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Sonoma Pharmaceuticals Successfully Transitions First Products to New EU MDR Requirements for Class IIb Medical Devices

BOULDER, CO / ACCESSWIRE / December 5, 2024 /Sonoma Pharmaceuticals, Inc. (Nasdaq:SNOA), a global healthcare leader developing and producing patented Microcyn® technology based stabilized hypochlorous acid (HOCl) products for a wide range of applications, including wound care, eye, oral and nasal care, dermatological conditions, podiatry, and animal health care, today announced it has successfully completed transition to the new European Union (EU) Medical Device Regulation (MDR) for four of its products in Europe.

Sonoma was granted classification as a Class IIb medical device for Microdacyn60® Wound Care and Microdacyn60 Hydrogel, its scar gel product Epicyn®, and Pediacyn® for atopic dermatitis.

The MDR was adopted in the EU in 2017 to replace the existing Medical Device Directive. The transition period for compliance was most recently extended to December 31, 2028 for non-implantable Class IIb and lower risk devices. In order to comply with the MDR, Sonoma's products needed to meet certain requirements relating to safety and performance and successfully undergo verification of regulatory compliance, or conformity assessment.

"Sonoma is pleased to have received the new Class IIb classification for our wound care, scar and atopic dermatitis products in the European Union, well ahead of the requisite compliance deadline," said Amy Trombly, CEO of Sonoma. "It is truly a testimony to the safety and efficacy of our products and strength of our clinical data. This is an important milestone made possible by the diligent preparation of our regulatory team to meet these new and more stringent standards for medical devices in Europe."

About Sonoma Pharmaceuticals, Inc.

Sonoma Pharmaceuticals is a global healthcare leader for developing and producing stabilized hypochlorous acid (HOCl) products for a wide range of applications, including wound, eye, oral and nasal care, dermatological conditions, podiatry, animal health care and non-toxic disinfectants. Sonoma's products are clinically proven to reduce itch, pain, scarring, and irritation safely and without damaging healthy tissue. In-vitro and clinical studies of HOCl show it to safely manage skin abrasions, lacerations, minor irritations, cuts, and intact skin. Sonoma's products are sold either directly or via partners in 55 countries worldwide and the company actively seeks new distribution partners. The company's principal office is in Boulder, Colorado, with manufacturing operations in Guadalajara,

Mexico. European marketing and sales are headquartered in Roermond, Netherlands. More information can be found at www.sonomapharma.com. For partnership opportunities, please contact busdev@sonomapharma.com.

Forward-Looking Statements

Except for historical information herein, matters set forth in this press release are forward-looking within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including statements about the commercial and technology progress and future financial performance of Sonoma Pharmaceuticals, Inc. and its subsidiaries (the "company"). These forward-looking statements are identified by the use of words such as "continue," "develop," "anticipate," "expect" and "expand," among others. Forward-looking statements in this press release are subject to certain risks and uncertainties inherent in the company's business that could cause actual results to vary, including such risks that regulatory clinical and guideline developments may change, scientific data may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, protection offered by the company's patents and patent applications may be challenged, invalidated or circumvented by its competitors, the available market for the company's products will not be as large as expected, the company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to meet the company's cash needs, fund further development, and the ability to meet a multitude of diverse regulatory and marketing requirements in different countries and municipalities, and other risks detailed from time to time in the company's filings with the Securities and Exchange Commission. The company disclaims any obligation to update these forward-looking statements, except as required by law.

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