

***BioAlliance Pharma announces third positive DSMB recommendation to continue its Phase III clinical trial with Livatag® in primary liver cancer***

**Paris, October 22, 2013** - BioAlliance Pharma SA (Euronext Paris - BIO), an innovative Company dedicated to the development of orphan oncology and to supportive care products, today announced that the International Independent Board of Experts' Data and Safety Monitoring Board (DSMB), in charge of the safety profile of the ReLive Phase III trial, unanimously recommended continuing the study without modification for the third time since the trial's initiation.

The DSMB meets every 6 months and/or after reaching 75 treated patients to evaluate the tolerance of Livatag® and to ensure patient safety. In continuance with its November 2012 and April 2013 recommendations, the DSMB unanimously confirmed its recommendation to continue the study, based on its positive assessment of all safety data of Livatag®.

ReLive is an international, randomized Phase III trial aiming at demonstrating the efficacy of Livatag® on survival in 400 patients with advanced Hepatocellular Carcinoma (primary liver cancer) after failure of intolerance to Sorafenib.

As of the end of September, about 20 centers are opened in France and enrollment is on track with the plan. The European extension of the trial is ongoing as planned with authorizations already obtained in 6 countries (Spain, Italy, Russia, Hungary, Austria and Belgium). The Company plans to expand the trial to the United States in 2014, enabling completion of recruitment in 2015 and data in 2016.

*"The follow up of Livatag®'s safety is a major aspect of the ReLive study. The reaffirmed recommendations of the DSMB and its positive evaluation of Livatag®'s safety data are crucial as they strengthen an acceptable safety profile of the product", comments Judith Greciet, CEO of BioAlliance Pharma. "Livatag® is a key drug for the Company with potential sales of several hundreds of millions and addressing patients for whom there is no other therapeutic alternative".*

## **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<sup>®</sup>/Oravig<sup>®</sup> (oropharyngeal candidiasis in immunocompromised patients): Registered in 26 countries (EU, US, Korea), commercialized in Europe and in the US.

Sitavig<sup>®</sup> (Acyclovir Lauriad<sup>®</sup>) (labialis herpes): Registered in the US and in 8 European countries, registration status in the other European countries.

Fentanyl Lauriad<sup>®</sup> (chronic cancer pain): Positive preliminary Phase I results

### **Orphan Oncology products**

Livatag<sup>®</sup> (Doxorubicin Transdrug<sup>™</sup>) (primary liver cancer): Phase III on going

Validive<sup>®</sup> (Clonidine Lauriad<sup>®</sup>) (mucositis): Phase II on going

AMEP<sup>®</sup> (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 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 ().*

### **BioAlliance Pharma SA**

Judith Greciet, CEO

[judith.greciet@bioalliancepharma.com](mailto:judith.greciet@bioalliancepharma.com)

Nicolas Fellmann, CFO

[nicolas.fellmann@bioalliancepharma.com](mailto:nicolas.fellmann@bioalliancepharma.com)

Tel.: +33 1 45 58 76 00

### **ALIZE RP**

Caroline Carmagnol

+33 6 64 18 99 59

[caroline@alizerp.com](mailto:caroline@alizerp.com)

Christian Berg

+33 6 31 13 76 20

[christian@alizerp.com](mailto:christian@alizerp.com)