

Epigenomics' Licensee ARUP Presents Clinical Data for Colorectal Cancer Blood Test at AMP

Epigenomics to host a corporate workshop on advances in blood-based colorectal cancer screening; ARUP Laboratories will present independent data for its laboratory-developed Septin9 test

Grapevine, TX, U.S.A., November 16, 2011 – Epigenomics AG, the German-American cancer molecular diagnostics company, announced today that its licensing partner ARUP will be presenting recent study data for its laboratory-developed Septin9 blood test for colorectal cancer (Septin9 LDT) at the 2011 Annual Meeting of the Association for Molecular Pathology in Grapevine, Texas. ARUP licensed the Septin9 biomarker from Epigenomics in 2009 and has been marketing Septin9 LDT since July 2010. The data will be presented at a workshop hosted by Epigenomics, entitled “Septin9 – A Plasma Marker for Colorectal Cancer”. Karen Heichman, Ph.D., Adjunct Assistant Professor of Pathology at the University of Utah School of Medicine and VP Oncology Technology Development and Licensing of ARUP Laboratories, Inc., Salt Lake City, UT, will present the ARUP study data.

In the study, ARUP's Septin9 LDT detected 90% of the colorectal cancer cases at a specificity of 88%. The detection rate for early, widely curable stage I and II disease was at 87%. The test detected cancer cases irrespective of the localization of the tumor in the colon. Using an alternative test interpretation algorithm that favors specificity over sensitivity, the test detected 70% of the cancer cases at 100% specificity, i.e. no false positive results. With these study results, ARUP's Septin9 LDT shows an impressive performance gain over earlier versions of Septin9 tests. Full results of the study will be published in the BMC Medicine medical journal later this year.

Karen Heichman, Ph.D., commented:

“The study results for our independently developed Septin9 tests show a significant improvement compared to historic data from earlier versions of the test and are in line with performances of other second generation Septin9 tests. With this performance and the convenience of a blood test, Septin9 tests can provide viable alternatives for average risk individuals unwilling or unable to undergo colonoscopy for colorectal cancer screening.”

Geert Nygaard, Chief Executive Officer of Epigenomics, added:

“We are pleased to see that the performance of Septin9 tests independently developed by our licensees like ARUP is comparable to previously released data for our own second generation Septin9 test product, Epi proColon® 2.0, which we recently launched in Europe. This underlines the value that blood-based Septin9 tests can bring to the detection of colorectal cancer.”

Further contributions to Epigenomics' corporate workshop include an overview by Brooks Cash, M.D., Bethesda, MD, of the colorectal cancer screening challenges from the perspective of a practicing gastroenterologist; he will also share the scope of this challenge in his everyday practice. Robert Day, M.D., President and Director Emeritus of the Fred Hutchinson Cancer Research Center, Seattle, WA, will give an account of the historical path that led to the identification of Septin9 as a biomarker for colorectal cancer early detection and address why new molecular screening tools are urgently needed. Nicolas Potter, Ph.D., Chief Scientific Officer and Director of Molecular Diagnostics at Molecular Pathology

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Laboratory Network, Inc., Maryville, TN, will describe the performance of an investigational use (IUO) diagnostic test kit for Septin9 being evaluated in a pivotal clinical trial sponsored by Epigenomics AG for FDA submission as well as share his operational and analytical observations relating to methylated Septin9 analysis and performance in a molecular diagnostic laboratory.

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Further Information

Epigenomics will host an AMP Annual Meeting 2011 Corporate Workshop entitled "Septin9 – A Plasma Marker for Colorectal Cancer" today, Wednesday, November 16, 2011 at 4 pm at the Gaylord Texan Convention Center, Level 3, Room Texas 4. The workshop will cover multiple perspectives of the challenges in colorectal cancer screening and will include presentations by:

- Karen Heichman, Ph.D., Adjunct Assistant Professor of Pathology at the University of Utah School of Medicine and VP Oncology Technology Development and Licensing of ARUP Laboratories, Inc., Salt Lake City, UT,
- Brooks Cash, M.D., Gastroenterologist, Bethesda, MD,
- Robert Day, M.D., President and Director Emeritus of the Fred Hutchinson Cancer Research Center, Seattle, WA, and
- Nicolas Potter, Ph.D., Chief Scientific Officer and Director of Molecular Diagnostics at Molecular Pathology Laboratory Network, Inc., Maryville, TN.

Contact Epigenomics AG

Antje Zeise | CIRO
Manager IR/PR
Epigenomics AG
Tel +49 (0) 30 24345 386
pr@epigenomics.com
www.epigenomics.com

Media inquiries can also be directed at:

Dr. Robert Mayer
Account Manager
Tel +49 (0)89 5238 8030
robert.mayer@collegehill.com

About Epigenomics

Epigenomics is a molecular diagnostics company developing and commercializing a pipeline of proprietary products for cancer. The Company's products enable doctors to diagnose cancer earlier and more accurately, leading to improved outcomes for patients. Epigenomics' lead product, Epi proColon[®], is a blood-based test for the early detection of colorectal cancer, which is currently marketed in Europe and is in development for the U.S.A. The Company's technology and products have been validated through multiple partnerships with leading global diagnostic companies including Abbott, QIAGEN, Sysmex, and Quest Diagnostics. Epigenomics is an international company with operations in Europe and the U.S.A.

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