Lilly and Sigilon Therapeutics Announce Strategic Collaboration to Develop Encapsulated Cell Therapies for the Treatment of Type 1 Diabetes

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- Sigilon’s Afibromer technology will be used to encapsulate insulin-producing cells for the potential treatment of type 1 diabetes
- Sigilon to receive upfront payment of $63 million and undisclosed equity investment

INDIANAPOLIS and CAMBRIDGE, Mass., April 4, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Sigilon Therapeutics today announced a global collaboration to develop encapsulated cell therapies for the potential treatment of type 1 diabetes. Sigilon is a privately-held biopharmaceutical company that is focused on discovering and developing "living therapeutics" with its Afibromer™ technology product platform. Lilly is a global biopharmaceutical company and a worldwide leader in diabetes care, offering a wide range of therapies and a strong commitment to cutting-edge research.

Encapsulated cell therapy is an emerging area of biopharmaceutical research that aims to unleash the therapeutic potential of cells to treat serious diseases without the need for immunosuppression. This approach holds promise to address chronic conditions, such as type 1 diabetes. In type 1 diabetes, pancreatic beta cells are destroyed by the immune system, leading to hyperglycemia (high blood sugar) and long-term complications if glucose levels are not managed effectively.

In the Lilly-Sigilon collaboration, Sigilon will create proprietary products comprised of induced pluripotent stem cells, a type of stem cell derived from adult cells, engineered into differentiated insulin-producing pancreatic beta cells and encapsulated using Sigilon's Afibromer technology. The goal of these products will be to restore insulin production over sustained periods, without triggering an immune reaction.

Research leading to the discovery of Afibromer biomaterials was funded by grants from JDRF International and the Leona M. Helmsley and Harry B. Helmsley Charitable Trust and conducted under the leadership of Daniel Anderson, Ph.D., and Robert Langer, Sc.D., of the Massachusetts Institute of Technology and Boston Children's Hospital.

"At Lilly, we endeavor to change the frontiers of what's possible in medicine, both through our own scientific labs and in collaboration with other leading researchers," said Daniel Skovronsly, M.D., Ph.D., senior vice president for clinical and product development and incoming president of Lilly Research Labs. "We are excited to be collaborating with, and investing in, Sigilon as they seek to develop encapsulated cell therapies, a potentially disruptive technology that could result in meaningful clinical advancements for chronic diseases such as type 1 diabetes."

"We are very pleased to partner with Lilly, a worldwide leader in diabetes care, as we seek to apply Sigilon's game-changing technology to the area of insulin-dependent diabetes," commented Paul Wotton, Ph.D., Chief Executive Officer of Sigilon Therapeutics. "At Sigilon, published studies have shown the ability to overcome the immune foreign body response with our proprietary Afibromer technology. This holds the promise for the creation of state-of-the-art allogeneic cell factories to be transplanted into patients, without the need for immune suppression. Our cell engineering and delivery system-based platform may allow us to program and control dynamic protein delivery for the long-term treatment of debilitating diseases."

Under the terms of the agreement, Lilly will receive an exclusive worldwide license to Sigilon's Afibromer technology for islet cell encapsulation. Sigilon will receive an upfront payment of $63 million and Lilly will make an undisclosed equity investment in Sigilon. Sigilon is also eligible to receive up to $410 million in development and commercialization milestones, as well as single to double digit tiered royalties on future product sales should the collaboration yield a commercially successful product. Sigilon will be responsible for all development activities and costs related to the collaboration until submission of an investigational new drug application (IND). After an IND is submitted, Lilly will be responsible for all clinical development and commercialization activities and costs related to the collaboration.

Sigilon was founded and created by Flagship Pioneering, a life science innovation firm, which unveiled the company in 2017 with $23.5 million in capital. Doug Cole, Managing Partner at Flagship Pioneering and Chairman of Sigilon's Board added, "We believe that unprecedented innovation, such as that at Sigilon, is necessary to uncover new solutions for patients. Sigilon's product platform offers the possibility of realizing the full potential of cell therapies, and we look forward to seeing the outcome of Lilly's and Sigilon's collaboration for type 1 diabetes."

As a result of this transaction, Lilly will incur an acquired in-process research and development charge to earnings of approximately $0.05 per share in the second quarter of 2018. The company's reported earnings per share guidance for 2018 is expected to be reduced by the amount of the charge. There will be no change to the company's non-GAAP earnings per share guidance as a result of this transaction.

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and http://newsroom.lilly.com/social-channels.

About Sigilon Therapeutics
Founded and created by Flagship Pioneering in conjunction with Daniel Anderson, Ph.D., and Robert Langer, Sc.D., of the Massachusetts Institute of Technology, Sigilon Therapeutics is a biopharmaceutical company that discovers and develops immune-privileged living therapeutic implants for the...
treatment of chronic diseases. Treatments based on Sigilon Therapeutics’ Afibromer™ technology platform include cell implants that act as responsive “living therapeutics,” providing more natural control for diseases that are currently treated with intermittent injection or infusion. Initial areas of focus include hematologic, enzyme deficiency, endocrine and metabolic disorders. More natural control would restore health and free patients from the need for therapies that are disruptive to quality of life. For more information please visit [www.sigilon.com](http://www.sigilon.com) or follow on Twitter at [https://twitter.com/Sigilon_Inc](https://twitter.com/Sigilon_Inc).

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**Lilly Forward-Looking Statement**

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about the benefits of a collaboration between Lilly and Sigilon, and reflects Lilly’s current beliefs. However, as with any such undertaking, there are substantial risks and uncertainties in the process of drug development and commercialization. Among other things, there can be no guarantee that Lilly will realize the expected benefits of the collaboration, or that the collaboration will yield commercially successful products. For a further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly’s expectations, please see Lilly’s most recent Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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