Approval to start ReLive (Livatag®)
Phase III Clinical Trial in Primary Liver Cancer in the US and Germany

Paris, December 4, 2013 – BioAlliance Pharma SA (Euronext Paris - BIO), an innovative Company dedicated to the development of orphan oncology and to supportive care products, announces that it has received authorization to start its Phase III ReLive clinical trial in primary liver cancer in the US (IND approval), following the review of the Livatag® development program by the FDA, as well as in Germany after the German health agency green light.

"The deployment strategy planned was to implement the clinical trial first in France, then to expand it to Europe and then to the United States in 2014. The schedule is currently fully respected as the study is already implemented in Europe since last summer, and clinical operations will now be able to start in the U.S in order to open investigating centers ", stated Pierre Attali, COO in charge of Strategy and Medical affairs.

Regarding Europe, BioAlliance Pharma is also enlarging the study to Germany following the authorization granted by the BfArM (German health agency). This extension in a territory with a strong recruitment potential follows authorizations already obtained in Spain, Italy, Russia, Hungary, Austria and Belgium.

ReLive, an international phase III randomized trial, aims to demonstrate the efficacy of Livatag® on survival in 400 patients with hepatocellular carcinoma after failure or intolerance to sorafenib. To date, twenty centers have been opened and more than 80 patients have been enrolled, in line with the recruitment objectives set by the Company.

The international extension of Livatag® trial is necessary to meet the recruitment timelines objectives which anticipate an end of recruitment in 2015 and preliminary results in 2016.

"The IND approval of our Phase III clinical trial protocol in the United States is a key milestone for BioAlliance. In addition to the geographic expansion and the acceleration of patient enrollment, the implementation of ReLive in the United States will allow world's leading experts in hepatology and oncology to build their own experience on the product", stated Judith Greciet, CEO of BioAlliance Pharma.

About BioAlliance Pharma

Dedicated to cancer and supportive care treatment with a focus on resistance targeting and orphan products, BioAlliance Pharma 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 26 countries (EU, US, Korea), commercialized in Europe and in the US.
Sitavig® (Acyclovir Lauriad®) (labialis herpes): Registered in the US and in 8 European countries, registration status in the other European countries.
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 2012 Reference Document filed with the AMF on April 18, 2013, 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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