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FOR IMMEDIATE RELEASE

AMP Delivers Oral Comments at FDA Workshop on Optimizing Regulatory Oversight of Next Generation Sequencing Diagnostic Tests

Recommends FDA Focus on Evaluating and Ensuring Consistent Performance of Next Generation Sequencing Diagnostic Tests

Bethesda, MD, February 20, 2015:

The Association for Molecular Pathology (AMP), the premier global, non-profit organization serving molecular laboratory professionals today presented at the U.S. Food and Drug Administration public workshop, "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests," outlining specific ways that FDA could best facilitate innovation of precision medicine. The purpose of the workshop is to discuss and receive feedback from the community on FDA's regulatory approach to diagnostic tests for human genetics or genomics using NGS technology.

A number of AMP members participated in the workshop today, including Roger D. Klein, MD, JD, Chair, AMP Professional Relations Committee who presented recommendations for FDA's role in assuring safe and effective NGS diagnostic tests. "Our members are among the early adopters and users of next-generation sequencing (NGS) in a clinical setting, and have accumulated substantial knowledge and expertise as it relates to this novel and powerful technology," said Dr. Klein. "On behalf of the many medical professionals who design, develop, perform, interpret, and communicate the results of clinical implications of these valuable diagnostic processes, we urge the FDA to consult with NGS experts and professional organizations in constructions of standards for NGS products."

AMP's oral comments emphasized four key points:

1. FDA can best contribute to patient care and public health by helping to ensure the performance characteristics of NGS products sold to customer laboratories.
2. FDA should partner with outside organizations and experts to set standards for FDA-cleared or approved products and to assist in development of recommendations and practice guidelines for clinical laboratories engaging in NGS testing.
3. The College of American Pathology (CAP), The American College of Medical Genetics and Genomics (ACMG), the Clinical Laboratory Standards Institute (CLSI), and other organizations have already produced laboratory accreditation requirements and practice guidelines that are used to ensure high-quality performance of NGS tests.
4. Although NGS represents a fairly new technology, the operational, validation and quality control procedures of the majority of medical NGS assays are extensions of those generally accepted for older technologies.

Furthermore, AMP points out that while they recommend FDA develop guidelines to safeguard proper performance of NGS products, they do not believe FDA has either the authority or the justification to regulate NGS beyond the instruments, software, test kits and reagents sold to customer laboratories. "The interpretation

and use of the genetic information derived from NGS diagnostic tests is at the heart of what we and ordering providers do," said Andrea Ferreira-Gonzalez, PhD, Chair of AMP's NGS Working Group. "As these activities are central to the practice of medicine, they must remain outside the purview of FDA."

AMP's oral comments are available here:
http://www.amp.org/advocacy/documents/AMPNGSMeetingcommentsFinalDraft.pdf

AMP plans to submit detailed written recommendations and comments to FDA on March 20, 2015.

About the Association for Molecular Pathology
The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. Through the efforts of its Board of Directors, Committees, Working Groups, and members, AMP is the primary resource for expertise, education, and collaboration on the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing. More information about AMP is available at www.amp.org.

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