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Press Release Search report

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Company: BioAlliance Pharma
Date: 2009-04-09

BIOALLIANCE PHARMA TO COMPLETE NDA FOR LORAMYC® WITH DATA ON DEBOSSSED MUCOADHESIVE TABLET

Paris, April 9, 2009 – BioAlliance Pharma SA (Euronext Paris: BIO), the specialty pharmaceutical company focused on the treatment of opportunistic infections in cancer and AIDS, today announced that the FDA did not accept the NDA for Loramyc® (miconazole) mucoadhesive buccal tablet (MBT) to be filed based on the lack of a tablet imprint code. Loramyc® was approved in Europe in 2007 and is currently marketed in several EU territories including France, Germany, the UK, Sweden, Finland and Denmark. While the EU does not require a unique tablet identifier, the U.S. FDA does require a tablet imprint code for drug identification purposes. Prior to the initial filing, BioAlliance initiated the development of a debossed tablet to fulfill this requirement. BioAlliance will work closely with the FDA on the introduction of the debossed tablet and will soon after resubmit the Loramyc® application.

Company: Eckert & Ziegler
Date: 2009-04-09

IBt and Russian state fund set up joint venture to manufacture prostate cancer implants in Russia

Berlin, 09 April 2009. International Brachytherapy S.A. (IBt), an associated company of Eckert & Ziegler AG (ISIN DE0005659700), together with the Russian state fund Rusnanotech and local partners, will set up a joint venture to supply Russian prostate cancer patients with therapeutic implants and other innovative medical devices. A declaration of the establishment of "NanoBrachyTech", in which IBt will hold a minority share, was signed yesterday in Berlin.

The joint venture, which will be based in Moscow, wants to invest up to EUR 23.2 million in the next five years on acquiring manufacturing licenses, building a production facility and expanding the distribution network. The special systems for producing the weakly radioactive implants are to be obtained from Pankow-based Eckert & Ziegler BEBIG GmbH, a world leader in the field of automation technology for radioactive components.

"The fact that the people in charge in Russia have chosen IBt as their comprehensive partner and supplier for their modernization work in the healthcare sector provides proof of the Group's competence and the international recognition that the treatment of prostate cancer with weakly radioactive implants has now attained," said Andreas Eckert, chairman of the board of Eckert & Ziegler and supervisory board chairman of IBt. "For IBT, in addition, the joint venture demonstrates that interesting growth prospects for innovative radiation technology exist not only within the European core markets but also in markets which were previously underdeveloped, such as Russia."

The Eckert & Ziegler Group, which is predicting turnover of around EUR 100 million for 2009 and has approximately 520 employees, is one of the world's largest suppliers of isotope technology components for radiation therapy and nuclear medicine.

Company: PAION
Date: 2009-04-09

PAION AND ERGOMED REPORT FULL DATA OF CNS 5161 PHASE IIA STUDY IN NEUROPATHIC CANCER PAIN

April 09, 2009--Aachen (Germany) and Frankfurt (Germany) 9 April 2009 – The biopharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8) and ERGOMED Clinical Research Limited today announce data from the open-label Phase IIA study with the NMDA receptor antagonist CNS 5161 which was completed in December 2008. The final reported data confirm that the substance is safe and welltolerated within the applied administration scheme which covered a large dose range. Adverse events were of mild and moderate intensity, relating mainly to the cardiovascular and the nervous system and were completely resolved following end of treatment. Importantly, none of the psychomimetic side effects normally associated with NMDA antagonist have been observed whilst signs of pain reduction were noted even at the second lowest dosing.

The study was intended to explore the optimal schedule for infusion of CNS 5161 in the management of neuropathic cancer pain and included 24 patients with opioid-refractory cancer pain. Its primary objective was to define the maximum tolerable dose and to assess the relationship between the plasma concentration of CNS 5161 and changes in pain level. In total, 24 patients received study treatment of which 22 patients received complete course of treatment. The patients were divided into six dose cohorts receiving cumulative dosages between 750 and 4,500 mcg which were applied as six short i.v. infusions every four hours over 20 hours. In the study no dose limiting toxicity was observed.

