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News Release

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FANNIN — INNOVATION STUDIO —

NIH Awards Fannin Phase I SBIR Grant for Chorioamniotic Membrane-Anchoring Device for Fetal Surgery

HOUSTON, March 7, 2018 Fannin Innovation Studio has been awarded a $224,642 grant from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) to develop and test a novel medical device for anchoring the chorioamniotic membrane to the uterine wall to minimize the chance of preterm delivery following fetal surgery. Awarded through the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program, the federal funds will be used to further development of a new device that will enable fetal surgeons to prevent preterm birth when using a minimally invasive procedure to repair major congenital defects in the 2nd trimester.

Dr. Jimmy Espinoza, MD, MSc and Michael Belfort, MD, PhD, two fetal surgeons at Texas Children's Fetal Center® and faculty members in the department of obstetrics and gynecology at Baylor College of Medicine, identified the need for a way to secure the chorioamniotic membranes to the uterine wall to prevent preterm premature rupture of the membranes (pPROM), which can lead to complications for the mother and her baby. The current method for reducing the risk of pPROM is to make an open incision in the mother's abdomen to gain access to the uterus and suture the membranes to the uterine wall. However, the skin incision requires the procedure to be performed under general anesthesia.

Espinoza, who is also co-director of Texas Children's Fetal Center and Belfort, chairman of the department of obstetrics and gynecology at Baylor College of Medicine and obstetrician and gynecologist-in-chief at Texas Children's Hospital collaborated with an engineering team at the Department of Biomedical Engineering at Texas A&M University to develop the initial concept and prototype. The new device is a linear, needle-shaped probe that will deploy two biodegradable anchors percutaneously, one inside the amniotic cavity and another outside the uterine wall, with a degradable suture in between. These anchors will then be cinched together to firmly secure the membranes to the uterine wall and minimize the risk of pPROM. The device allows these anchors to be placed through the skin under local anesthesia without the need for a skin incision.

Recognizing the potential impact of the device for mothers and their unborn children, Fannin Innovation Studio is bringing the technology under its management and building a commercialization plan to develop the device and bring the product to market. Fannin is an early-stage life-sciences development group that partners with academic institutions and researchers to bring technologies

through clinical proof of concept. A core component of Fannin's business model is the pursuit of non-dilutive grant funding to support early-stage development of life-science technologies.

"At Fannin Innovation Studio, we are looking for creative ways to bring new technologies for children to the clinic because the economic opportunity for pediatric devices is not as large as the adult market. Our partnership with Texas Children's and Baylor College of Medicine is a model for how academic institutions and small businesses can work together to capital efficiently develop new medical solutions that can have a significant impact on the lives of children and their families," said Atul Varadhachary, Managing Partner at Fannin.

Fetal surgery is a relatively new discipline that aims to reduce the risk for fetal death or long-term complications in conditions such as twin-to-twin transfusion syndrome, severe fetal anemia, congenital diaphragmatic hernia, fetal hydrops, or spina bifida. Texas Children's and Baylor are at the forefront of fetal surgery in the U.S. and have innovated techniques to make fetal surgery safer for mothers and their unborn children, but fetal surgery is not without risks.

"Any fetal surgery involves disrupting the amniotic sac, which is made of two thin membranes that do not heal particularly well. As a result, the most common complication of fetal surgeries is pPROM and subsequent preterm birth," said Espinoza. "This device has the potential to reduce the risk of complications associated with fetal surgery for the mother and her unborn child."

The chorioamniotic anchor project is part of a larger collaboration between Fannin Innovation Studio, Texas Children's Hospital, and Baylor College of Medicine to develop new technologies that target the pediatric population, a market that is largely overlooked by traditional innovation models.

"Fannin Innovation Studio and Texas Children's have partnered to create an effective method to develop and de-risk new ideas in pediatrics in a cost-efficient way. By working to bring more pediatric-focused devices to market, Fannin's passion and dedication for children is helping Texas Children's Hospital continue to offer the most advanced care for our children and their families," said James Hury, Director for Innovation Partnerships at Texas Children's Hospital.

Fannin Innovation Studio, Texas Children's Hospital, and Baylor College of Medicine plan to continue to explore this new model of medical device development to accelerate the pace of innovation in pediatrics. The SBIR Phase I grant from the NICHD is the first step toward advancing the device to the clinic and will allow the team to further refine the device and perform pre-clinical studies that are critical for securing a larger SBIR Phase II grant.

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About Fannin Innovation Studio

Houston-based Fannin Innovation Studio is an early-stage life sciences development group focused exclusively on commercializing medical technologies. Fannin partners with life science innovators to co-found startup companies and provides a pooled management team, funding, and administrative support. To further bridge the commercialization gap, Fannin's internship and fellowship programs

provide aspiring entrepreneurs with hands-on development experience with its portfolio companies. For more information, visit www.FanninInnovation.com or email innovate@fannininnovation.com.

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