Eargo Applauds Proposed Rule for OTC Hearing Aids and Submits Public Comments to FDA

January 20, 2022

SAN JOSE, Calif., Jan. 20, 2022 (GLOBE NEWSWIRE) -- Eargo, Inc. (Nasdaq: EAR), a medical device company on a mission to improve the quality of life of people with hearing loss, today announced the submission of public comments to the Food and Drug Administration (FDA) concerning its proposed rule to create a new regulatory category of over the counter (OTC) hearing aids. Eargo is supportive of the FDA's proposed rule and applauds the FDA's efforts to broaden consumer access to hearing technology. Historically, most people with hearing loss who would benefit from wearing a hearing aid have never used them, even though unaddressed hearing loss is associated with significant negative health outcomes and increased costs.[1,2] Eargo believes the FDA's efforts to establish a regulatory framework for OTC hearing aids with appropriate measures to ensure consumer safety will help increase adoption of necessary hearing technology.

Christian Gormsen, Eargo's President and Chief Executive Officer, said, "Eargo was founded to create an affordable hearing aid that consumers actually want to use, and to offer a purchase experience that is accessible and empowering. We believe our founding principles align very closely with the objectives of creating an OTC hearing aid category: removing barriers to access, driving innovation, ensuring customer safety, and reducing cost. This industry is long overdue for the types of positive changes the FDA is proposing, which we believe will benefit consumers and allow more people to take steps toward hearing better. We are very supportive of the FDA's proposed rule and look forward to the positive changes this will have on the future of hearing health."

"We also believe the FDA's proposed removal of certain selling restrictions for OTC hearing aids will allow Eargo to expand the way we serve customers. If finalized as written, we believe adding full retail and physical locations to our current online experience would become simplified and scalable, expanding our capabilities to meet customers where they are."

"As an innovator in hearing wellness, with more than 100,000 gross hearing aid systems shipped to help people hear life to the fullest, Eargo supports a regulatory framework that aims to improve access and lower cost to consumers."

The new OTC category applies to certain air-conduction hearing aids intended for adults aged 18 and older who have perceived mild to moderate hearing loss. If finalized as written, all air conduction hearing aids that do not meet the requirements for OTC hearing aids will become prescription devices. When finalized, the rule would allow hearing aids within the OTC category to be sold directly to consumers in stores or online without a medical exam or the need for supervision, prescription, order, involvement, or intervention of a licensed hearing professional.

About Eargo

Eargo is a medical device company dedicated to improving the quality of life of people with hearing loss. Our innovative product and go-to-market approach address the major challenges of traditional hearing aid adoption, including social stigma, accessibility and cost. We believe our Eargo hearing aids are the first and only virtually invisible, rechargeable, completely-in-canal, FDA regulated, exempt Class I or Class II devices for the treatment of hearing loss. Our differentiated, consumer-first solution empowers consumers to take control of their hearing. Consumers can purchase online or over the phone and get personalized and convenient consultation and support from a dedicated customer support team, including licensed hearing professionals, via phone, text, email or video chat. The Eargo device is offered to consumers at approximately half the cost of competing hearing aids purchased through traditional channels in the United States.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact contained in this press release are forward-looking statements, including statements regarding the future effects of the FDA's proposed rule for OTC hearing aids, the Company's ability to add full retail and physical locations to its current online experience in a simplified and scalable manner, and the impact of the FDA final rule. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions that could cause actual results and events to differ materially from those anticipated, including, but not limited to, risks, uncertainties and assumptions related to: the outcomes of the previously disclosed U.S. Department of Justice ("DOJ") investigation and third-party payor audits; potential related penalties, fines and actions that may ensue as a result of the DOJ investigation, the third-party payor audits and/or any other action that may arise therefrom; recoupments of previous claims paid as a result of the DOJ investigation, the third-party payor audits and/or any other action that may arise therefrom; the impact of the DOJ investigation and third-party payor audits on the Company's business and results of operations; the Company's expectations concerning additional orders by existing customers; the Company's expectations regarding the potential market size and size of the potential consumer populations for its products and any future products, including the Company's ability to maintain or increase insurance coverage of Eargo hearing aids going forward; the Company's ability to release new hearing aids and the anticipated features of any such hearing aids; developments and projections relating to the Company's competitors and its industry, including competing products; the Company's ability to maintain its competitive technological advantages against new entrants in its industry; the pricing of the Company's hearing aids; the Company's expectations regarding the ability to make certain claims related to the performance of its hearing aids relative to competitive products; the Company's expectations with regard to changes in the regulatory landscape for hearing aid devices, including the implementation of the pending OTC hearing aid pathway regulatory framework; and the Company's estimates regarding the COVID-19 pandemic, including but not limited to, its duration and its impact on the Company's business and results of operations. These and other risks are described in greater detail under the section titled "Risk Factors" contained in the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other filings with the U.S. Securities and Exchange Commission. Any forward-looking statements in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, are based on current expectations, forecasts and assumptions, and speak only as of the date of this press release. Except as required by law, the Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Media Contact
Emma Martin

EargoPR@AllisonPR.com

Investor Contact
Nick Laudico
Senior Vice President of Corporate Strategy and Investor Relations
ir@eargo.com

[1] National Institute on Deafness and Other Communication Disorders. Quick statistics about hearing

[2] Reed et al. (2019). Trends in health care costs and utilization associated with untreated hearing loss over 10 years. *JAMA Otolaryngol Head Neck Surg,* 145(1), 27-34.