



Origin Successfully Achieves Phase IIb GENESIS Trial Objectives Ahead of Schedule and Announces Early Termination of Study

Princeton, New Jersey – Apr. 18, 2018 - Origin, Inc., a Phase IIb clinical-stage biotechnology company, today announced that the US Food and Drug Administration has approved its request to conclude patient recruitment in the “GENESIS” dose-ranging (Phase IIb) trial of plasma generated nitric oxide in patients with chronic diabetic foot ulcers (DFUs). The request to conclude the trial follows positive interim analysis and evidence of healing in chronic DFUs, with 83 patients randomized.

An independent third-party review of interim data from the GENESIS trial confirmed Origin’s conclusion that there is sufficient data to recommend a clinically effective and safe treatment time and frequency. This data allows Origin to develop the safety and effectiveness hypotheses required to move forward to a pivotal trial (Phase III) design.

Origin has developed a proprietary technology which, for the first time, generates and delivers therapeutic quantities of plasma-generated nitric oxide topically through the dermis into the tissue. Beyond an initial focus on DFUs, the technology has the potential to address unmet needs in various areas of wound care, dermatology, dental, skin infection and inflammation and pain.

“The decision to end our study ahead of time following positive interim results is an excellent outcome, and underscores Origin’s position at the forefront of advancements in the DFU treatment landscape. We previously reported promising evidence of healing in the GENESIS trial, including 95% average wound-size reduction at 12 weeks, with 71% of wounds achieving complete closure in the strongest performing study arm,” said Michael Preston, Chairman and CEO of Origin.

“Backed by these favorable results and the early conclusion of the trial, we are one step closer to bringing this potential new therapy to the clinic and addressing the unmet needs of approximately two million people in the US suffering from chronic DFUs.”

Dr. David Dantzker, Vice Chairman and Chief Medical Officer of Origin, and former Chairman of the American Board of Internal Medicine, commented, “We believe the topical delivery of nitric oxide could alter the course of wound-healing. The development of an effective wound closure treatment represents a significant market opportunity, with the potential to address a wide range of unmet medical needs.”

The GENESIS trial¹ was a 27-week study recruiting up to 100 patients across 15 clinical sites in the U.S. The trial was designed to demonstrate safety and healing, as well as determine the optimal treatment regimen for chronic diabetic DFUs. After a two-week run-in period, patients were randomized into one

of four different treatment regimens or an SOC-only treatment arm. Wound sizes ranged from 1.0 – 9.9 cm².

- 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.

With 83 of 100 patients randomized, the Company has observed a meaningful difference in healing response for wounds in the 4x12 arm (Arm 5 above).

About Diabetic Foot Ulcers

Diabetic foot ulcers (DFUs) are chronic, non-healing, penetrating wounds of the foot in patients with type 1 and type 2 diabetes mellitus. Over 30 million people in U.S. have diabetes² and it is estimated that at least 15%³ will develop a DFU in their lifetime, resulting in approximately \$15,000 annual incremental cost per patient⁴ (excluding amputation). An estimated 60% of these wounds are not healed after initial treatment with standard of care, and are then considered chronic⁵. An estimated 85% of all diabetic lower-extremity amputations are preceded by a chronic, non-healing foot ulcer⁶ and approximately 15% of diabetic patients will have an amputation during their lifetime⁷. The five-year mortality rate for DFU patients with an amputation is estimated up to 74%, higher than that for several types of cancer including breast, colon, prostate and Hodgkin's disease⁸⁻¹¹.

About Origin

Origin, Inc. is a Phase IIb clinical-stage biotechnology company that applies its proprietary technology to generate and deliver nitric oxide (NO) from a defined high-energy plasma stream. Origin's unique plasma stream delivers therapeutic concentrations of NO directly to the targeted area and stimulates NO activity below the skin. NO is a biologically active agent, shown to modify disease pathways through anti-microbial, anti-inflammatory, tissue-regenerative and vasodilatory activities. Origin's technology is currently being studied in several highly unmet medical conditions, including the treatment of wounds, ulcers, and acute and chronic infections. Planned expansion of the clinical pipeline includes potential indications in dermatology, dentistry, and pain and inflammation. Origin, Inc. was founded in 2010 and is based in Princeton, New Jersey.

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

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1. www.clinicaltrials.gov/ct2/show/NCT03078933?cond=apt-001&rank=2 (FDA drug phase II equivalent).; 2. <http://www.diabetes.org/assets/pdfs/basics/cdc-statistics-report-2017.pdf>; 3. Reiber GE. The epidemiology of diabetic foot problems. *Diabet Med.* 1996;13:(suppl 1) S6-S11.; 4. Rice et al. Burden of Diabetic Foot Ulcers for Medicare and Private Insurance. *Diabetes Care.* 2013.; 5. 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. 6. Pecoraro RE, Reiber GE, Burgess EM. Pathways to

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