Efficacy signals were observed in all but the lowest dose cohort. On the 10- grade numerical pain rating scale (NPRS), mean values dropped by 3.0 points from 6.2 to 3.2 at 32 hours, excluding the first (lowest dose) cohort. This represents an approximately 50% reduction in pain in these patients. EMEA guidelines for neuropathic pain indicate that a 30-50% reduction in pain can be considered a response.

Dr Wolfgang Söhngen, PAION's CEO commented: "Based on the encouraging results of the study, good tolerability paired with efficacy signs already at low dosing, we are positive that CNS 5161 warrants further testing in opioid refractory cancer pain. The next logical step would be an extended placebocontrolled Phase II study in order to show proof-of-concept. This could be achieved with a reasonable investment. Together with our partner ERGOMED we have come to the conclusion that we seek third party (co)-funding."

Dr Miro Reljanovic, CEO of ERGOMED added, "As co-development partner we are very pleased with the results of this study and are looking forward to working with PAION to find a partner to continue to work with us on the further development of CNS 5161."

Company: Micromet
Date: 2009-04-08

Pre-Clinical Data on CEA-specific BiTE Antibody Published in Journal of Immunotherapy Demonstrate Potent Control of Tumor Growth

BETHESDA, Md., April 8, 2009 -- Micromet, Inc. (Nasdaq: MITI), a biopharmaceutical company developing novel, proprietary antibodies for the treatment of cancer, inflammation and autoimmune diseases, today announced the publication of data in the peer-reviewed *Journal of Immunotherapy* (1) demonstrating the potent anti-tumor activity of a BiTE antibody binding to carcinoembryonic antigen (CEA) and to CD3 on T cells. Micromet and MedImmune are jointly developing MT111/MEDI-565, a CEA-specific BiTE, which is in pre-clinical development.

CEA, also called CD66e or CEACAM5, was selected as target antigen for development of a new BiTE antibody program because CEA is widely expressed on the surface of human carcinoma cells. In its soluble form, CEA serves as a marker in patients' blood for progression of colorectal and other forms of solid cancers. Conventional CEA-targeting antibodies can be blocked by soluble CEA and prevented from binding to CEA on the surface of cancer cells, thereby limiting antibody efficacy. The new study shows that novel BiTE antibodies have strong activity against CEA-expressing cancer cells in vitro and in animals, even in the presence of high levels of soluble CEA.

"Our new publication demonstrates not only that BiTE antibodies can be designed to bind to well established target antigens of conventional monoclonal antibodies, but also that BiTE antibodies have features that improve on the properties of conventional antibodies," commented Micromet's Chief Scientific Officer Dr. Patrick A. Baeuerle. "Many target antigens for cancer therapy are released by cancer cells into the blood stream, a process called shedding. The example of the CEA-specific BiTE antibody suggests that high levels of shed antigens may not pose a limitation for the anti-tumor activity of BiTE antibodies."

Reference

(1)Lutterbuese, R. et al. (2009). Potent control of tumor growth by CEA/CD3- bispecific single-chain antibody constructs that are not competitively inhibited by soluble CEA. *Journal of Immunotherapy*, April 1, 2009 [epub ahead of print]

Company: Ark Therapeutics
Date: 2009-04-07

Cerepro® Phase III trial update

London, UK, 7 April, 2009 - Ark Therapeutics Group plc (AKT:LSE) ("Ark" or "the Company") is pleased to announce that it has completed the first update of the results of its Cerepro® Phase III trial (Study 904) in accordance with reporting regulations. Cerepro®, Ark's novel gene-based medicine, is being developed as an Orphan Drug for the treatment of operable malignant glioma. The update showed the main results strengthening in Cerepro's® favour.

