Origin™ Announces First Randomized Patients into Phase IIb-equivalent Dose-Ranging Study in Diabetic Foot Ulcers

Princeton, New Jersey – 22 March 2017 – Origin, Inc., a medtech company based in Princeton, NJ, today announced that treatment has begun on the first patients in its US dose-ranging ”GENESIS” trial (Phase IIb-equivalent). Origin has developed a proprietary technology to produce and deliver therapeutic quantities of plasma-generated Nitric Oxide (NO) for a wide range of potential human health benefits. The GENESIS trial is designed to demonstrate healing and optimize the treatment regimen for chronic Diabetic Foot Ulcers (DFUs).

Study design
GENESIS is a single-blinded 27-week study which will recruit up to 100 patients across 15 clinical sites in the U.S. After a two-week run-in period, patients will be randomized into one of four different dosing regimens or a standard of care (SOC) treatment arm to assess efficacy and safety. Patients will be treated over 12 weeks and monitored for 12 weeks post treatment.

- Arm 1: SOC alone, including dressing changes, wound cleansing, pressure relief (off-loading) and wound debridement
- Arm 2: 6 minute dose of plasma-generated nitric oxide, 2 times per week, along with SOC
- Arm 3: 6 minute dose of plasma-generated nitric oxide, 4 times per week, along with SOC
- Arm 4: 12 minute dose of plasma-generated nitric oxide, 2 times per week, along with SOC
- Arm 5: 12 minute dose of plasma-generated nitric oxide, 4 times per week, along with SOC

Effectiveness will be measured by wound closure rate (in cm^2 of epithelium coverage per week) and wound closure percentage (effectiveness measures for the study analysed through a maximum of 12 weeks of treatment). Safety will be measured by wound-related adverse events, which include adverse events of all causes that affect the wound.

“Diabetes and consequential diabetic foot ulcers are a growing healthcare burden impacting millions of people,” said Michael Preston, Chairman and CEO of Origin. “Plasma-generated Nitric Oxide has the potential to offer a new safe and effective therapy to close wounds actively, serving a large unmet need. This marks another step forward in our mission to become the advanced therapy of choice for the treatment of DFUs. We look forward to providing an update and initial readout of the interim results in the fourth quarter of 2017.”

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About DFUs

Diabetic foot ulcers (DFUs) are chronic, non-healing, penetrating wounds of the foot in patients with type 1 and type 2 diabetes mellitus. Over 49 million people in US and EU have diabetes[1] and 7-15% will develop DFUs at $11,000-16,000 annual incremental cost per patient[2]. 60% of patients are not healed after initial treatment with standard of care[1]. There is clear need for new and effective therapies.

About Origin

Origin, Inc. is a clinical-stage medtech company that incorporates its proprietary technology to deliver Nitric Oxide (NO) from a defined high-energy plasma stream to enhance and save lives. NO is a biologically active agent, with the ability to modify disease pathways through proven anti-microbial, anti-inflammatory, tissue-regenerative and vasodilatory activities. Origin's technology will be initially applied to several highly unmet conditions, including the treatment of wounds, ulcers, and acute and chronic infections. Origin's first potential product is a device focused on diabetic foot ulcers (DFU) a market estimated to be $13 billion[2]. Origin, Inc. (formerly Advanced Plasma Therapies, Inc.) was founded in 2010 and is based in Princeton, New Jersey.

For more information, please visit www.originww.com.

[1] Worldwide Wound Management, Forecast to 2024: Established and Emerging Products, Technologies and Markets in the Americas, Europe, Asia/Pacific and Rest of World. MedMarket Diligence, LLC. Published December 2015. [2] Rice et al. Burden of Diabetic Foot Ulcers for Medicare and Private Insurance. Diabetes Care. 2013.