



## **Breakthrough positive phase III results with acyclovir Lauriad<sup>®</sup> Primary and secondary endpoints met – Final results**

**Paris, December 10, 2009** – BioAlliance Pharma SA (Euronext Paris – BIO), a company dedicated to the treatment and supportive care of cancer and AIDS patients, today announces final positive results of its pivotal phase III clinical study in immunocompetent patients with recurrent herpes labialis (LIP Study) treated with acyclovir Lauriad<sup>®</sup>. Primary and secondary endpoints have been met with marked efficacy and good tolerance.

This international multicenter randomized, double-blind, placebo-controlled study compared the efficacy and safety of a single dose of acyclovir Lauriad<sup>®</sup> 50mg Mucoadhesive Buccal Tablet (MBT) versus matching placebo in 1727 randomized and 775 treated patients suffering from recurrent herpes labialis.

A single dose of acyclovir Lauriad<sup>®</sup> 50mg MBT significantly reduced the time to healing of primary vesicular lesion ( $p=0.043$ , primary endpoint). Secondary clinical endpoints showed the duration of episode from the first prodromal symptoms to healing to be significantly decreased ( $p=0.0062$ ), the percentage of patients with abortive episode (episode not progressing to vesicular lesion) to be increased ( $p=0.045$ ) and the duration of abortive episode to be reduced ( $p=0.042$ ).

Among patients who accepted to be followed for 9 months after this single administration of treatment, the time to recurrence to the next herpes episode was markedly delayed after the application of acyclovir Lauriad<sup>®</sup> 50mg MBT (37 days delay versus placebo,  $p=0.054$ ).

Finally, acyclovir Lauriad<sup>®</sup> 50mg MBT was extremely well tolerated with very minor side effects, comparable to those observed with placebo, in particular diarrhea, headache, and local irritation were rare in contrast to systemic or topical treatments.

*“A single administration of acyclovir Lauriad<sup>®</sup> 50mg MBT demonstrates its activity on all stages of oro-facial herpes infection in this very large study including 775 patients”, said Dominique Costantini, President and CEO of BioAlliance Pharma. “For the first time, one single application of a 50mg dose acyclovir delivered through MBT is able to prevent the occurrence of vesicular lesions and to have an impact upon long term recurrences of oro-facial herpes episodes. Acyclovir Lauriad<sup>®</sup> represents today a major product opportunity, shaping a new paradigm in the treatment of oro-facial herpes. This positive phase III trial provides therefore a good basis for dossier submission to regulatory authorities and validates for the second time the Mucoadhesive Buccal Tablet concept based on early targeted treatment. BioAlliance is capitalizing on this MBT with more products to come”, added Dominique Costantini.*

### **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 [www.bioalliancepharma.com](http://www.bioalliancepharma.com).

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