Study 904 was a multicentre, standard care controlled, pivotal trial in 236 patients. The study was designed to confirm the safety and efficacy of Cerepro® in patients with operable high grade glioma (brain cancer) against current standard care treatment options. Standard care was surgery and radiotherapy or surgery and radiotherapy followed approximately 40 days post-operatively by temozolomide, depending on the investigating centres' standard practice and patient suitability. Patients were randomised to either standard care plus Cerepro® (one administration by multiple injection into the healthy brain at the end of the tumour resection procedure) or standard care alone. The primary endpoint was survival, defined as time to death or re-intervention(1). At randomisation, the treatment groups were well matched in terms of demographics and the standard prognostic features (age, Karnofsky Score etc).

Results of the Phase III trial were first reported on 30 July 2008 when 53 patients had yet to reach a primary endpoint. In the latest update analysis, median survival and adverse event profile results are consistent with those previously reported. On the primary endpoint of death or re-intervention, Kaplan Meier curves have improved to show a clear sustained separation from around 4 months post surgery in favour of Cerepro® treatment. Significance levels associated with the main data have improved in the update analyses. Twenty nine patients have still to reach a primary endpoint event (versus 53 previously), of which 18 have been treated with Cerepro® and 11 received standard care.

In relation to secondary endpoints, Magnetic Resonance Image (MRI) assessment of the progression free survival time, accounting for pseudo-progression, are supportive of the primary endpoint results. The effect of Cerepro® on overall survival (all cause mortality) is, as expected, complicated by the number of crossover therapies used after reintervention. Data do however show increasing support for improved overall survival in patients receiving Cerepro® after about 500 days with 56 patients in the trial still alive.

A marketing approval application (MAA) for Cerepro® was filed with EMEA in Q4 2008 and regulatory review commenced early this year. An opinion from the CHMP is expected in Q4 of this year.

(1) Re-intervention is defined as any kind of treatment (surgery, chemotherapy or radiotherapy) given to prolong survival after tumour recurrence.

Dr. Nigel Parker, Chief Executive of Ark commented: "We are pleased with the latest update of the study. The pattern we are seeing appears to be closely tracking our experiences with the previous Phase II studies where results strengthened in favour of Cerepro® treatment as the data on the longer surviving patients becomes available. The update will be provided to the regulators in accordance with standard process. Overall, our adenoviral platform and portfolio is making consistent progress and we look forward to providing the market with further updates on the portfolio in due course."

Company: Genmab
Date: 2009-04-03

ARZERRA™ (OFATUMUMAB) GRANTED PRIORITY REVIEW BY FDA

Copenhagen, Denmark; April 3, 2009 – Genmab today announced that the US Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) for Arzerra™ (ofatumumab) to treat patients whose chronic lymphocytic leukemia (CLL) is resistant (refractory) to previous therapies and has granted ofatumumab priority review status.

Under priority review, the FDA sets the target date for a decision from regulators at six months, rather than the standard 10 month review. If approved, ofatumumab would be the first monoclonal antibody targeted to CD20 available for this patient population. In addition, the FDA has granted ofatumumab orphan designation for the treatment of CLL. The BLA was submitted on January 30, 2009.

“We are pleased that the ofatumumab BLA has been accepted for review by the FDA and look forward to the outcome of the review process,” said Lisa N. Drakeman, Ph.D., Chief Executive Officer of Genmab.

The acceptance of the BLA will trigger a milestone payment from GSK to Genmab of DKK 87 million (approximately \$15 million). In addition, Genmab will also receive a one-time payment of \$4.5 million from GSK in exchange for terminating its option to co-promote Arzerra™. In December 2008, GSK and Genmab amended their initial agreement and GSK now has exclusive global commercialization rights to Arzerra for all potential indications.

