



### ***FDA Accepts Drug Application for Miconazole Lauriad® (Loramyc®) to Treat Oropharyngeal Candidiasis***

**Paris, August 19, 2009** – BioAlliance Pharma SA (Euronext Paris – BIO), a company dedicated to the treatment and supportive care of cancer and AIDS patients, today announced that the U.S. Food and Drug Administration (FDA) has accepted the new drug application (NDA) for miconazole Lauriad® (Loramyc®) Mucoadhesive Buccal Tablets (MBT) to treat oropharyngeal candidiasis (OPC). Miconazole Lauriad® delivers the antifungal miconazole via a mucoadhesive buccal tablet that is designed to enable once-daily dosing of the active ingredient at the site of infection.

The NDA submission was based primarily on data from a Phase III study demonstrating noninferiority to Mycelex® Troche (clotrimazole)\* in the complete resolution of signs and symptoms of OPC. The randomized, double-blind, double-dummy study was conducted in 577 HIV-positive patients in 40 sites in the United States, Canada, and South Africa. This represents the largest study ever conducted in OPC.

*“The NDA acceptance of miconazole Lauriad® represents a significant milestone for BioAlliance Pharma towards providing an innovative and effective option for OPC treatment to patients and healthcare providers in the USA,”* said Dominique Costantini, President and CEO of BioAlliance Pharma. If approved, Strativa Pharmaceuticals, the proprietary products division of Par Pharmaceutical, Inc. (NYSE: PRX), BioAlliance Pharma’s partner for commercialization in the USA, could launch miconazole Lauriad® in the second half of 2010. This innovative product is protected in the USA by granted patents and patent applications in force until 2028.

OPC familiarly known as thrush, is an oral fungal infection most common in individuals with weakened immune systems, particularly those with HIV/AIDS and those undergoing cancer treatments. OPC is a disruptive condition that results in lesions and inflammation in the mouth, and includes symptoms such as soreness, burning and/or altered taste.

Miconazole Lauriad® was approved in 11 European countries and is currently being marketed in France under the trade name Loramyc®. While miconazole Lauriad® would be the first miconazole treatment available in oral form in the U.S., other dosage forms of miconazole have been marketed around the world. Under a licensing agreement with BioAlliance Pharma SA, Strativa is the exclusive U.S. distributor of BioAlliance’s miconazole Lauriad®. Upon FDA approval of the product, Strativa will pay BioAlliance \$20 million, as well as a royalty on future net sales. BioAlliance may also be entitled to milestone payments if net sales achieve specified targets.

## **About BioAlliance Pharma**

As a preferred partner for hospital-based specialists, BioAlliance Pharma is a company which develops and markets innovative products in France, especially in the fields of opportunistic infections and chemotherapy complications. In areas where medical needs are insufficiently met, our targeted approaches help overcome drug resistance and improve patient health & quality of life. BioAlliance Pharma's ambition is to become a leading player in these fields by coupling innovation to patient needs. For more information, visit the BioAlliance Pharma web site at <http://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 2008 Reference Document filed with the AMF on April 7, 2009, which is available on the AMF website (<http://www.amf-france.org>) or on BioAlliance Pharma S.A.'s website (<http://www.bioalliancepharma.com>).*

### **BioAlliance Pharma SA**

Dominique Costantini, President and CEO

Tel.: +33 1 45 58 76 01

[dominique.costantini@bioalliancepharma.com](mailto:dominique.costantini@bioalliancepharma.com)

Nicolas Fellmann, CFO

Tel.: +33 1 45 58 71 00

[nicolas.fellmann@bioalliancepharma.com](mailto:nicolas.fellmann@bioalliancepharma.com)

### **ALIZE RP**

Caroline Carmagnol

Tel.: +33 6 64 18 99 59

[caroline@alizerp.com](mailto:caroline@alizerp.com)

\* MYCELEX® is registered trademark of Bayer Healthcare LLC