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Dance Biopharm Presents Encouraging Data from Phase 2 Clinical Trial of Dance 501 Inhaled Insulin Therapy at American Diabetes Association Meeting

- Faster onset of action shown for Dance 501 compared to subcutaneous injection of insulin lispro –

- No changes in lung function and no cough observed in patients receiving inhaled Dance 501 –

SAN FRANCISCO--(BUSINESS WIRE)--Dance Biopharm Holdings, Inc., a privately-held clinical stage biopharma company focused on the development of novel soft mist inhalable formulations of biologics for people living with chronic diseases, today presented Phase 2 Samba 04 clinical trial results for its inhaled preservative-free human insulin, Dance 501, for the treatment of type 2 diabetes. The results showed a faster onset of action for Dance 501 inhaled insulin compared to comparable doses of subcutaneously administered insulin lispro. These findings are being presented at the 79th Scientific Sessions of the American Diabetes Association (#ADA2019), being held in San Francisco.

“Our presentations at ADA underscore Dance’s ongoing commitment to develop innovative, patient-centric inhaled therapies that lead to improved health outcomes for people living with chronic diseases like diabetes,” said Anne Whitaker, chief executive officer of Dance Biopharm. “We are excited to present new data that further reinforce the potential of Dance 501, our inhaled preservative free human insulin, as an alternative treatment to injectable insulin for diabetes. These data demonstrate the excellent performance of our soft mist inhaler platform and emboldens us to rapidly progress the development of our pipeline of novel, soft mist biologics as treatments for severe and chronic diseases.”

Trial Design and Results

This Phase 2 trial, Samba 04, was designed as a randomized, crossover, open label, active-comparator-controlled study that enrolled 24 subjects with type 2 diabetes currently receiving insulin therapy or metformin. Each patient received 3 doses of inhaled Dance 501 and 3 doses of subcutaneous insulin lispro under medical supervision or administration. The inhalation device is a small hand held electronic aerosol device with a vibrating mesh micro-pump technology that transforms the liquid insulin formulation into a mist upon patient inhalation. Doses administered were 12, 24 and 48 U for both Dance 501 (assuming 13% delivery efficiency) and lispro. Each patient received all 6 doses over 6 visits 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 presented from the trial include the following:

1. Dance 501 showed comparable pharmacodynamic properties and more rapid onset of action compared to insulin lispro.

2. Greater action in the first hour of administration for inhaled human insulin (INH) compared to lispro at all three doses with median relative differences of 107%, 57% and 45%, ($p < 0.05$).

3. Time to maximum insulin action was comparable for each dose level.

4. 30 of 31 adverse events were observed and rated as mild to moderate, 13 reported for INH and 18 for lispro. One serious adverse event was reported after lispro dosing but was deemed unlikely related to test medication.

5. Dance 501 showed good tolerability overall, no cough was observed with INH dosing, and no changes in lung function were observed.

The poster titled, *Dance 501 Inhaled Human Insulin (INH): Linear Dose Response, Earlier Onset of Action, and Higher Early Effect than s.c. Insulin Lispro (LIS), may be found on the Dance Biopharm website at:* https://www.dancebiopharm.com/dance-501.

About Dance Biopharm

Dance Biopharm is a private company focused on developing novel inhaled formulations of biologics to treat severe and chronic diseases. The company's novel inhalation delivery technology platform may be utilized with liquid formulations of biologics with the goal of providing effective and convenient treatment options to patients along with wireless connectivity to improve disease management. Dance, headquartered in the San Francisco Bay Area, was founded by John Patton, Ph.D., who has over 25 years of experience developing numerous inhaled therapies. For more information, please visit http://dancebiopharm.com.

FORWARD-LOOKING STATEMENTS

All statements other than statements of historical fact included in this press release are forward-looking statements that are subject to certain risks, trends and uncertainties that could cause actual results and achievements to differ materially from those expressed in such statements. We have based these forward-looking statements upon information available to management of Dance as of the date of this release and management's expectations and projections about certain future events. It is possible that the assumptions made by management for purposes of such statements may not materialize. Actual results may differ materially from those projected or implied in any forward-looking statements. Such statements may involve risks and uncertainties, including but not limited to those relating to our limited operating history, our ability to successfully develop product candidates, including Dance 501, the cost and uncertainty of obtaining regulatory approvals, our ability to bring product candidates, including Dance 501, to multiple markets and our ability to develop inhaled formulations of other medicines.

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Investors
Robert H. Uhl
Managing Director
Westwicke IR
858-356-5932
Robert.uhl@westwicke.com

Media
Jim Heins
Senior Vice President
Westwicke PR
203-682-8251
james.heins@icrinc.com

Source: Dance Biopharm Holdings, Inc.