

Hovione Licenses Inhaler Technology for Influenza Drug to Sankyo & Biota

Hovione recently announced the signature of an agreement in which Sankyo Company Ltd. and Biota Holdings Ltd. have jointly licensed Hovione's dry powder inhaler technology for the delivery of long-acting neuraminidase inhibitors (LANI) owned by Sankyo and Biota, which are active against the influenza virus. An improvement over other approved medicines that have to be taken repeatedly is that this novel compound is expected to remain active for several days and require to be taken once only. Hovione retains all inhaler rights outside the field of influenza.

Under the agreement, Hovione has developed a low-cost disposable inhaler, TwinCaps, specifically for this indication. In addition, Hovione carried out inhaler compatibility studies and comprehensive formulation development to demonstrate that the lead clinical candidate CS-8958 can be delivered by inhalation. Sankyo and Biota are responsible for the clinical development of the drug product, which is expected to start in the near future. CS-8958 has already completed Phase I clinical trial in a prototype inhaler.

Peter Villax, Hovione Vice-President, said, "This agreement is the confirmation that Hovione is recognized as a reliable partner in inhalation product development. We are the only independent company with expertise in every aspect of inhalation, from chemical development to particle design, from device to formulation development."

"We will now be able to accelerate both the program with Sankyo and marketing this potentially important new product to other licensees," added Peter Cook, Biota's CEO. "Biota has an impressive pipeline in anti-viral drugs, and we expect that inhaled LANIs will

offer further effective and convenient first line of defense against the influenza virus."

Hovione is a specialist company in Active Pharmaceutical Ingredient (API) manufacturing and inhaled formulation development. Through its expertise in API processing, Hovione has acquired significant know-how in particle design and engineering. This knowledge has permitted Hovione to offer a unique range of compliant services in API process development, particle design, and inhalation formulations. Development services are available through Hovione facilities in Loures, Portugal, and in New Jersey.

Daiichi Sankyo Company, Limited was established in 2005 as the joint holding company of two major Japanese pharmaceutical companies (Sankyo Co., Ltd., and Daiichi Pharmaceutical Co., Ltd.). Daiichi Sankyo is a global pharmaceutical innovator, continuously generating innovative drugs and services and maximizing its corporate value.

Based in Melbourne, Australia, Biota has a proud history as a world-leader in antiviral drug development and a track-record of bringing products to the market. Biota's initial success was the discovery of zanamivir, the first-in-class neuraminidase inhibitor for the treatment and prevention of influenza. Zanamivir is licensed to GlaxoSmithKline and marketed as Relenza, which is used to treat seasonal influenza and is currently being stockpiled by various governments for defense against possible pandemic outbreaks of avian (bird) influenza. The company also developed influenza diagnostics FLU OIA and FLU OIA A/B, currently marketed by Inverness Medical as part of the BioStar range.