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1 of 1

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AVAVA Receives FDA 510(k) Clearance to Treat Benign Pigment Lesions, Including Hyperpigmentation

Waltham, Mass., Wednesday, August 17, 2022 – [AVAVA Inc.](#), (“AVAVA” or the “Company”), a disruptive medical aesthetics technology platform company providing breakthrough treatments for all skin tones, today announced that its AVAVA pigment disorder product has received FDA 510(k) clearance to treat benign pigmented lesions of the skin, including hyperpigmentation. This clearance marks AVAVA’s second received from the FDA for its new class of focused intradermal laser products powered by Focal Point Technology™ to deliver energy at any depth with pinpoint accuracy for ideal patient outcomes.

Dr. Irina Erenburg, CEO of AVAVA, said, “We are thrilled to announce our FDA clearance, a key milestone achievement for AVAVA, as we move to address the unmet needs of over 4 million women with pigmentary disorders, a \$1 billion annual procedure market.” Dr. Erenburg added, “In pioneering our technology, we harnessed over 30 years of clinical experience and developed an AI enabled, precise three-dimensional laser treatment that results in the optical breakdown of melanin (pigment), whether near the surface or deep under the skin. This achieves an optimal patient and provider experience without pain, downtime, or side effects. We look forward to continuing to build a body of clinical evidence supporting our indication and to finally offering to the clinical community a best-in-class solution for pigmentary disorders, a top 5 concern for skin of color patients in the US.”

“In today’s treatment market, where the lack of effective solutions for pigment disorders is well understood, we warmly welcome and are excited to be able provide the AVAVA therapy to our patients. We believe that with AVAVA, there is finally hope for patients with hyperpigmentation, dark spots after acne, and other pigmentary disorders, who have given up or chosen to not seek treatment,” said Dr. Roy G. Geronemus, Director of the Laser & Skin Surgery Center of New York and CEO of Navaderm Partners.

The AVAVA Focal Point Technology™ is complemented by a high-resolution interactive imaging system, which provides inter- and intra-treatment intelligence to map and guide real-time therapy with actionable data, to unlock safe and effective treatments for all skin tones.

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About Blossom Innovations

AVAVA is a disruptive medical aesthetics technology platform company providing breakthrough treatments for all skin types. AVAVA develops and markets a new class of FDA cleared, non-invasive medical aesthetic products that utilize patented precision Focal Point Technology and proprietary skin AI visualization to provide best in class patient and provider experience for all skin tones. The AVAVA Focal Point Technology™ is complemented by a IntelliView, a high-resolution interactive imaging system, which provides treatment intelligence to map and guide real-time therapy with actionable data, to unlock safe and effective treatments. For more information, please visit: avavaaesthetics.com.