Sitavig® Licensing Strategy: Execution of licensing agreement with Innocutis for North America and Positive opinion from French and German Health Authorities for Marketing Authorization

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BioAlliance Pharma SA (Euronext Paris – BIO), an innovative Company dedicated to the development of orphan oncology products, announced major advancements in the licensing strategy of Sitavig® (acyclovir Lauriad®) for the treatment of recurrent labial herpes, with the execution of a licensing agreement with Innocutis Holding LLC to commercialize Sitavig® in North America. In Europe, the Company received a positive opinion from the Health Authorities in France and Germany for the Market Authorization of the drug.
Innocutis, based in Charleston (South Carolina), is a pharmaceutical company dedicated to Dermatology, with "best-in-class" branded prescription products in skin related therapies. Innocutis deploys a direct sales force to promote its products to the fastest-adopting, highest-prescribing dermatologists in the United States, providing clinicians with improved solutions for managing the challenges presented in their daily practice.

Innocutis will promote Sitavig® to dermatologists and top tier general practitioners alone, or with a sublicensee, allowing coverage of the largest panel of patients in the U.S. Product launch in the U.S. is expected as early as early third quarter 2014.

Under this agreement, BioAlliance Pharma is eligible to receive a total of $5 million in upfront and milestones payments. The agreement also includes double-digit royalties which should represent significant downstream revenues. In addition, Innocutis shall fund a major portion of the pediatric clinical study required by the FDA, as well as U.S. regulatory taxes. Locust Walk Partners, LLC served as transaction advisor to BioAlliance Pharma.

"Sitavig® represents a unique opportunity for Innocutis corporately and will change the way clinicians will treat herpes labialis. In order maximize Sitavig® opportunity, Innocutis will pursue sublicensing opportunities in multiple specialty fields while the Innocutis sales force focuses on dermatology. As an organization, Innocutis couldn't be more pleased with the partnership that has been develop with BioAlliance Pharma and we look forward to a successful launch of Sitavig® in North America", commented Joe Pecora, CEO of Innocutis Holdings LLC.

Regarding Europe, Sitavig® had already been registered in 8 countries through a decentralized procedure successfully achieved in December 2012. As its registration strategy, the Company had filed in these countries first to ensure optimized registration timelines, and then filed a mutual recognition procedure in France and Germany, which are two major European countries with the greatest commercial potential in the European herpes labialis market.

This second procedure is now finalized and both Health Authorities have issued a positive opinion for the registration of Sitavig®.

"Obtaining the opinion from these two countries was key, as they together represent more than 60% of the total European market, estimated to €90 million. Indeed, these will significantly accelerate the discussions with potential European partners, which are our priority now that Sitavig® is licensed in the U.S.", declared Aude Michel, Head of Corporate Development of BioAlliance Pharma.
"These 2 steps are key advancements in our licensing strategy for Sitavig.
We are delighted with this agreement with Innocutis, a strategic U.S. partner with a highly skilled management team and a dedicated sales force, and we trust this collaboration will ensure the rapid and successful commercialization of Sitavig® in the U.S., the largest sales potential market, estimated up to $500M", commented Judith Greciet, CEO of BioAlliance Pharma. *In Europe, regulatory procedure has been finalized with success and Sitavig® is now approved in all key countries. Indeed, we are confident that it will significantly help licensing discussions with potential European partners, already fairly well advanced".*
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