

DiagnaMed Granted FDA Orphan Drug Designation for Molecular Hydrogen to Treat Amyotrophic Lateral Sclerosis

Toronto, Ontario--(Newsfile Corp. - March 3, 2025) - DiagnaMed Holdings Corp. (CSE: DMED) (OTCQB: DGNMF) ("DiagnaMed", "DMED", or the "Company"), a leading provider of cutting-edge technology solutions for the hydrogen and life sciences industries, today announced in a significant advancement for rare disease research, the Company has been granted Orphan Drug Designation (ODD) for molecular hydrogen in the treatment of amyotrophic lateral sclerosis (ALS) by the U.S. Food and Drug Administration (FDA). This designation underscores the potential of molecular hydrogen as a novel therapeutic option for ALS patients and highlights ongoing efforts to address unmet medical needs in rare disease communities.

ALS is a progressive neuromuscular disease that attacks nerve cells responsible for controlling voluntary muscle movement, leading to paralysis and, ultimately, respiratory failure, and has a life expectancy of only two to six years after diagnosis. Currently, there is no known cure for ALS. ALS affects approximately 50,000 people in the U.S. and Europe, with over 5,000 new cases diagnosed annually. With limited treatment options available, the FDA's recognition of molecular hydrogen as an orphan drug offers hope to patients and families impacted by this debilitating illness.

Molecular hydrogen, a small molecule with antioxidant and anti-inflammatory properties, has shown early promise in preclinical studies for its ability to mitigate oxidative stress and inflammation-key factors implicated in ALS progression. The FDA's decision paves the way for DiagnaMed to accelerate its discovery and development programs with molecular hydrogen.

One of DiagnaMed's strategic initiatives regarding hydrogen is to unlock the medical potential of molecular hydrogen for neurodegenerative diseases and brain health conditions ([press release](#)). The Company's commercialization strategy involves partnering with specialty pharmaceutical companies to fund the development of its medical programs involving molecular hydrogen.

Letter of Intent with Revive Therapeutics Ltd (CSE: RVV) (OTCQB: RVVTF) ("Revive")

DiagnaMed and Revive have entered into a non-binding letter of intent (LOI), dated February 28, 2025, with Revive to acquire the full rights to DiagnaMed's intellectual property (the "Acquired Assets") pertaining to molecular hydrogen for ALS (the "Acquisition"). The final terms of the Acquisition will be agreed to by the parties after the completion of due diligence by Revive. The Acquisition is expected to close on or before March 31, 2025, subject to customary closing conditions, including but not limited to, the negotiation and execution of a definitive agreement.

Fabio Chianelli, Chairman and CEO of DiagnaMed, commented:

"Receiving orphan drug designation from the FDA is a significant milestone for DiagnaMed and validates the promise of molecular hydrogen as a potential treatment for ALS. We are excited to partner with Revive Therapeutics to advance this program and meet the urgent needs of the ALS community."

The Orphan Drug Designation provides DiagnaMed with key incentives, including tax credits for clinical trial costs, exemption from certain FDA fees, and the potential for seven years of market exclusivity upon approval. These benefits are designed to encourage the development of therapies for rare diseases that might otherwise lack sufficient commercial interest.

About DiagnaMed

DiagnaMed Holdings Corp. (CSE: DMED) (OTCQB: DGNMF) delivers innovative technology solutions

for the cleantech and life sciences industries, with a focus on hydrogen production and AI-driven drug discovery and diagnostics. Visit DiagnaMed.com.

For more information, please contact:

Fabio Chianelli
Chairman and CEO
DiagnaMed Holdings Corp.
Tel: 416-800-2684
Email: info@diagnamed.com
Website: www.diagnamed.com

Neither the Canadian Securities Exchange nor its Regulation Services Provider have reviewed or accept responsibility for the adequacy or accuracy of this release.

Cautionary Statement

Certain statements in this news release are forward-looking statements, including with respect to future plans, and other matters. Forward-looking statements consist of statements that are not purely historical, including any statements regarding beliefs, plans, expectations or intentions regarding the future. Such information can generally be identified by the use of forwarding-looking wording such as "will", "may", "expect", "could", "can", "estimate", "anticipate", "intend", "believe", "projected", "aims", and "continue" or the negative thereof or similar variations. The reader is cautioned that assumptions used in the preparation of any forward-looking information may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company, including but not limited to, business, economic and capital market conditions, the ability to manage operating expenses, and dependence on key personnel. Such statements and information are based on numerous assumptions regarding present and future business strategies and the environment in which the Company will operate in the future, anticipated costs, and the ability to achieve goals. Factors that could cause the actual results to differ materially from those in forward-looking statements include, the continued availability of capital and financing, litigation, failure of counterparties to perform their contractual obligations, loss of key employees and consultants, and general economic, market or business conditions. Factors that could cause actual results to differ materially from those anticipated in these forward-looking statements are described under the caption "Risk Factors" in Company's management's discussion and analysis for the three-months ended December 31, 2024 ("MD&A"), dated February 24, 2025, which is available on the Company's profile at www.sedarplus.ca. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. The reader is cautioned not to place undue reliance on any forward-looking information. The forward-looking statements contained in this news release are made as of the date of this news release. Except as required by law, the Company disclaims any intention and assumes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

This news release does not constitute an offer to sell or the solicitation of an offer to buy, and shall not constitute an offer, solicitation or sale in any state, province, territory or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state, province, territory or jurisdiction.



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