BioAlliance Pharma announces the forthcoming extension of its phase II clinical trial with Validive® in the United States

Paris, February 14, 2013 - BioAlliance Pharma SA (Euronext Paris - BIO), an innovative Company dedicated to the development of orphan oncology products and to supportive care products, announces the extension of its phase II clinical trial with Validive® (clonidine Lauriad™) in the United States in radio/chemotherapy-induced oral mucositis prevention in patients with head and neck cancer.

Further to approval by the United States FDA (Food and Drug Administration), BioAlliance Pharma will extend its clinical trial to the United States, increasing the number of clinical investigation centers involved in this randomized double blind phase II trial.

So far almost 50% of planned patients have been enrolled in about 30 European centers. With the upcoming initiation of several centers in the United States, BioAlliance Pharma expects to finalize trial recruitment in early 2014 with results expected the same year.

"Beyond accelerating recruitment, the extension of the trial to the United States is also a key factor to reinforce our international panel of scientific experts and clinical investigators around Validive®. This will raise awareness and create hands-on experience of the drug of future key prescribers of Validive® in major US centers specialized in oncology and radiotherapy", stated Judith Greciet, CEO of BioAlliance Pharma.

Severe oral mucositis is a particularly invalidating pathology occurring in more than 60% of patients treated with radio/chemotherapy for head and neck cancer and has currently no validated curative or preventive treatment. It may induce intense oral pain and eating disability requiring enteral or parenteral nutritional support. Thirty per cent of patients need to be hospitalized as a result and symptoms can force patients to stop treatment for an undefined period thus reducing treatment efficacy.

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): Registered in 8 European countries, registration status in the US
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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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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