Company: Helsinn Healthcare
Date: 2009-04-02

PALONOSETRON “PREFERRED” 5-HT₃ ANTAGONIST FOR EMESIS PREVENTION IN ONCOLOGY PATIENTS RECEIVING HIGHLY EMETOGENIC CHEMOTHERAPY

Lugano (Switzerland), April 2nd 2009 – Based on the important multicenter study published in *The Lancet Oncology* by the equipe of Dr. Mitsue Saito, last February (Saito M., Aogi K., Sekine I. et al.; *Lancet Oncology* 2009 Feb; 10(2):115-24. Epub 2009 Jan 8), the National Comprehensive Cancer Network (NCCN, a not-for-profit alliance of 21 of the world’s leading cancer centres), antiemesis panel members have reached consensus to include only palonosetron, the second generation 5-HT₃ receptor antagonist, as the “preferred” 5-HT₃ antagonist, in the combined regimen recommended for emesis prevention in patients undergoing highly emetogenic chemotherapy. According to the NCCN, the newly recommended regimen comprises: palonosetron (0.25 mg IV on day 1) plus aprepitant (125 mg PO on day 1, and 80 mg PO daily on days 2 and 3; on day 1, aprepitant may be substituted by fosaprepitant 115 mg IV) plus dexamethasone (12 mg PO or IV on days 1 to 4).

The decision follows the data recently published by Saito, who showed, in a phase III comparator trial conducted in Japanese patients undergoing highly emetogenic chemotherapy including antracycline and cyclophosphamide containing regimens (AC/EC) that palonosetron is better than granisetron, a first generation drug of the same class, in preventing chemotherapy-induced nausea and vomiting (CINV) during the delayed phase, defined as 24-120 hours after the initiation of anti-cancer treatment. In the acute phase, defined as the first 24 hours of the start of chemotherapy, palonosetron is as effective as granisetron with a comparable safety profile.

“The NCCN recommendation is an important recognition of palonosetron’s therapeutic value and a new milestone achievement for the product”, commented Andrea Meoli, Chief Commercial Officer at Helsinn, the Swiss pharmaceutical group developer and worldwide licensor of palonosetron.

Company: Micromet
Date: 2009-04-02

Micromet Receives Milestone Payment for Filing of the First Clinical Trial Application for MT203

BETHESDA, Md., April 2, 2009 -- Micromet, Inc. (Nasdaq: MITI), a biopharmaceutical company developing novel, proprietary antibodies for the treatment of cancer, inflammation and autoimmune diseases, today announced the filing of the first clinical trial application (CTA) in Europe by its partner Nycomed for the anti-GM-CSF antibody MT203. Micromet received a payment of 1.5 million Euro (US\$ 2.0 million) from Nycomed for the achievement of this milestone.

Under a 2007 agreement between the two companies, Micromet and Nycomed are developing MT203, a human anti-GM-CSF antibody that may be useful for the treatment of various inflammatory and autoimmune diseases. Preclinical studies support development of MT203 for the treatment of rheumatoid arthritis and several other diseases, including multiple sclerosis, psoriasis, asthma and chronic obstructive pulmonary disease.

"Since the start of our collaboration with Nycomed in 2007, we have made excellent progress on the preclinical development of MT203," said Jens Hennecke, Micromet's Senior Vice President of Business Development. "The filing of the CTA represents an important milestone and we are looking forward to the start of clinical trials with MT203."

Company: MolMed
Date: 2009-04-02

Results of Phase I/II trial of MolMed's TK therapy in high risk acute leukaemia published in The Lancet Oncology

Milan, Italy - April 2 2009 – MolMed S.p.A. (MLM.MI) announces that results obtained in the European multicentric Phase I/II study (TK007) of its TK therapy have been published in the April issue of the prestigious medical journal The Lancet Oncology, issued today.

The article - Infusion of suicide gene-engineered donor lymphocytes after family haploidentical hemopoietic transplantation for leukemia: the TK007 phase I/II trial - gives insight into the outcome of the trial, conducted on 54 adult patients, that resulted in significant survival improvement of patients affected by high risk acute leukaemia receiving bone marrow transplants from a partially compatible family donor (haplo-transplants). In this context, the introduction of TK therapy allows the use of add-backs of donor T lymphocytes, that promote a rapid and wide immune reconstitution, abating transplant-related mortality and permitting long-term survival.

