



***BioAlliance Pharma submits application for orphan medicinal product designation for clonidine Lauriad™ in Europe and the United States***

**Paris, June 24, 2011** – BioAlliance Pharma SA (Euronext Paris - BIO), a company dedicated to the supportive care and treatment of cancer patients, today announced the submission to the European (EMA) and American (FDA) Drug Agencies of an application for orphan medicinal product designation for clonidine Lauriad™, in the prevention of radiotherapy-induced oral mucositis in patients with head and neck cancer.

Clonidine Lauriad™, presently in phase II clinical trial in Europe, is dedicated to the prevention of oral mucositis, a debilitating inflammation of the oral mucosa possibly altering the general condition of patients with head and neck cancer treated with radiotherapy and radio- and chemotherapy (the number of new patients in Europe and the United States is estimated to be 120,000 per year). Nearly 80% of these patients are affected by this severe disease which currently has no proven cure.

*“The orphan drug designation for clonidine Lauriad™, which should be granted by the end of 2011, will permit to optimize its development plan as well as its access to the market. Clonidine Lauriad™ is thus a key asset of our “Orphan Oncology Products” portfolio and its orphan designation in two major territories is particularly important for the continuation of its development. This product joins our orphan product portfolio currently undergoing clinical development”,* declares Judith Greciet, COO.

The orphan medicinal product designation is defined by the number of patients affected by the disease, between 200,000 and 250,000 in the US and Europe, and benefits from incentive measures notably related to the development plan and to the patent protection duration of orphan designated products.

## 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)

Setofilm® (prevention and treatment of nausea and vomiting post chemo-radiotherapy and post operative) - Registered in EU

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: Phase II results on survival

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](http://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>).*

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