

January 10, 2023



# Inogen Achieves Regulatory Milestones to Support Current and Future Products

*Inogen Announces Receipt of EU Quality Management Certification under the Medical Device Regulation for Portable Oxygen Concentrators*

*Inogen Announces U.S. Food and Drug Administration 510(k) clearance for its Latest Portable Oxygen Concentrator*

*Inogen to Launch New Rove Series Portable Oxygen Concentrators in the US This Year*

GOLETA, Calif.--(BUSINESS WIRE)-- [Inogen, Inc.](#) (Nasdaq: [INGN](#)), a medical technology company offering innovative respiratory products for use in the homecare setting, today announced that it has achieved regulatory milestones in the EU and the US to support its portable oxygen concentrator products.

Inogen received European Medical Device Regulation (EU MDR) certification from its Notified Body, the British Standards Institution (BSI) in December 2022, granting permission to sell and commercialize Inogen One G4 and the updated version of its Inogen One G5 portable oxygen concentrators in the EU.

Additionally on December 9, 2022, Inogen was granted clearance for its 510(k) premarket notification by U.S. Food and Drug Administration (FDA) for a new portable oxygen concentrator, Rove 4, which will take Inogen's leadership in portability of POCs to the next level.

These regulatory achievements enhance Inogen's portfolio of portable oxygen concentrator products with the addition of the Rove series. Rove 6, a new and improved 6-setting device has already been launched in European countries where reimbursement is grandfathered, and Rove 4, a 4-setting device delivering ultimate performance and portability, is expected to launch in the US by the back half of 2023 having received FDA market clearance in December 2022.

"We are pleased to announce the receipt of both the EU MDR certification and US FDA clearance," said Nabil Shabshab, President and Chief Executive Officer. "This is an important next step in Inogen cementing its commitment to continue leading POC innovations to serve patients in need of oxygen therapy around the world. The Rove series will serve as our next generation POC platform with product launches being planned for 2023. We are excited about these new products and the progress in the overall innovation roadmap towards next generation offerings to serve COPD patients and beyond."

## About Inogen

Inogen, Inc. (Nasdaq: INGN) is a leading global medical technology company offering

innovative respiratory products for use in the homecare setting. Inogen supports patient respiratory care by developing, manufacturing, and marketing innovative best-in-class portable oxygen concentrators used to deliver supplemental long-term oxygen therapy to patients suffering from chronic respiratory conditions. Inogen partners with patients, prescribers, home medical equipment providers, and distributors to make its oxygen therapy products widely available allowing patients the chance to remain ambulatory while managing the impact of their disease.

For more information, please visit [www.inogen.com](http://www.inogen.com).

## **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, among others, Inogen's expectations regarding its plans for future product releases and innovation. Any statements contained in this communication that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible," and similar expressions are intended to identify forward-looking statements. Forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from currently anticipated results, including but not limited to, risks arising from regulatory approvals; risks related to the Company's supply chain and limited availability of parts used in our POCs, the risk of further slowdowns or temporary halts to production, or cost inflation for such components; the impact of changes in reimbursement rates and reimbursement and regulatory policies; and the possible loss of key employees, customers, or suppliers. In addition, Inogen's business is subject to numerous additional risks and uncertainties, including, among others, risks relating to market acceptance of its products; competition; its sales, marketing and distribution capabilities; its planned sales, marketing, and research and development activities; interruptions or delays in the supply of components or materials for, or manufacturing of, its products; seasonal variations; unanticipated increases in costs or expenses; and risks associated with international operations. Information on these and additional risks, uncertainties, and other information affecting Inogen's business operating results are contained in its Annual Report on Form 10-K for the year ended December 31, 2021, Quarterly Report on Form 10-Q for the period ended September 30, 2022, and in its other filings with the Securities and Exchange Commission. Additional information will also be set forth in Inogen's Annual Report on Form 10-K for the period ended December 31, 2022, to be filed with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. Inogen disclaims any obligation to update these forward-looking statements except as may be required by law.

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Agnes Lee  
[ir@inogen.net](mailto:ir@inogen.net)

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