BioAlliance Pharma announces positive preliminary phase I clinical results with its AMEP® biotherapy for metastatic melanoma

Paris, September 13, 2011 - BioAlliance Pharma SA (Euronext Paris - BIO), a company dedicated to specialty and orphan oncology products, today announced preliminary phase I clinical results with its AMEP® biotherapy developed in advanced or metastatic melanoma, an invasive skin cancer of bad prognosis.

The objectives of this first phase I trial were to evaluate the safety of intratumoral electrotransfer of AMEP® biotherapy and to detect a first signal of efficacy. The evolution of the AMEP electrotransferred melanoma lesions was compared with that of a distant lesion in the same patient, with the same initial size. Ten intratumoral electrotransfers have been performed in 3 specialized centers in Europe: in Denmark at the Copenhagen University Herlev Hospital, in France at the Gustave Roussy Institute of Villejuif and in Slovenia at the Institute of Oncology of Ljubljana.

Safety has been shown to be satisfactory at doses assessed, 0.5mg and 1mg. A stabilization of tumor growth has been obtained in 60% of lesions treated with AMEP® biotherapy whereas all control tumors, not treated, were progressing. Moreover, objective tumor regression has been observed in 20% of cases.

AMEP® targets specific receptors (integrins), particularly expressed by melanoma cells, both involved in tumor growth and tumor angiogenesis. These preliminary phase I results validate the clinical concept of AMEP® and enable to prepare the next step: AMEP® will be administered via intramuscular route to confirm its safety and to obtain a systemic effect in patients with metastatic melanoma.

"These preliminary clinical results confirm the interest of the AMEP® biotherapy. It is a breakthrough treatment combining a new target, integrins, to an original transfer of therapeutic nucleic acid. This program, co-financed by OSEO's Strategic Industrial Innovation Program to the "Cancer Anti-invasive Program" (CAP), is developed in a consortium associating the academic research, industrials and melanoma clinicians, with notably a research extended to specific "companion" markers, necessary to the follow up of these patients suffering from a severe disease", explains Pierre Attali, COO of BioAlliance Pharma, in charge of Strategy and Medical Affairs.

"It was important to AMEP® to have efficacy together with in situ safety data to prepare the next step of its development. AMEP® is one of the 3 "Orphan oncology products" portfolio in clinical phase supporting BioAlliance's ambition to become a major player in this area", comments Judith Greciet, CEO of BioAlliance Pharma.

About the electrotransfer technology
The electrotransfer technology enables chemical or biological substances to be transferred to target cells thanks to an effective, safe, simple, and repeatable delivery of electric pulses. Used for several years in chemotherapy for cutaneous and subcutaneous metastatic lesions, notably in skin, breast and head & neck cancers, this technology is specifically used for the transfer of biological active substances, such as AMEP® plasmid.

About BioAlliance Pharma
Dedicated to cancer and supportive care treatment with a focus on resistance targeting and orphan products — BioAlliance conceives and develops innovative products, for specialty markets especially in the hospital setting and for orphan or rare diseases.
Created in 1997 and introduced to the Euronext Paris market in 2005, BioAlliance Pharma's ambition is to become a leading player in these fields by coupling innovation to patient needs. The company's teams have the key competencies required to identify, develop and register drugs in Europe and the USA; the products' commercialization rights are licensed to international commercial partners invested in the hospital setting. In areas where medical needs are insufficiently met, its targeted approaches help overcome drug resistance and improve patient health & quality of life.
BioAlliance Pharma has developed an advanced product portfolio:

Specialty products
Loramyc®/Oravig® (oropharyngeal candidiasis in immunocompromised patients): Registered in 28 countries (EU US, Korea)
Sitavir® (Acyclovir Lauriad™) (labialis herpes): Positive phase III final results; registration status
Fentanyl Lauriad™ (chronic cancer pain): Positive preliminary Phase I results

Orphan Oncology products
Livatag® (Doxorubicin Transdrug™) in primary) liver cancer: Authorization for Phase III clinical trial
Clonidine Lauriad™ (mucositis): Phase II on going
AMEP® (invasive melanoma): Phase I on going
For more information, visit the BioAlliance Pharma web site at www.bioalliancepharma.com

Disclaimer
This communication expressly or implicitly contains certain forward-looking statements concerning BioAlliance Pharma SA 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 BioAlliance Pharma SA to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. BioAlliance Pharma SA 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.
For a discussion of risks and uncertainties which could cause actual results, financial condition, performance or achievements of BioAlliance Pharma SA to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the 2010 Reference Document filed with the AMF on April 7, 2011, which is available on the AMF website (http://www.amf-france.org) or on BioAlliance Pharma SA's website (http://www.bioalliancepharma.com).

BioAlliance Pharma SA
Judith Greciet, CEO
Tel +33 1 45 58 76 00
judith.greciet@bioalliancepharma.com
Nicolas Fellmann, CFO
Tel.: +33 1 45 58 71 00
nicolas.fellmann@bioalliancepharma.com

ALIZE RP
Caroline Carmagnol
Tel.: +33 6 64 18 99 59
caroline@alizerp.com