

New International Consensus Statement Proposes “Difficult-to-treat Depression” as a More Clinically Useful Definition than “Treatment-Resistant Depression”

London, February 19, 2020 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology and innovation company, commends the recent international consensus statement published in the *Journal of Affective Disorders* for recommendations to identify, assess and manage depression for patients unable to achieve or sustain symptom remission despite serial treatment trials.¹ While the diagnosis for these patients is often “Treatment-Resistant Depression” (TRD), the authors conclude that “Difficult-to-treat Depression” (DTD) has semantic and conceptual advantages.

The international consensus group, comprised of psychiatrists from around the globe, reviewed relevant literature on TRD and DTD. They identified and consented on terminology describing DTD, information about the identification and assessment of patients with DTD, and treatment options for DTD. They proposed the definition of DTD as “depression that continues to cause significant burden despite usual treatment efforts.”

“Reconceptualizing ‘Treatment-Resistant Depression’ as ‘Difficult-to-treat’ is significant for many reasons. Describing a person’s depression as ‘treatment resistant’ can often simply increase their sense of hopelessness. It can also be used by some clinicians as a way of absolving themselves of their inability to help the person recover from their illness. Conversely, describing depression as ‘difficult to treat’ helps move the clinician and patient into a more proactive, multi-dimensional framework, identifying addressable barriers to successful treatment and considering a broad range of treatment options,” said Prof. Hamish McAllister-Williams, lead author and Professor of Affective Disorders at Newcastle University in the United Kingdom. “The group synthesized the body of evidence and concluded that Difficult-to-treat Depression, rather than Treatment-Resistant Depression, provides a more clinically useful conceptualization as it implies a search for the obstacles that prevent a patient from achieving a sustained symptom-free state. The framework described in this consensus statement emphasizes the importance to patients of focusing on optimizing daily psychosocial functioning and quality of life and not just symptom control.”

The consensus paper explains that focusing on steps in the treatment pathway provides greater scope for addressing factors that could influence DTD patient outcomes. Recommended key principles in the treatment pathway include: a thorough initial assessment after identifying a patient as having DTD and long-term follow-up assessments at regular intervals; the use of a framework to facilitate identification of barriers to successful treatment; a patient-centered approach based on shared decision making around all aspects of treatment; and optimizing medication choices and doses for each patient, along with specific psychosocial interventions in order to achieve optimal symptom control.

“LivaNova is committed to helping people for whom depression remains a significant burden despite conventional treatment. This consensus statement emphasizes a more empathetic and multi-modal assessment and treatment approach,” said Bryan Olin, LivaNova Senior Vice President for Clinical, Quality and Regulatory Affairs. “Our company fully embraces the use of ‘Difficult-to-treat Depression’ as a designation going forward given that it conveys a more holistic and humanistic connotation for patients and clinicians.”

While the costs of a consensus meeting were met through an unrestricted educational grant made available by LivaNova, the Company had no input as to the content of the consensus statement.

About LivaNova

LivaNova PLC is a global medical technology and innovation company built on nearly five decades of experience and a relentless commitment to provide hope for patients and their families through innovative medical technologies, delivering life-changing improvements for both the Head and Heart. Headquartered in London, LivaNova employs approximately 4,000 employees and has a presence in more than 100 countries for the benefit of patients, healthcare professionals and healthcare systems worldwide. LivaNova operates as two businesses: Cardiovascular and Neuromodulation, with operating headquarters in Mirandola (Italy) and Houston (U.S.), respectively.

For more information, please visit www.livanova.com.

Safe Harbor Statement

This news release contains “forward-looking statements” concerning our goals, beliefs, expectations, strategies, objectives, plans and underlying assumptions and other statements that are not necessarily based on historical facts. Actual results may differ materially from those

indicated in our forward-looking statements as a result of various factors, including those factors set forth in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018, as supplemented by any risk factors contained in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. We undertake no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

References

- 1 *R.H. McAllister-Williams, C. Arango, P. Blier, K. Demyttenaere, P. Falkaj, P. Gorwood, M. Hopwood, A. Javed, S. Kasper, G.S. Malhi, J.C. Soares, E. Vieta, A.H. Young, A. Papadopoulos, A.J. Rush, The identification, assessment and management of difficult-to-treat depression: An international consensus statement, Journal of Affective Disorders (2020), doi: <https://doi.org/10.1016/j.jad.2020.02.023>.*

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