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Vericel Reports Three-Year Follow-Up Results From Phase 3 SUMMIT Extension Study of MACI(TM) Implant

Poster Presentation at AAOS Annual Meeting Shows Continued Benefit Over Microfracture Bone Marrow Stimulation Procedure

CAMBRIDGE, Mass., March 25, 2015 (GLOBE NEWSWIRE) -- Vericel Corporation (Nasdaq:VCEL), a leading developer of patient-specific expanded cellular therapies for the treatment of severe diseases and conditions, today reported that positive results from the three-year extension of the Phase 3 SUMMIT study with MACI™ (matrix-applied characterized autologous cultured chondrocytes) were presented at the annual meeting of the American Association of Orthopedic Surgeons in Las Vegas. In a poster presentation (number P169) entitled "SUMMIT Trial: Matrix-induced Autologous Chondrocyte Implant versus Microfracture at 3 Years," Professor Mats Brittberg, Cartilage Research Unit, University of Gothenburg, Sweden, and colleagues reported that patients followed for three years following treatment with MACI had consistent results as those reported previously in the two-year SUMMIT trial.

In the open-label, multi-center Phase 3 SUMMIT study, 144 patients with symptomatic articular cartilage defects in the knee were randomized to receive treatment with MACI implant or microfracture bone marrow stimulation (MFX) and followed for two years. The study found that treatment with MACI was clinically and statistically significantly better than MFX, with similar structural repair tissue and safety. The SUMMIT study concluded that "MACI offers a more efficacious alternative than MFX with a similar safety profile for the treatment of symptomatic articular cartilage defects of the knee."[1]

In the SUMMIT Extension trial, 128 patients (men and women aged 18 to 55) from the original SUMMIT study continue to be followed. The co-primary endpoints of the extension study are change in knee injury and osteoarthritis outcome (KOOS) pain and function scores at year 3, the same primary endpoint from the two-year SUMMIT trial. Patients treated with MACI versus MFX continue to show a statistically significant improvement from baseline in the co-primary endpoint of KOOS pain and function at year 3 ($p = 0.046$) with higher responder rates in the MACI group (81.5%) than in the MFX group (66.7%). Patients treated with MACI versus MFX also showed significant improvement in knee-related quality of life and other measures. The authors concluded that "the co-primary endpoints of pain and function showed significant improvement with MACI, which was statistically significantly better than with MFX." The incidences of treatment emergent adverse events and serious adverse events were similar between treatment groups at year 3 and no unexpected safety findings were reported.

David Recker, M.D., Vericel's chief medical officer, stated: "These findings appear to support the positive risk-benefit profile of MACI implantation in patients who require knee cartilage repair surgery that was first demonstrated in the pivotal Phase 3 SUMMIT study. We are extremely encouraged by the favorable clinical and efficacy of MACI compared to MFX after 3 years of follow-up."

[1] D. Saris et al., "Matrix-Applied Characterized Autologous Cultured Chondrocytes Versus Microfracture; Two-Year Follow-up of a Prospective Randomized Trial," The American Journal of Sports Medicine, Vol. 42, No. 6, April 2014

About MACI

MACI is a third-generation autologous chondrocyte implantation (ACI) product for the treatment of focal chondral cartilage defects in the knee. MACI has been approved but is not currently marketed in Europe and is a Phase 3 product candidate in the United States. The pivotal clinical trial supporting MACI registration in Europe (Superiority of MACI Implant to Microfracture Treatment, or SUMMIT) demonstrated a statistically significant and clinically meaningful improvement in the co-primary endpoint of pain and function for those patients treated with a MACI implant compared to microfracture, the previous standard of care. MACI has the potential advantages of a shorter, less-invasive surgical procedure and faster recovery period than current biological treatments for knee cartilage repair. Vericel plans to meet with the FDA this year to discuss the requirements for registration of MACI in the United States.

About Vericel Corporation

Vericel Corporation (formerly Aastrom Biosciences, Inc.) is a leader in developing patient-specific expanded cellular therapies for use in the treatment of patients with severe diseases and conditions. The company markets two autologous cell therapy products in the U.S.: Carticel® (autologous cultured chondrocytes), an autologous chondrocyte implant for the treatment of cartilage defects in the knee, and Epicel® (cultured epidermal autografts), a permanent skin replacement for the treatment of patients with deep-dermal or full-thickness burns comprising greater than or equal to 30% of total body surface area. Vericel is also developing MACI™, a third-generation autologous chondrocyte implant for the treatment of cartilage defects in the knee,

and ixmyelocel-T, a patient-specific multicellular therapy for the treatment of advanced heart failure due to ischemic dilated cardiomyopathy. For more information, please visit the company's website at www.vcel.com.

This document contains forward-looking statements, including, without limitation, statements concerning anticipated progress, objectives and expectations regarding the commercial potential of our products and growth in revenues, intended product development, clinical activity timing, integration of the acquired business, and objectives and expectations regarding our company described herein, all of which involve certain risks and uncertainties. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "we believe," "we intend," and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "potential," "could," "may," or similar expressions. Actual results may differ significantly from the expectations contained in the forward-looking statements. Among the factors that may result in differences are the inherent uncertainties associated with competitive developments, integration of the acquired business, clinical trial and product development activities, regulatory approval requirements, the availability and allocation of resources among different potential uses, estimating the commercial potential of our products and product candidates and growth in revenues, market demand for our products, and our ability to supply or meet customer demand for our products. These and other significant factors are discussed in greater detail in Aastrom's Annual Report on Form 10-K for the year ended December 31, 2013, filed with the Securities and Exchange Commission ("SEC") on March 13, 2014, Quarterly Reports on Form 10-Q and other filings with the SEC. These forward-looking statements reflect management's current views and Aastrom does not undertake to update any of these forward-looking statements to reflect a change in its views or events or circumstances that occur after the date of this release except as required by law.

CONTACT: Chad Rubin

The Trout Group

crubin@troutgroup.com

(646) 378-2947

Lee Stern

The Trout Group

lstern@troutgroup.com

(646) 378-2922