Current Agreements

Dealdoc

Collaborative R&D and licensing agreement for DNA methylation biomarker septin 9

Abbott Laboratories
Epigenomics

Sep 26 2007

Collaborative R&D and licensing agreement for DNA methylation biomarker septin 9

Companies:	Abbott Laboratories Epigenomics
Announcement date:	Sep 26 2007

Details

Announcement date:	Sep 26 2007
Industry sectors:	Bigpharma Pharmaceutical Diagnostic
Therapy areas:	Oncology » Colorectal cancer
Technology types:	Biomarkers Diagnostics
Deal components:	Collaborative R&D Development Licensing Option
Stages of development:	Discovery
Geographic focus:	Worldwide

Financials

Milestones, US$m:	n/d : milestone payments
Royalty rates, %:	n/d : royalties on product sales
More details:	Reimbursements in connection with the PRESEPT study.

Termsheet

Non-exclusive strategic collaboration and license agreement in molecular diagnostics with Abbott.

Abbott and Epigenomics intend to develop an in vitro diagnostic blood test for the early detection of colorectal cancer based on Epigenomics' proprietary DNA methylation biomarker Septin 9.

The agreement also contains provisions for the evaluation by Abbott of some of Epigenomics' other proprietary biomarkers for additional cancer indications.

Expanded agreement - Nov 2008

Expanded non-exclusive strategic partnership and amended their collaboration and license agreement in molecular diagnostics closed on September 25, 2007 accordingly.

Under the amended agreement Abbott obtains additional non-exclusive commercial licenses to Epigenomics' proprietary DNA methylation technology to develop and commercialize a blood test for colorectal cancer detection based on Epigenomics' biomarker Septin 9.

Further, Abbott obtains access to blood samples collected in the ongoing PRESEPT clinical study sponsored by Epigenomics.

The samples are to be used in the clinical validation of an Abbott Septin 9 IVD test product for regulatory approval in the U.S.

In return, Epigenomics will receive a technology license fee, certain milestone payments and reimbursements in connection with the PRESEPT study and royalties on product sales.

Press Release

Epigenomics AG Announces Strategic In Vitro Diagnostics Partnership with Abbott Molecular

Date: Wednesday, 26.09.2007

Collaboration focuses on development and global commercialization of a molecular diagnostic test for the early detection of colorectal cancer

Abbott obtains non-exclusive worldwide rights to Epigenomics' proprietary DNA methylation biomarker Septin 9 Anticipate European market launch in 2009; filing for U.S. approval in 2010 Epigenomics to receive an up-front fee, milestone payments and royalties Option to expand partnership on multiple Epigenomics biomarkers to other cancer indications

Berlin, Germany, and Seattle, WA, USA,

Epigenomics AG (Frankfurt Prime Standard: ECX; ISIN: DE000A0BVT96) has signed today a non-exclusive strategic collaboration and license agreement in molecular diagnostics with Abbott, a global healthcare company. Under the agreement, Abbott and Epigenomics intend to develop an in vitro diagnostic blood test for the early detection of colorectal cancer based on Epigenomics' proprietary DNA methylation biomarker Septin 9.

The companies anticipate launching a CE-marked test in Europe in 2009 followed by regulatory filing for U.S. approval in 2010. Under the terms of the agreement, Epigenomics will receive an up-front fee, milestone payments and royalties on product sales.

The agreement also contains provisions for the evaluation by Abbott of some of Epigenomics' other proprietary biomarkers for additional cancer indications.

End of Ad hoc

"We are very excited about the agreed partnership with Abbott, one of the global industry leaders in molecular diagnostics. This agreement is an important step towards the commercialization of our key value driver, the blood-based colorectal cancer test. It validates the clinical utility and the commercial attractiveness of this test as well as our revised non-exclusive partnering strategy and creates a potential route to market for our entire early cancer detection franchise," commented Geert Nygaard, Chief Executive Officer of Epigenomics.

