Two key validation steps achieved by BioAlliance Pharma

Validation of Phase III clinical trial application for Livatag®

Validation of « orphan drug » designation application for clonidine Lauriad™ in Europe and the United States

Paris, July 13, 2011 – BioAlliance Pharma SA (Euronext Paris - BIO), a company dedicated to specialty and orphan oncology products, announces the validation of its application for a Phase III clinical trial for Livatag® (doxorubicin Transdrug™) in the treatment of primary liver cancer submitted to the French Drug Agency (Afssaps). This will enable the review of the preclinical and clinical dossiers by the experts of the Agency.

Submitted on June 27, 2011, the Phase III clinical trial application is based on particularly striking survival data observed in the Phase II trial (17-month increase in the median overall survival as compared to that of chemoembolization) together with a new administration scheme, validated on an animal model, enabling to significantly prevent acute pulmonary adverse events. This trial aims at demonstrating efficacy of Livatag® on survival in patients with hepatocellular carcinoma after failure of or intolerance to sorafenib. A regular monitoring will be performed by an independent expert board.

"The validation of our application means that the French Drug Agency (Afssaps) is to start the evaluation procedure, thus allowing us to confirm our schedule with the initiation in 2012 of the Phase III clinical trial, the last step of Livatag®'s development", comments Pierre Attali, COO, Strategy and Medical Affairs of BioAlliance Pharma.

Moreover, the European (EMA) and American (FDA) Drug Agencies have validated the application for orphan medicinal product designation for clonidine Lauriad™, in the prevention of radiotherapy-induced oral mucositis in patients with head and neck cancer.

« The orphan drug designation for clonidine Lauriad™ will strengthen its place in our "Orphan Oncology Products" portfolio and will permit us to benefit from major incentive measures such as optimized development duration and costs, a commercial exclusivity in Europe and in the United States, as well as attractive price levels", declares Judith Greciet, COO.

This validation confirms the announced schedule for the grant of orphan status designation of this product, expected in Q4 2011.

« The validation of both applications strengthens the development steps and the progress of these two leading products in our "Orphan Oncology Products" portfolio", added Judith Greciet. *Made of products with high potential turnover and particularly attractive profitability profiles, this portfolio will enable to accelerate growth, notably thanks to a potential direct commercialization on some territories. This strategy should optimize our revenues while being more independent from partners, and maximize our profit".*

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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BioAlliance Pharma SA
Judith Greciet, CEO
Tel +33 1 45 58 70 61
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