The intention-to-treat (ITT) analysis shows that treatment with TK proved to greatly improve safety and efficacy of haplo-transplants, thus enabling feasibility and effectiveness of transplants in adult patients from partially incompatible family donors.

Fabio Ciceri and Chiara Bonini, first authors of the article and principal investigators of TK therapy at the San Raffaele Hospital, the coordinator centre of trial TK007, commented: "Treatment with TK proved to be an effective tool for promoting immune reconstitution in transplants from partially compatible donors: most importantly, the remarkable results obtained in this trial definitively show that early and sustained immune-reconstitution results in abatement of mortality, thus making haplo-transplants widely possible in a safe and effective manner".

Claudio Bordignon, Chairman and Chief Executive Officer of MolMed, as well as senior and corresponding author of the article, stressed: "In fact, today TK is the only investigational new therapy addressing the issue of enabling safe and effective haplo-transplants in adult recipients without immune-suppression or immune-depletion, and thereby opening the door of bone marrow transplant to all patients".

The very positive outcome of Phase I/II trial TK007, as already communicated to the market and included in MolMed's Offering Circular, allowed MolMed to get authorisation to begin a Phase III randomised trial that started in Italy in Spring 2008, and will be expanded to other European clinical centres this year: Phase III trial TK008 is pivotal for the registration of TK therapy, that could become among the very first cell therapies using genetically engineered cells to obtain marketing approval.

MolMed's partner for the Asian markets, Takara Bio Inc. (OTCPK:TKBIF), started clinical development of TK in Japan in October 2008, with a Phase I trial in relapsed leukaemia patients conducted at the National Cancer Center in Tokyo.

Company: Immutep
Date: 2009-04-01

A Phase I clinical trial of ImmuFact IMP321 in pancreatic cancer has started at Washington University in Saint Louis (MO)

April 01, 2009 -- Immutep S.A. announced today the first administration of IMP321 in pancreatic cancer patients in a Phase I trial conducted by Dr. William G. Hawkins at the Washington University School of Medicine in Saint Louis (MO).

IMP321 is a first-in-class immunopotentiator that stimulates antigen-presenting cells (APC), such as dendritic cells and monocytes, leading to markedly improved cytotoxic CD8 T cells responses against tumours in patients. The pancreatic cancer trial follows the promising results obtained in metastatic breast cancer with a similar chemo-immunotherapy protocol.

The phase I study is an open-label, two-arm, dose escalation trial in advanced pancreatic cancer treated by first-line gemcitabine alone or associated with increasing doses of IMP321 (3, 6.5, 13 and 26 mg). Investigators will assess the safety and tolerability of this new chemo-immunotherapy combination. The other points to be studied include IMP321's pharmacokinetics, pharmacodynamics, immunogenicity, a preliminary assessment of anti-tumour activity as well as the exploration of the molecule's mechanism of action. IMP321 will be given s.c. q14 for a 6-month period the day after gemcitabine administration, with an option for additional months of therapy if disease improvement or stabilisation is observed. Approximately 33 patients are expected to be enrolled.

Company: QIAGEN
Date: 2009-04-01

Landmark Study in New England Journal of Medicine Shows HPV Testing Significantly Reduces Deaths from Cervical Cancer, Compared to other Methods Including Pap

Venlo, The Netherlands - April 1, 2009 - Results from an eight-year trial involving more than 130,000 women published today in The New England Journal of Medicine (NEJM) demonstrate that in low-resource settings a single round of HPV testing significantly reduces the numbers of advanced cervical cancers and deaths, compared with Pap (cytology) testing or visual inspection with acetic acid (VIA). The trial used QIAGEN's (NASDAQ: QGEN; Frankfurt, Prime Standard: QIA) digene HPV Test, which detects high-risk types of human papillomavirus that cause cervical cancer.

