BioAlliance Pharma submits a phase III clinical trial application for Livatag® (doxorubicin Transdrug™) to the French Drug Agency (Afssaps)

Paris, June 27, 2011 – BioAlliance Pharma SA (Euronext Paris - BIO), a company dedicated to specialty and orphan oncology products, today announces the submission of a phase III clinical trial application for Livatag® in the treatment of primary liver cancer to the French Drug Agency (Afssaps).

This application follows the phase II survival data announced by BioAlliance Pharma in March 2011 and showing a doubled median survival in Livatag® treated patients (32 months, to be compared with 15 months for patients treated with best of care TACE transarterial chemoembolisation with a cytotoxic drug). This 17 months difference in survival strongly reinforces the interest in the product and justifies a phase III clinical trial application.
These results have been accepted for oral communication at the International Liver Cancer Association (ILCA) 2011 congress.

Moreover, BioAlliance has validated a new administration regimen in animal models, which significantly reduces acute pulmonary adverse events. The phase II trial had been hold in July 2008 due to pulmonary toxicity, whereas patients' survival has been followed up, upon request from the independent study Drug Safety Monitoring Board.

" The survival data jointly with the validated administration scheme aiming to prevent acute pulmonary adverse events justify to re-open the dialog with the French Drug Agency, for a phase III clinical trial that could be initiated in 2012", comments Pierre Attali, COO, Strategy and Medical Affairs of BioAlliance Pharma.

"This application represents a major step within the final development stage of Livatag® before registration, as it has been granted an orphan drug status. The primary liver cancer still represents a high unmet medical need in terms of survival. The global potential turnover of such a product can be evaluated between 800 million and 1 billion Euros. We expect a launch on the market in a 3 to 5 years time, according to the clinical trial results, either through international partnerships, or through direct commercialization in Europe", comments Judith Greciet, COO, Operations & R&D.

About Livatag®

Primary liver cancer, or hepatocellular carcinoma, is the fifth cancer in incidence and the third leading cause of cancer deaths worldwide. This cancer is highly chemo-resistant, very often diagnosed at an advanced stage and still represents a high unmet medical need.
Livatag® is a treatment presented in nanoparticles able to deliver doxorubicin in chemoresistant cells. Livatag® was granted an orphan drug status in Europe and in the United States.

Livatag® is today the leader in the orphan oncology products portfolio, also including clonidine Lauriad™ in the prevention of radiotherapy-induced oral mucositis in patients with head and neck cancer (phase II) and AMEP® in metastatic melanoma (phase I).

About ILCA

The International Liver Cancer Association (ILCA) is the only international organization devoted exclusively to liver cancer research for experts from all related disciplines. It aspires towards advancing research in the pathogenesis, prevention, and treatment of liver cancer.

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: 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

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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 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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