FDA grants Validive® (clonidine Lauriad®) with a Fast Track Designation for the prevention and treatment of oral mucositis induced by anticancer treatments

Paris, January 23, 2014 – BioAlliance Pharma SA (Euronext Paris - BIO), an innovative Company dedicated to the development of orphan oncology, announced today that Validive® (clonidine Lauriad®) received a Fast Track designation from the U.S. Food and Drug Administration (FDA) for the prevention and treatment of oral mucositis induced by radiotherapy and/or chemotherapy in cancer patients.

The Fast Track procedure is designed to facilitate interactions with the FDA and optimize the development time and review period for drugs investigated as treatments for serious or life- threatening diseases with a high unmet medical need.

Severe oral mucositis is a highly disabling disease, induced by intensive radiochemotherapy protocols, particularly frequent in patients treated for head and neck cancer. At severe stage, it induces intense oral pain and eating disability, requiring enteral or parenteral nutritional support. Hospitalization is needed in about 30% of patients and symptoms can lead to anticancer treatment breaks or delays, impacting overall chance of success for the treatment. No validated curative or preventive treatment is currently available.

"The FDA's decision to grant Fast Track Designation to Validive® reflects FDA's awareness about the seriousness of oral mucositis disease, the strong need for an effective treatment and Validive®'s potential to address this highly disabling disease. This designation is key for Validive® development, it will allow an accelerated review period by the FDA at the time where we are finalizing our large international double blind phase II trial. Last patient is planned to be enrolled in the coming weeks and top line data should be issued in the second half of the year. Validive® is the second most advanced product of our orphan oncology program, which drives the company growth. The achievement of the phase II program is a major step to be achieved soon for one of our key assets", commented Judith Greciet, CEO of BioAlliance Pharma.

Validive® (clonidine Lauriad®) is a mucoadhesive tablet based on our Lauriad® technology that delivers high concentrations of an anti-inflammatory active principle (clonidine) directly in the oral cavity, the site of irradiation in the treatment of head and neck cancer.

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): Phase I on going
For more information, visit the BioAlliance Pharma web site at www.bioalliancepharma.com

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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 (www.bioalliancepharma.com).

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