BioAlliance Pharma pursues the development plan of its Loramyc® in Japan through its partner Sosei

Initiation of the pivotal registration phase III trial

Paris, March 12, 2013 - BioAlliance Pharma SA (Euronext Paris - BIO), an innovative Company dedicated to the development of orphan oncology products and to supportive care products, announces the initiation of Loramyc®/Oravig® Phase III clinical trial for the treatment of oropharyngeal candidiasis by its Japanese partner Sosei. This is the final step before registration of the drug by Japanese authorities.

In May 2011, BioAlliance Pharma signed a licensing agreement with Sosei Co. Ltd. (a wholly owned subsidiary of Sosei Group Corporation – TSE Mothers Index: 4565) for the conduct of development program and commercialization rights in Japan for Loramyc®/Oravig® (miconazole Lauriad®) muco-adhesive buccal tablet.

As traditionally required by Japanese authorities, a complementary development plan driven by Sosei has been initiated to complete the registration dossier and meet Japanese regulatory requirements. Following the successful phase I clinical trial finalized in July 2012, Sosei is now starting the final step of development with the phase III open-label, randomised trial versus miconazole gel. This study is anticipated to last 12 to 18 months.

"Loramyc®/Oravig® represents a true innovation in the treatment of oropharyngeal candidiasis as compared with available treatments and is expected to improve patients' compliance and quality of life", comments Shinichi Tamura, CEO of Sosei Group Corporation. "*The initiation of this phase III trial is a key step for us, not only in the development plan of the product in Japan but also in our discussions with potential partners for commercialization once the product is approved".*

"We are very pleased with this new step taken by our partner Sosei in Japan, which should lead them to the final stage of registration in the coming months. From there, commercialization of Loramyc® should then start in one of the major Asian markets that is Japan", adds Judith Greciet, CEO of BioAlliance Pharma.

About BioAlliance Pharma

Dedicated to cancer and supportive care treatment with a focus on resistance targeting and orphan products, BioAlliance conceives and develops innovative products, for specialty markets especially in the hospital setting and 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:

Specialty products

Loramyc®/Oravig® (oropharyngeal candidiasis in immunocompromised patients): Registered in 26 countries (EU, US, Korea)
Sitavir®/Sitavig® (Acyclovir Lauriad®) (labialis herpes): Registered in 8 European countries, registration status in the US
Fentanyl Lauriad® (chronic cancer pain): Positive preliminary Phase I results

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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