The colorectal cancer test will represent the first cancer diagnostic in the growing menu of assays on Abbott's automated m2000 instrument, which is gaining strong acceptance in molecular diagnostics laboratories throughout the world. Abbott will conduct clinical trials and seek regulatory approval worldwide.

Conference Call

The management of Epigenomics will host a conference call at 9 am EST / 3 pm CET today to provide further details and answer questions by investors, analysts, and media. The dial-in numbers for the conference call are:

Dial-in number (within Germany): +49 (0) 6958 999 0805

Dial-in number (US and outside Germany): +1-480-293-1744

Participants are kindly requested to dial in 10 minutes prior to the start of the call.

A recording of the conference call will be provided on Epigenomics' website subsequently:
http://www.epigenomics.com/en/down_loads/corporate_material/

About Colorectal Cancer Testing and the Septin 9 Biomarker

Colorectal cancer is the second leading cause of cancer related death. With a cure rate of over 90 percent if diagnosed in early stages, early detection through testing would be valuable. This type of test targets almost 300 million people in Europe, the U.S., and Japan, a market that, in our opinion, is worth more than USD 3 billion in total. The gold standard screening test is colonoscopy, an invasive procedure, whereby the physician visually inspects the inside of the colon. This procedure, which has excellent specificity and sensitivity characteristics, not only identifies cancer but also pre-cancerous lesions known as adenomas. Due to the nature of this procedure and its high cost, it is not widely used at short intervals. A non-invasive first-line test therefore would be useful to screen individuals at risk so that they then undergo colonoscopy. Currently, most non-invasive screening is carried out with the fecal occult blood testing (FOBT) procedure using stool samples. However, due to the inconvenient nature of the test, the compliance rate is comparatively low (approximately 16 percent in the United States). The introduction of a more convenient, patient-friendly test could potentially increase the number of individuals tested. If positive, the patients would be followed up

by colonoscopy. This could increase the chances of the disease being caught early with the goal of reducing mortality from colorectal cancer.

Epigenomics' technology sensitively detects DNA based on specific DNA methylation patterns in blood plasma samples or other body fluids. The Septin 9 gene encodes a protein involved in cell division and is thought to play a role in the onset of cancer. Epigenomics has demonstrated in multiple clinical case control studies with about 3,000 blood plasma samples from colorectal cancer patients, healthy controls, and patients with non-cancerous colon diseases that methylated DNA of Septin 9 shed by tumors into the blood stream can serve as a biomarker for the sensitive and specific detection of colorectal cancer.

About DNA methylation

DNA methylation is a tightly controlled biological process that fundamentally affects gene expression and genome stability. Cytosine, one of the four bases in DNA, can be modified by the covalent addition of a methyl group. DNA methylation in gene regulatory regions (i.e. gene promoters) helps control gene activity. Every cell type has its unique DNA methylation fingerprint that changes in various normal biological processes and in many diseases, in particular cancer. In our opinion, DNA methylation thus provides a rich source for highly specific biomarkers for organ-specific disease diagnosis, classification and prediction for therapeutic intervention.

About Epigenomics AG

Epigenomics is a molecular diagnostics company with a focus on the development of novel products for cancer. Using DNA methylation biomarkers, Epigenomics' tests can potentially diagnose cancer at an early stage and help guide physicians to select an appropriate therapy. Epigenomics' defined business strategy covers two complementary core business areas:

The company develops diagnostic screening tests for the early detection of cancer. Based on body fluid samples (e.g. blood and urine), these tests are aimed at finding cancer at an early stage before symptoms occur. Epigenomics' product pipeline contains a validated biomarker panel for the early detection of colorectal cancer in blood plasma, and further proprietary DNA methylation biomarkers at various stages of development for prostate and lung cancer detection in body fluids. Epigenomics aims at giving patients and doctors early access to these biomarkers through reference laboratory testing services. For development and global commercialization as in vitro diagnostic test kits, Epigenomics pursues a non-exclusive partnering strategy with diagnostics industry players.

