengthening scientific dialogue and transparency between FDA and the sponsor during the review of a novel drug or biologic, with the goal of minimizing review issues that can delay patient access to needed treatments.

"To help advance American innovation and promote the development of the next generation of modern medicines, FDA has also committed to a philosophy that timely, interactive communication with biotechnology and life science companies during drug development is a core Agency activity. Additionally, the agreement makes new resources available to modernize regulatory science, for example, in the areas of personalized medicine and rare disease drug research. It will also enable the FDA to conduct outreach to patients to better understand patient perspectives on disease severity and unmet medical need.

"Under the agreement, industry has reinforced its commitment to a well-funded drug and biologics program that supports sound, science-based regulation consistent with FDA's public health mission. However, user fees are intended to support limited FDA activities around the drug review process and were never intended to supplant a sound base of appropriations. User fees currently account for nearly two-thirds of the cost of human drug review. We urge Congress to support FDA's mission and fund the Agency at the Administration's FY12 requested levels.

"Finally, it is critical for PDUFA to be reauthorized well in advance of PDUFA IV's expiration in September 2012 in order to avoid a reduction in force at the FDA. Even the threat of a downsizing at the FDA would be devastating to the Agency's public health mission and its ability to review new drugs and biologics.

"BIO looks forward to working with Congress and FDA to fully implement these enhancements under PDUFA V."

*FDA published the PDUFA V recommendations at
http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf.

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