



Presentation of Phase I clinical results with AMEP[®] biotherapy in the treatment of metastatic melanoma

At the European Society for Medical Oncology Congress (ESMO)

Paris, October 1, 2012 - BioAlliance Pharma SA (Euronext Paris - BIO), an innovative Company dedicated to the development of orphan oncology products and to supportive care products, presented safety and tolerance results of the phase I clinical study with the AMEP[®] biotherapy in the metastatic melanoma at the annual congress of ESMO (European Society for Medical Oncology) in Vienna, Austria (September 28th – October 1st).

These results were presented by Dr Julie Gehl (Clinical Associate Research Professor at University of Copenhagen Department of Oncology, Herlev Hospital of Copenhagen, Denmark), Principal Investigator of the study, in the form of an abstract and of a poster: *“Proof of concept of gene therapy using plasmid AMEP in disseminated melanoma: Safety and efficacy results of a phase I first-in-man study”*. Two other specialized European cancer centers were also involved in the study: the Gustave Roussy Institute in Villejuif (France) and the Institute of Oncology in Ljubljana (Slovenia).

AMEP[®] targets specific receptors (integrins) particularly expressed by melanoma cells and vascular endothelial cells, both involved in tumor growth and tumor angiogenesis (formation of neovascularization inducing tumour growth). This first phase I clinical trial, conducted in advanced or metastatic melanoma, has shown a very good safety profile of the biotherapy administered by local electrotransfer (intratumoral) as well as satisfactory signals of efficacy. Based on these positive results, BioAlliance Pharma is pursuing the development of its biotherapy and obtained last June the approval of the phase I/II clinical trial application from the regulatory authorities. This trial, to be conducted on a European level, aims now at evaluating the safety and efficacy profile of the AMEP[®] biotherapy administered via systemic route (intramuscular) in the same indication.

« The presentation of the first results of AMEP[®]'s clinical development at a renowned European oncology congress, shows the interest and the innovation of a promising and original project whose clinical development is conducted by specialized European centers », declares Dr Bérangère Vasseur, Clinical Development Director of BioAlliance Pharma.

“This first-in-man study showed that gene electrotransfer of plasmid AMEP[®] could be safely administered, and transfection was obtained in tumors. This represents the successful conclusion of a European collaboration to perform gene therapy using this novel agent. Already follow-up studies are approved, and we look forward to the results of this continued effort to explore novel treatment paradigms”, declares Dr Julie Gehl.

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.

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[®]/Sitavig[®] (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[™]) (primary liver cancer): Phase III on going

Validive[®] (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

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