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Sonoma Pharmaceuticals Receives New FDA 510(k) Clearance with Expanded Indications for Over-the-Counter Microcyn(R)-Based Solution

BOULDER, CO / ACCESSWIRE / September 17, 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 received a new 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its Microcyn technology-based solution, including specific over-the-counter indications for the face, eyelid and eyelashes.

Per this new clearance, Sonoma's Microcyn wound care solution can be used for OTC management of minor skin abrasions, lacerations and irritations, and intact skin on the face, eyelid and eyelashes. Sonoma believes these are the strongest OTC eye care claims in the HOCl industry. Additionally, the new claim referencing the face will expand how Sonoma can market its OTC dermatology products.

To support this 510(k) clearance, Sonoma was able to demonstrate safety, efficacy and stability for the 2 ounce product size, offering Sonoma a new opportunity to package certain of its products in smaller sizes appealing to consumers.

"These new extended claims exemplify Sonoma's leadership in developing products based on hypochlorous acid technology under its Microcyn brand. Our new claims around the face, eyelid and eyelash will allow us to further develop industry-leading products to treat common conditions," said Amy Trombly, CEO of Sonoma. "The FDA review process requires increasingly rigorous biocompatibility and performance testing. The expanded indications validate our unparalleled proprietary technology and expertise developed over two decades of working with HOCl as well as our commitment to innovation."

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, as well as uncertainties relative to the COVID-19 pandemic and economic development, varying product formulations and 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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