

***BioAlliance Pharma provides updates on its major achievements and reports  
2013 consolidated financial results***

***2013: Significant progress on key strategic programs***

- *Livatag® phase III (ReLive): European expansion and authorization from the FDA to perform the trial in the US*
- *Validive®: Fast track designation granted, allowing future accelerated review by the FDA*
- *NDA granted for Sitavig® by FDA. For the second time, BioAlliance succeeds to register a drug in the US*

***2014: Consolidation and key milestones achievement***

- *Validive® international Phase II preliminary results expected Q4 2014*
- *US expansion of ReLive trial (Livatag®)*
- *License agreements with Sitavig® expected in the coming months*

**Paris, February 27, 2014** – BioAlliance Pharma SA (Euronext Paris - BIO), an innovative Company dedicated to the development of orphan oncology products, today published its 2013 financial results, major achievements on its clinical programs in 2013 and its prospects 2014.

The year 2013 was marked by key milestones achieved in the development of its two major products, Livatag® and Validive®:

- ReLive, Livatag® phase III clinical trial in the treatment of primary liver cancer, has continued in line with the international expansion strategy of the study.

Since mid-2013 the trial has been extended to 7 European countries and is being implemented in the United States, following the Investigational New Drug (IND) authorization received from the FDA at the end of 2013. More than 100 patients have been enrolled and the geographic expansion will support patients' enrolment increase. Last patient is scheduled to be enrolled late 2015 with preliminary results expected in 2016.

Finally, as part of its bi-annual review, the international Board of independent experts (Data Safety Monitoring Board) confirmed the product's good safety profile twice in 2013.

- Validive® phase II clinical trial in the prevention of severe oral mucositis has been strongly accelerated and nearly 95% of the patients have already been enrolled to date. The Company expects to complete patient recruitment in the coming weeks with preliminary results expected in the second half of 2014.

*Fast track* designation has been granted from US FDA to Validive®, a status dedicated to treatments addressing very serious diseases, with high unmet medical needs. This designation will allow for the

accelerated review of clinical data, thereby reducing the time to potential market authorization by about 3 to 6 months.

Both products, at an advanced stage of their development, target severe diseases with poor therapeutic alternatives. Positioned in markets of hundreds of millions Euros, they represent major growth drivers for the Company in the short and medium term.

For the second time, BioAlliance Pharma has succeeded to register a drug in the US with NDA granted for Sitavig® in the treatment of recurrent labial herpes. Advanced discussions regarding partnerships are ongoing and agreements are expected in the coming months.

Key figures from the consolidated financial statements for the financial year 2013 are summarized in the table below:

|                          | <i>In'000s of Euros</i>          | <b>31/12/2013</b> | <b>31/12/2012</b> |
|--------------------------|----------------------------------|-------------------|-------------------|
| Total sales              |                                  | 1 467             | 4 028             |
|                          | <i>Incl. non recurring sales</i> | 530               | 3010              |
| Total operating expenses |                                  | 16 909            | 15 559            |
| Operating income         |                                  | -15 437           | -11 515           |
| Net income               |                                  | -15 320           | -11 548           |

Consolidated income amounted to €1.5 million in 2013 and mainly resulted from the commercial partners' activity related to Loramyc®/Oravig®. The difference as compared to the previous year is due to the recognition in 2012 of non-recurrent payments under license agreements with Therabel and Vestiq companies for a total amount of €2.5 million. Considering Oravig®'s sales level, no payment of milestone from American partner Vestiq is expected in the short term.

Operating expenses amounted to €17 million (+ 8.6% as compared to 2012), including €10 million expenses for R&D, increased by 26% compared to 2012, excluding regulatory taxes. This significant financial effort has primarily supported the acceleration and international expansion of Validive® and Livatag® clinical programs, while also reflecting the Company's efforts to control general and administrative expenses.

The consolidated cash position as of December 31, 2013 amounted to €11.3 million, notably following a €8.4 million fund raising realized in July 2013, which was oversubscribed by 155%. Beyond licensing agreements expected in the coming months, the Company is considering the most appropriate funding strategy to pursue the dynamic deployment of its programs.

*"The Company's strategy is to become a key player in the orphan oncology diseases and its growth will be sustained by both its key products in these pathologies. In 2013, significant progress has been achieved on these programs, and especially in the United States with the IND for Livatag® and the Fast track designation for Validive®. Phase II preliminary results for Validive®, expected in Q4 2014 will represent a major catalyst of value creation for this asset. Based on our expertise and supported by the dynamic advancement of our programs, BioAlliance has everything in place for a strong growth",* comments Judith Greciet, CEO of BioAlliance Pharma.

**BioAlliance will comment on major current issues and its annual financial statements during its SFAF meeting which will be held on February 28, 2014 at 9:30am at the Company's headquarters (49 boulevard Martial Valin, Paris 15°, France), and during the audio/web conference the same day at 6:00 pm:**

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<https://bioalliancepharma-en.webex.com/bioalliancepharma-en/j.php?MTID=mb91c47bc59bbfc7d5785a7fd1dd34d8c> / Meeting nb: 702 301 629 / Password: product

For replay: Nb +33 (0)1 72 00 15 00 / Conf Nb: 285911#

#### **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](http://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).*

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