

## BioAlliance Pharma announces a new positive DSMB recommendation to continue its Phase III clinical trial with Livatag<sup>®</sup> in primary liver cancer

**Paris, April 14, 2014** - BioAlliance Pharma SA (Euronext Paris - BIO), an innovative Company specialized in the development of drugs in orphan oncology diseases, today announced that the European Independent Board of Experts (Data Safety and Monitoring Board, DSMB), in charge of the safety profile of the ReLive Phase III trial, today held its fourth meeting and once more unanimously recommended continuing the study without modification.

The DSMB meets every 6 months and/or after reaching 75 treated patients to evaluate the tolerance of Livatag<sup>®</sup> and to ensure patient safety. For the fourth time since November 2012, the DSMB unanimously recommended to continue the study without modification, based on its positive assessment of all safety data of Livatag<sup>®</sup> and thus confirmed the good safety profile of the product.

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

As of today, about 40 centers are opened in Europe and more than 25% of patients are enrolled, on track with the plan. The trial is still expanding in Europe and implementation of investigator centers is ongoing in the United States further to the green light obtained from the FDA last December. The recruitment should be completed end of 2015 for expected data end of 2016.

"Each new positive recommendation from our DSMB – now covering over 25% of enrolled patients – strengthens the tolerance evaluation of Livatag<sup>®</sup>," comments Judith Greciet, CEO of BioAlliance Pharma. "This positive evaluation is a major step forward in the overall assessment of this drug being developed for a rare cancer with no or few therapeutic alternatives, and representing sales potential estimated at nearly  $\notin$ 800 million."

## About BioAlliance Pharma

Dedicated to cancer treatments with a focus on resistance targeting and orphan products, BioAlliance Pharma conceives and develops innovative products 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:

## **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

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