"The implications of the findings of this trial are immediate and global: international experts in cervical-cancer prevention should now adapt HPV testing for widespread implementation," wrote Drs. Mark Schiffman and Sholom Wacholder of the U.S. National Cancer Institute in an editorial that accompanied the study in the NEJM. "The remarkable promise of the Indian trial presents a worthy global challenge to implement smart, regionally tailored strategies that will efficiently save millions of lives in the years ahead."

Following this milestone study, over the next five years QIAGEN will donate one million HPV tests, with a total estimated value of over US\$30 million (based on U.S. list prices), as part of its broader global access program to provide the highest quality cervical cancer screening technologies to women in developing countries. Nearly 300,000 women die of cervical cancer every year, with 80% of deaths occurring in developing countries.

QIAGEN's commitment to expanded access to HPV screening includes:

HPV test donation programs, in partnership with leading public health institutions and health non-governmental organizations (NGOs)

Development of next-generation HPV technologies, including the careHPV test - designed specifically for low-resource, developing countries

Tiered-pricing initiatives for low-resource countries

"This landmark study further validates the value of QIAGEN's HPV test as the gold standard for cervical cancer screening and demonstrates that the incidence of advanced cervical cancer and deaths are actually reduced - and hence lives saved - when HPV screening is implemented," said Peer Schatz, Chief Executive Officer of QIAGEN. "QIAGEN's HPV testing technology is already being used to routinely screen millions of women in the United States and Europe. We're committed to working together with the public health community to ensure that women everywhere have access to the best cervical cancer prevention tools." Moving forward QIAGEN will collaborate with a team of global health partners - including the International Planned Parenthood Federation and Jhpiego, an international non-profit health organization affiliated with Johns Hopkins University - on the administration of the donation program.

Led by Dr. Rengaswamy Sankaranarayanan of the International Agency for Research on Cancer (IARC), the randomized, controlled trial compared the efficacy of three methods of cervical cancer screening: VIA, Pap testing (cytology) and HPV testing with QIAGEN's hybrid capture 2 (hc2) DNA testing technology (called the digene HPV Test). The study was conducted in the Maharashtra state of India, and was supported with funding by the Bill & Melinda Gates Foundation.

It is the first randomized controlled trial to measure incidence of cervical cancer and associated rates of death as the primary outcomes, using different tools for screening. In addition to being "associated with a significant reduction in the numbers of advanced cervical cancers and deaths from cervical cancer," QIAGEN's HC2 HPV testing platform "was the most objective and reproducible of all cervical cancer screening tests and was less demanding in terms of training and quality assurance," the study authors state. The study is posted to <http://content.nejm.org/>.

QIAGEN broadens access to HPV testing

QIAGEN's donation of 1 million HPV tests builds upon the company's programs to increase access to HPV testing and cervical cancer prevention technologies for women worldwide through QIAGENcares, a corporate social responsibility program to improve the access to better screening methods for infectious diseases in emerging and developing countries. Current commitments include donation programs, development of next generation HPV technologies, tiered-pricing initiatives and on-the-ground pilot cervical cancer screen-and-treat projects.

To ensure that HPV testing can reach women in all regions of the world, QIAGEN is working with PATH and the Bill & Melinda Gates Foundation to develop a new version of its state-of-the-art HPV test - to be called the careHPV test - for public-health programs in low-resource, developing countries. The careHPV test, currently in development, can be performed without electricity or running water and offers HPV detection results in a matter of hours - a critical characteristic for women traveling to clinics from isolated villages and for those women who may need to be treated the same day. Both QIAGEN HPV screening technologies - careHPV and the digene HPV Test - are expected to play a key role in reducing cervical cancer worldwide. Both will be included in the donation program.

As part of its on-the-ground programs, QIAGEN is preparing to launch a mobile cervical cancer screening clinic in India. India has more cervical cancer cases than any other country in the world and cervical cancer is the number one cause of cancer related death among women. Additionally, in China, QIAGEN is providing HPV testing products to 29 hospitals as part of a nationwide prevention campaign organized by the Cancer Foundation of China. For more information on QIAGENcares and the donation program, visit www.qiagen.com/QIAGENcares.