BioAlliance Pharma announces major achievements on Validive®

- ***Enrollment completion in the international Phase II trial with Validive® in severe oral mucositis***

- ***Presentation of preclinical data at the next ASCO annual meeting***

Paris, May 5, 2014 - BioAlliance Pharma SA (Euronext Paris - BIO), an innovative Company specialized in the development of drugs in orphan oncology diseases, today announced the completion of enrollment in the Phase II clinical trial with Validive® (clonidine Lauriad®) in the prevention and treatment of severe oral mucositis induced by radiotherapy and/or chemotherapy in head and neck cancer patients.

This large and robust randomized, double-blind, placebo-controlled phase II trial, planned to include 183 patients, has been conducted in more than thirty centers in Europe and in the United States. The trial is assessing the efficacy and safety of Validive® 50 µg and 100 µg versus placebo in prevention of severe oral mucositis, a highly disabling condition with currently no approved treatment. BioAlliance Pharma expects to announce preliminary results Q4 2014.

Moreover, BioAlliance Pharma was selected to present preclinical data on Validive® at the 50th ASCO Meeting that will take place in Chicago from 31 May to 3 June, 2014. Two publications were accepted by the scientific committee of this internationally recognized scientific association.

« The recruitment phase being completed, we are now eager to enter the upcoming step: the preliminary results, expected Q4 2014, which will be the basis for the development strategy to lead the product to registration. With the "Fast track" designation granted by the FDA earlier this year, and the "orphan status" obtained for Europe, Validive® will benefit from major advantages to optimize review periods from both agencies ", comments Judith Greciet, CEO of BioAlliance Pharma.

"To be selected by the ASCO scientific committee to present preclinical data reflects the interest and the quality of our data, and is a great honour and pride for our teams. Validive® is the second leading program of our "orphan oncology products" portfolio. All operations are now in place to continue the development of this strong asset for the Company, whose sales potential could reach €200 to €400 million".

About oral mucositis

Severe oral mucositis is a particularly invalidating pathology induced by radio/chemotherapy treatments and very frequent in patients with head and neck cancer. 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. Oral mucositis has currently no validated curative or preventive treatment.

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® (Doxorubicin Transdrug™) (primary liver cancer): Phase III on going
Validive® (Clonidine Lauriad®) (mucositis): Phase II on going
AMEP® (invasive melanoma): Preclinical phase

BioAlliance Pharma has announced a merger project with the Danish listed company Topotarget on April 16th 2014.
For more information, visit the BioAlliance Pharma web site at 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 2013 Reference Document filed with the AMF on April 7, 2014, which is available on the AMF website (http://www.amf-france.org) or on BioAlliance Pharma SA's website (www.bioalliancepharma.com).

BioAlliance Pharma SA
Judith Greciet, CEO
judith.greciet@bioalliancepharma.com
Nicolas Fellmann, CFO
nicolas.fellmann@bioalliancepharma.com
Tel.: +33 1 45 58 76 00

ALIZE RP
Caroline Carmagnol
+33 6 64 18 99 59
bap@alizerp.com