



***BioAlliance Pharma announces two new key steps  
in the development of its AMEP® biotherapy***

**Paris, April 26, 2012** – BioAlliance Pharma SA (Euronext Paris - BIO), a company dedicated to orphan oncology products and specialty products, today announces the validation by the French drug agency (Afssaps) of its application for a phase I/II clinical trial with Amep® in the metastatic melanoma, and the signature of a partnership agreement for the development of its biotherapy with the Department of Oncology of the Herlev Hospital of Copenhagen.

Submitted end of January 2012, the phase I/II clinical trial application follows the positive preliminary results of a first phase I trial via local administration (intratumoral) in patients with metastatic melanoma. This phase I/II trial, to be conducted on a European level, aims at evaluating the safety and efficacy profile of the Amep® biotherapy via systemic route (intramuscular) in the same indication. The growing incidence of metastatic melanoma and the short survival duration of patients make this cancer a disease with a very strong therapeutic need.

Moreover, BioAlliance Pharma and the Herlev Hospital of Copenhagen have recently signed a partnership agreement to conduct a complementary phase I clinical trial with Amep® in Denmark. This trial, currently under evaluation by the Danish Medicines Agency, aims at evaluating the safety and the efficacy of the Amep® biotherapy in patients with different types of metastatic solid tumors. It will be conducted by Dr Julie Gehl, Oncologist, Clinical Associate Research Professor at University of Copenhagen, who was already actively involved in the first phase I trial via local route, and thus reinforces the development plan of this asset.

*“As planned, we are pursuing the European development of a particularly innovative therapy, developed and valued in a consortium associating academic research, industrials and melanoma clinicians, and co-financed by OSEO's Strategic Industrial Innovation Program”, declares Judith Greciet, CEO of BioAlliance Pharma. “The collaboration with a great European oncology centre, in partnership with Dr Julie Gehl, to evaluate the interest of Amep® in other types of cancers is an interesting opportunity that reinforces the value of this key asset. The receivability of the phase I/II trial via intramuscular route, together with this partnership agreement, represent two key achievements in the clinical development of Amep®, an original biotherapy of our strategic portfolio”.*

## **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<sup>®</sup>/Oravig<sup>®</sup> (oropharyngeal candidiasis in immunocompromised patients): Registered in 28 countries (EU, US, Korea)

Sitavir<sup>®</sup> (Acyclovir Lauriad<sup>™</sup>) (labialis herpes): Positive phase III final results; registration status

Fentanyl Lauriad<sup>™</sup> (chronic cancer pain): Positive preliminary Phase I results

### **Orphan Oncology products**

Livatag<sup>®</sup> (Doxorubicin Transdrug<sup>™</sup>) in primary liver cancer: Authorization for Phase III clinical trial

Clonidine Lauriad<sup>™</sup> (mucositis): Phase II on going

AMEP<sup>™</sup> (invasive melanoma): Phase I on going

For more information, visit the BioAlliance Pharma web site at [www.bioalliancepharma.com](http://www.bioalliancepharma.com)

### **Disclaimer**

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*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 2011 Reference Document filed with the AMF on April 24, 2012, which is available on the AMF website (<http://www.amf-france.org>) or on BioAlliance Pharma SA's website (<http://www.bioalliancepharma.com>).*

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