



JDRF Announces Two Partnerships to Develop Stable, Pumpable Glucagon to Support Advanced Generation Artificial Pancreas Systems

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-- Xeris Pharmaceuticals, Inc., and LATITUDE Pharmaceuticals, Inc., will develop two different formulations of soluble glucagon for use in infusion pumps, and better determine their impact in regulating blood-glucose levels in people with type 1 diabetes--

NEW YORK, June 20, 2013 /PRNewswire-USNewswire/ -- JDRF announced today partnerships with both Xeris Pharmaceuticals, Inc., and LATITUDE Pharmaceuticals, Inc. (LPI), to support the development soluble glucagon formulations—an important step toward the advancement of future generation, fully automated and multi-hormonal artificial pancreas systems for people with type 1 diabetes (T1D).

First-generation artificial pancreas systems currently being tested in JDRF-supported outpatient clinical trials use technologies already available; they combine a continuous glucose monitor (CGM) with an insulin pump using computer software, to partially automate the right amount of insulin delivery at the right times for people with T1D.

"Studies have demonstrated the game-changing value of first generation artificial pancreas systems in improving blood-glucose control and alleviating some of the burdens of managing type 1 diabetes," said Sanjoy Dutta, Ph.D., JDRF's senior director of treat therapies. "Still, future generation artificial pancreas systems are expected to do even more. To become fully automated, closed loop systems, new technologies and drugs—including stable, pumpable glucagon—will be required in order to more closely and accurately mimic the functions of a healthy pancreas. Both near-term and long-term projects to advance the artificial pancreas are important research priorities for JDRF."

While first-generation artificial pancreas systems will deliver insulin, one of the

aspects of future generations will be their ability to deliver multiple hormones, such as glucagon. Glucagon is a naturally occurring hormone that raises blood-sugar levels to prevent hypoglycemia (low blood sugar), but its regulation is impaired in people with T1D, for whom hypoglycemia can be dangerous. In a healthy pancreas, it complements the function of insulin to provide the natural fine-tuning of blood-glucose control, and previous studies supported by JDRF and others have shown that the addition of glucagon to insulin treatment in T1D reduces the frequency of hypoglycemia.

One major hurdle in developing an advanced generation, multi-hormonal artificial pancreas system is that commercially available glucagon does not remain stable; the powder and solution mix into a short-lived liquid form not suitable for long-term use in a pump. Xeris and LPI will develop two different approaches to making glucagon usable for infusion pumps.

Xeris—a specialty pharmaceutical company based in Austin, TX, focused on developing injectable therapeutics—will study its stable, room-temperature, and non-aqueous injectable glucagon (G-Pump™ Glucagon) to treat hypoglycemia. Clinical studies will take place at Oregon Health & Science University (OHSU) with two years of milestone-based funding from JDRF.

"Our partnership with JDRF enables us to move forward in pursuing an improved approach to controlling blood glucose levels by enabling a fully closed loop system that addresses both hyperglycemia and hypoglycemia," said Steve Prestrelski, Ph.D., chief executive officer at Xeris. "We look forward to working with JDRF to make this a successful program."

LPI—a drug formulation development company based in San Diego, CA—will use a unique, proprietary, solvent-free, glucagon nanoemulsion (Nano-G) to solubilize and stabilize the molecule, such that it is not vulnerable to degradation and remains biologically active. With milestone-based funding from JDRF for one year, LPI plans to begin clinical testing in the United States in 2014.

"LATITUDE is truly honored to partner with a prestigious and leading organization such as JDRF," said Andrew Chen, Ph.D., LPI's president. "This partnership will accelerate LATITUDE's stable, soluble glucagon formulation and its potential for new medical applications. Our partnership with JDRF will give us an opportunity to provide a missing piece needed to make the bi-hormonal artificial pancreas a reality."

Both Xeris and LPI are using approaches distinct from the [ongoing JDRF-supported research program led by W. Kenneth Ward, M.D.](#) at OHSU, which is utilizing a liquid solution of glucagon at a high pH in order to stabilize the

drug.

Said Dr. Dutta: "We are excited to explore whether the novel glucagon formulations by Xeris and LATITUDE could prove effective for use in an infusion pump, thereby bringing us closer to the future of closed loop artificial pancreas systems by 'resetting' the missing hormonal balance in people with type 1 diabetes."

About T1D

In T1D, a person's pancreas stops producing insulin, a hormone that enables people to get energy from food. People with T1D need to test their blood sugar and give themselves insulin (with injections or an insulin pump) multiple times every day, and carefully balance insulin doses with eating and daily activities throughout the day and night. However, insulin is not a cure for diabetes, and even with that intensive care, a significant portion of the day is still spent with either high or low blood sugar, placing people with T1D at risk for devastating complications such as heart attack, stroke, blindness, and amputation.

About JDRF

JDRF is the leading global organization funding type 1 diabetes (T1D) research. JDRF's goal is to progressively remove the impact of T1D from people's lives until we achieve a world without T1D. JDRF collaborates with a wide spectrum of partners and is the only organization with the scientific resources, regulatory influence, and a working plan to better treat, prevent, and eventually cure T1D.

As the largest charitable supporter of T1D research, JDRF is currently sponsoring \$530 million in scientific research in 17 countries. In 2012 alone, JDRF provided more than \$110 million to T1D research. More than 80 percent of JDRF's expenditures directly support research and research-related education. In 2012 *Forbes* magazine named JDRF one of its five All-Star charities, citing the organization's efficiency and effectiveness.

For more information, please visit jdrf.org.

About Xeris Pharmaceuticals, Inc.

Xeris is a specialty pharmaceutical company based in Austin, Texas focused on improving injectable therapeutics by eliminating reconstitution, simplifying administration, and easing the pain of injections for patients and caregivers. In the diabetes space, Xeris is developing a stable, non-aqueous, injectable glucagon for the treatment of hypoglycemia. The company has developed a room-temperature stable formulation which is being leveraged for multiple

opportunities ranging from a rescue pen (the G-Pen™) for treatment of severe hypoglycemia, to a pump-based formulation (G-Pump™ Glucagon) for use in a bi-hormonal artificial pancreas.

About LATITUDE Pharmaceuticals, Inc.

LPI is a leading drug formulation development group that incorporates innovative and leading-edge approaches into its client projects and into its own reformulation programs. The company is recognized for its success with highly insoluble drugs and for developing inventive approaches and intellectual property for its clients. LPI's internal programs focus on developing outlicense-ready 505(b)(2) NDA opportunities.

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