As a second core business area, Epigenomics develops specialty diagnostics for individuals at high risk for cancer and cancer patients. These tests include surveillance applications of our colorectal cancer biomarkers and a tissue-based prognostic cancer molecular classification test for prostate cancer patients. Our tissue-based prostate cancer application is developed in strategic partnerships with Qiagen (pre-analytics) and Affymetrix (diagnostic device platform). The biomarkers for cancer specialty diagnostic applications will be made available through testing services in centralized reference laboratories. Epigenomics retains the flexibility to decide on further commercialization as in vitro diagnostic test kits in Europe.

Pharma, diagnostics and biotech partners can access Epigenomics' portfolio of proprietary DNA methylation technologies and biomarkers protected by more than 190 patent families (granted patents and patent applications) through Biomarker Services, IVD Development Collaborations, and Licensing. The company is headquartered in Berlin, Germany, and has a wholly owned subsidiary in Seattle, WA, USA. For more information, please visit Epigenomics' website at www.epigenomics.com.

Epigenomics AG and Abbott Molecular Inc. Expanded Strategic In Vitro Diagnostics Partnership

18.11.2008

Epigenomics AG (Frankfurt Prime Standard: ECX; ISIN: DE000A0BVT96) and Abbott Molecular Inc. (Abbott) today have expand their non-exclusive strategic partnership and amended their collaboration and license agreement in molecular diagnostics closed on September 25, 2007 accordingly.

Under the amended agreement Abbott obtains additional non-exclusive commercial licenses to Epigenomics' proprietary DNA methylation technology to develop and commercialize a blood test for colorectal cancer detection based on Epigenomics' biomarker Septin 9. Further, Abbott obtains access to blood samples collected in the ongoing PRESEPT clinical study sponsored by Epigenomics. The samples are to be used in the clinical validation of an Abbott Septin 9 IVD test product for regulatory approval in the U.S. In return, Epigenomics will receive a technology license fee, certain milestone payments and reimbursements in connection with the PRESEPT study and royalties on product sales.

Both companies jointly work with good progress and according to plan on the development of a Septin 9 IVD test product for Abbott's m2000 molecular diagnostics instrument and continue anticipating the launching of a CE-marked test in Europe in late 2009 followed by regulatory filing for U.S. approval in 2010.

The Septin 9 blood test for colorectal cancer detection is Epigenomics' leading product in development. With the PRESEPT clinical study, Epigenomics intends to demonstrate that blood testing for colorectal cancer with the Septin 9 biomarker fulfills the requirements of current U.S. guidelines for colorectal cancer screening and has the potential to provide health economic benefits.

Epigenomics AG: Strategic Partner Abbott Launches Colorectal Cancer Blood Test in Europe and Asia/Pacific 21.12.2009

Epigenomics AG (ISIN: DE000A0BVT96), a cancer molecular diagnostics company, informs that its strategic licensing and collaboration partner Abbott launched a molecular diagnostic blood test to aid in the diagnosis of colorectal cancer in Europe and Asia/Pacific. The in vitro diagnostic test is based on Epigenomics' proprietary biomarker Septin9. Abbott licensed the non-exclusive worldwide rights to Septin9 in September 2007. The in vitro diagnostic test is commercialized by Abbott under the brand name Abbott RealTime mS9 Colorectal Cancer Assay and is optimized for Abbott's RealTime system m2000. The launch triggers a milestone payment to Epigenomics. Going forward Epigenomics will participate in the commercial success of the mS9 Colorectal Cancer Assay through royalties on product sales as well as certain sales-related milestones. With the launch Epigenomics continues executing its dual business model of non-exclusive licensing and direct commercialization of its cancer molecular diagnostic tests.

End of Ad hoc

Epigenomics legal disclaimers. This communication expressly or implicitly contains certain forward-looking statements concerning Epigenomics AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of Epigenomics AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Epigenomics AG is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

Filing Data

Not available.

Contract

Not available.