

Livatag® receives Fast Track Designation from the FDA for the treatment of primary liver cancer

Paris, May 19, 2014 - BioAlliance Pharma SA (Euronext Paris - BIO), an innovative Company specialized in the development of drugs in orphan oncology diseases, today announced that Livatag[®] (doxorubicin Transdrug[™]) received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of hepatocellular carcinoma (primary liver cancer) after treatment with Sorafenib.

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

Primary liver cancer, also called hepatocellular carcinoma, is a particularly aggressive cancer resistant to chemotherapy treatments. It represents the second leading cause of cancer-related deaths worldwide. Few therapeutic alternatives are available and there is a major medical need to improve patients' survival.

Livatag® is a chemotherapy drug using a nanoparticulate formulation. This BioAlliance Pharma's proprietary innovative formulation is designed to overcome the resistance mechanisms developed by tumor cells, mainly responsible for the lack of efficacy of usual chemotherapies. Livatag® is currently in a phase III trial in Europe and in the US as second-line treatment of hepatocellular carcinoma after Sorafenib, at a stage with no available approved treatment.

"This Fast Track designation is a major achievement for the development of Livatag®. It will allow BioAlliance to benefit from frequent and interactive exchanges with the FDA and accelerated review processes. This notably includes, within the product's registration application, the eligibility for priority review meaning a reduced time required for FDA evaluation from 10 to 6 months", comments Judith Greciet, CEO of BioAlliance Pharma. "As of today, more than 25% of patients are enrolled in the ReLive study. With the completion of enrollment planned at the end of 2015 and expected data end of 2016, this development program is the most advanced of our orphan oncology products portfolio, with a drug representing estimated sales potential of nearly €800 million".

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

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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 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