



Dance Biopharm Presents Phase 2 Clinical Data Highlighting Rapid Effects of Inhaled Human Insulin at European Association for the Study of Diabetes Meeting

- *Data demonstrated earlier onset of action and higher early effect of Dance 501 inhaled insulin compared to injected insulin lispro in patients with type 2 diabetes*
- *Validated smart inhaler delivers optimal and precise doses of inhaled therapy through the lungs with good tolerability*

DURHAM, N.C., Sept. 19, 2019 (GLOBE NEWSWIRE) --[Dance Biopharm Holdings, Inc.](#), a clinical-stage company reimagining the treatment of chronic diseases with inhaled therapies, today presented data from its Phase 2 clinical study of Dance 501, a novel gentle mist formulation of human insulin administered with its smart inhaler, in patients with type 2 diabetes (T2D). The data were presented at the [55th Annual Meeting of the European Association for the Study of Diabetes](#) on September 19, 2019, in Barcelona, Spain. Study results showed Dance 501 inhaled human insulin (INH) had comparable glucodynamic properties to injected insulin lispro (LIS), but delivered a faster onset of action.

“These encouraging study results demonstrate the potential of Dance 501 INH to offer a clinically meaningful benefit over rapid-acting insulin injections for patients with type 2 diabetes, while also providing a more comfortable patient experience,” said Melissa Rhodes, Ph.D., chief development officer of Dance Biopharm. “This study also further validates our smart inhaler’s ability to deliver an optimal and precise dose of inhaled therapies through the lungs. A number of diseases could benefit from the frequent pulsatile administration afforded by an inhaled delivery option, so we are exploring inhaled therapies beyond human insulin where our platform could achieve better treatment efficiency.”

“Dance 501 inhaled human insulin demonstrated faster onset and greater action in the first hour of administration compared to subcutaneous insulin lispro, with good tolerability in patients with type 2 diabetes,” said Eric Zijlstra, Ph.D., lead study author and presenter. “Not only does this allow for Dance 501 INH to be administered shortly before meals, but the ease of use could potentially motivate more patients to better comply with standard medical guidance.”

Trial Design and Results

The randomized, controlled clinical study evaluated the pharmacodynamic action and safety of Dance 501 inhaled human insulin in comparison to injected insulin lispro in T2D patients. The study enrolled 24 subjects with type 2 diabetes on daily insulin therapy. Each patient received three doses 12, 24 and 48 U of Dance 501 (assuming a 13% relative biopotency) and subcutaneous insulin lispro. Patients received a total of six doses, administered over six visit that occurred 3 to 17 days apart. Insulin action was measured using the automated glucose clamp method over a 10-hour period following dosing.

Key findings from the clinical trial:

- Dance 501 showed comparable pharmacodynamic properties and more rapid onset of action compared to insulin lispro, with median differences of 6.5 to 20 min, $p < 0.02$.
- Dance 501 showed greater action in the first hour of administration to lispro at all three doses with median relative differences of 45% to 107%, $p < 0.05$.
- Time to maximum insulin action was comparable for each dose level.
- No safety issues, cough or acute changes in lung function were observed with any inhalation.

About Dance Biopharm

Dance Biopharm is a clinical-stage company reimagining the treatment of chronic diseases with inhaled therapies. Our gentle mist inhaler is designed with smart technology to optimize the precise delivery of biologic therapies

through the lungs. We are building a diverse pipeline of inhaled biologic products with initial focus on rare and severe diseases in the endocrinology, respiratory and cardiovascular space, where our platform and expertise present a unique opportunity to achieve better treatment efficiency. We have initiated development programs in glucagon-like peptide-1 (GLP-1), parathyroid hormone (PTH) and human growth hormone (HGH). For more information, visit: <https://www.dancebiopharm.com>.

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