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Diffusione presunta
Oggetto : FDA Clears the revolutionary Accure Laser
for the Treatment of Mild to Severe
Inflammatory Acne Vulgaris

Testo del comunicato

Vedi allegato.

3.1 REGEM

Press release

FDA Clears the revolutionary Accure Laser for the Treatment of Mild to Severe Inflammatory Acne Vulgaris

The Accure Laser is the next generation light-based platform for the treatment of acne.

The Accure Laser is the first 1726nm-based laser platform with both FDA and CE Mark clearance

Firenze - November 22, 2022 – El.En. Spa, leader on the laser market, listed on the Euronext STAR Milan ("STAR") of Borsa Italiana reported that its affiliate Accure Acne, Inc (www.accureacne.com), a pioneer in the development of innovative solutions for the treatment of acne, announced it has received FDA clearance for its Accure Laser™ System to treat mild to severe inflammatory acne vulgaris. The Accure Laser's technology, developed in cooperation with Quanta System, builds upon the unique selectivity of the 1726nm laser wavelength, adding proprietary technology to precisely control thermal gradient depth. This technology breakthrough is accomplished through a unique pulsing algorithm, integrated temperature monitoring, and automated yet precise control of the laser.

Through its subsidiary Quanta System, El.En.'s group holds today 15% of Accure Acne Inc's shares.

Accure's clinical and technical development teams represent an enduring collaboration of engineering acumen and clinical expertise. **Prof. Rox Anderson**, M.D., Head of the Wellman Center for Photomedicine at Massachusetts General Hospital Co-Founder and Chief Scientific and Medical Officer of Accure, an influential medical scientist and inventor dedicated to the field of light and energy-based devices used in dermatology, medical aesthetics, and various specialties, stated, "It has been my passion for two decades to bring lasting relief to acne sufferers throughout the world. The Accure Laser is a significant leap forward, and I congratulate Accure in achieving this important milestone ". **Marco Tagliaferri**, PhD, head of El.En.'s medical R&D and leader of Quanta System's team that contributed substantial design input, resources and expertise to the development of the Accure Laser, said: "Accure is a first-in-class laser technology and a pioneering new solution to treat acne vulgaris. It was rewarding to collaborate with world recognized physicians and Accure Acne Inc to achieve this important FDA milestone. Prior to the FDA clearance, our Group and Accure made history, creating the first ever CE marked 1726 nm energy-based device, designed to effectively blast sebaceous glands, sparing epidermis ".

Paolo Salvadeo, PhD, General Manager of El.En., commented, "Quanta is known globally as a leader in engineering, design, quality and precision of laser manufacturing. We are proud to be integral to the development of the Accure Laser System and look forward to cooperating with Accure on this very innovative solution for active acne".



“The Accure Laser System clearance is tremendously exciting for dermatologists and their patients. This platform is much more than the 1726nm wavelength laser that selectively targets sebaceous glands; this innovative intellectual property brings a new level of sophistication to energy-based devices targeting acne,” commented **Christopher Carlton**, Accure Acne Co-Founder, Chairman and CEO. “Accure Acne was founded over seven years ago to develop this disruptive technology to address multiple clinical applications. We have carefully built a positive safety profile and strive for best-in-class clinical results.”

In the U.S. alone, acne vulgaris affects more than 50 million teens and adults annually, making acne one of the most treated skin conditions by healthcare providers.

The Accure Laser will first be made available in a controlled, limited commercial release with selected board-certified dermatologists.

The authorization does not change the guidance provided for the current year.

El.En., an Italian company, is the parent of a high-.tech industrial group operating in the optoelectronics sector. Based on proprietary technology and multidisciplinary know-how, the El.En Group manufactures laser sources (gas, semiconductor, solid-state and liquid) and innovative laser systems for medical and industrial applications. The El.En. Group is the laser market leader in Italy and among the top operators in Europe. It designs, manufactures and sells worldwide:

- Medical laser equipment used in dermatology, cosmetics, physiotherapy, dentistry and gynecology;
- Industrial laser systems for applications ranging from cutting, marking and welding metals, wood, plastic and glass to decorating leather and textiles and restoring/conserving artwork;
- Laser systems for scientific research

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