BioAlliance Pharma's Sitavig® receives Market Authorization in the US for the treatment of Herpes labialis

- *Second BioAlliance Pharma drug registered in the US*
- *An effective and innovative medicine for the treatment of a frequent infection, recurrent Herpes labialis in adults*

Paris, April 15, 2013 – BioAlliance Pharma SA (Euronext Paris - BIO), today announced the receipt of marketing authorization from the U.S. Food and Drug Administration (FDA) for Sitavig® in the treatment of recurring *Herpes labialis*, marking the successful conclusion to the assessment procedure carried out by the American authorities.

After Loramyc ®, registered in 26 countries including the United States, BioAlliance Pharma for the second time has successfully passed the FDA review. The registration of Sitavig, developed internally, shows once again the teams' capacity and expertise.

Based on proprietary Lauriad® technology, Sitavig® comes in the form of a mucoadhesive tablet which the patient places on the gum and which delivers a high concentration of acyclovir directly to the lip, the site of the cold sore infection. In a phase III international study conducted on 775 patients, Sitavig® demonstrated a high level of efficacy in terms of healing time with one single tablet containing 50mg of acyclovir and an excellent tolerance profile.

In addition to its efficacy, Sitavig® offers a unique unobtrusive and simple formulation with a single application for the episode's entire duration, representing major advantages for patients suffering from recurrent herpes sores.

"Herpes labialis is an infection that affects a very large number of patients around the world and for which there is a real need for effective treatment with appropriate presentation. We participated in the phase III clinical trial in our center and were able to test the benefits of Sitavig®. We are very pleased with the outcome of this development which will allow patients, once the product is on the market, to have a

drug that meets their needs," says Professor Stephen Keith Tyring of the Dermatology Department at the University of Texas Health Sciences Center in Houston.

Herpes labialis is an extremely widespread condition. Its estimated annual prevalence is 15% of the adult population[1], namely some 40 million people in the United States with more than 100 million episodes of Herpes labialis annually, representing a significant potential market of hundreds of millions of dollars.

Sitavig®, the second drug of BioAlliance's 'Specialty Products' portfolio, is intended to be marketed via international partnership agreements and to generate significant income for the company. Obtaining the MA will allow the company to accelerate discussions with potential partners for marketing in the United States.

"Drug approval in the United States represents for all laboratories, whether large or small, both a challenge and a major success once it has been obtained since the process is so complex and significant levels of competence and expertise are required. This MA demonstrates once more the ability of BioAlliance teams to successfully complete the development and registration of a drug with international agencies such as those in Europe and the United States, and also strengthens its unique positioning within the current landscape of French Biotechs through its second drug registered for the major markets and three products in advanced clinical phase. This is a key step in creating company value for our shareholders and should allow us to generate revenue, thereby fully participating in the growth and success of BioAlliance," states Judith Greciet, CEO of BioAlliance Pharma.

1: A Survey on the prevalence of orofacial herpes in France (the Instant Study) - G. Lorette et al (J Am Acad Dermatol 2006; 66; 225-32)

About BioAlliance Pharma
A company dedicated to specialty and orphan products in the treatment of cancers and supportive care, with an approach focused on drug resistance. BioAlliance Pharma designs and develops innovative medicines mainly intended for hospital use and drugs in rare or orphan diseases. Created in 1997 and listed on the Euronext stock exchange in Paris in 2005, the company has ambitions to become a key player in these areas by linking innovation to patient needs. It possesses the key skills to identify, develop and register drugs in Europe and the United States.
For more information, visit the BioAlliance Pharma website at www.bioalliancepharma.com

BioAlliance Pharma has developed a portfolio of advanced products:
Specialty products:
Loramyc®/Oravig® (Oropharyngeal candidiasis in immune compromised patients): Approved in 26 countries (Europe, USA, Korea), marketed in Europe and the United States.
Sitavig® (Herpes labialis): Registered in the U.S. and in 8 European countries, undergoing process in other European countries.
Fentanyl Lauriad® (chronic pain in cancer patients): Positive preliminary clinical Phase I results

Orphan Oncology products
Livatag® /doxorubicine Transdrug™ (Hepatocellular carcinoma): Phase III
Validive® / clonidine Lauriad® (Mucositis post-chemotherapy and radiotherapy in head and neck cancer): Phase II
Biotherapy AMEP® (Invasive metastatic melanoma): Phase I

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