Lilly Announces Agreement to Acquire Prevail Therapeutics

December 15, 2020

Acquisition will establish a gene therapy program at Lilly, anchored by Prevail's portfolio of neuroscience assets, and will broaden Lilly's commitment to use novel modalities to attempt to address otherwise fatal genetic forms of neurodegenerative disease

INDIANAPOLIS and NEW YORK, Dec. 15, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Prevail Therapeutics Inc. (NASDAQ: PRVL) today announced a definitive agreement for Lilly to acquire Prevail for $22.50 per share in cash (or an aggregate of approximately $880 million) payable at closing plus one non-tradable contingent value right ("CVR") worth up to $4.00 per share in cash (or an aggregate of approximately $160 million), for a total consideration of up to $26.50 per share in cash (or an aggregate of approximately $1.040 billion). The CVR is payable (subject to certain terms and conditions) upon the first regulatory approval of a product from Prevail's pipeline as set forth in more detail below. Prevail is a biotechnology company developing potentially disease-modifying AAV9-based gene therapies for patients with neurodegenerative diseases.

The acquisition will establish a new modality for drug discovery and development at Lilly, extending Lilly's research efforts through the creation of a gene therapy program that will be anchored by Prevail's portfolio of clinical-stage and preclinical neuroscience assets. Prevail's lead gene therapies in clinical development are PR001 for patients with Parkinson's disease with *GBA1* mutations (PD-GBA) and neuronopathic Gaucher disease (nGD) and PR006 for patients with frontotemporal dementia with *GRN* mutations (FTD-GRN). Prevail's preclinical pipeline includes PR004 for patients with specific synucleinopathies, as well as potential gene therapies for Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis (ALS), and other neurodegenerative disorders.

"Gene therapy is a promising approach with the potential to deliver transformative treatments for patients with neurodegenerative diseases such as Parkinson's, Gaucher and dementia," said Mark Mintun, M.D., vice president of pain and neurodegeneration research at Lilly. "The acquisition of Prevail will bring critical technology and highly skilled teams to complement our existing expertise at Lilly, as we build a new gene therapy program anchored by well-researched assets. We look forward to completing the proposed acquisition and working with Prevail to advance their groundbreaking work through clinical development."

"Lilly is an established leader in neuroscience drug development and commercialization who shares our commitment to patients with neurodegenerative diseases, and I'm excited for Prevail to join the Lilly family," said Asa Abeliovich, M.D., Ph.D., founder and chief executive officer of Prevail. "I'm incredibly proud of the Prevail team, who have made great progress advancing our pipeline of gene therapy programs for patients with these devastating disorders. In just over three years, Prevail has advanced two first-in-class gene therapy programs into clinical development for PD-GBA, nGD, and FTD-GRN, established two manufacturing platforms, and developed a broad pipeline with great potential to impact patients in need of disease-modifying treatment options. With its global scale and resources, Lilly will be the ideal organization to maximize the potential of our pipeline and accelerate our ability to bring these therapies to as many patients as possible. We look forward to working together to advance our shared mission."

Under the terms of the agreement, Lilly will commence a tender offer to acquire all outstanding shares of Prevail Therapeutics Inc. for a purchase price of $22.50 per share in cash (or an aggregate of approximately $880 million) payable at closing plus one non-tradeable CVR. The CVR entitles Prevail stockholders to up to an additional $4.00 per share in cash (or an aggregate of approximately $160 million) payable (subject to certain terms and conditions) upon the first regulatory approval for commercial sale of a Prevail product in one of the following countries: United States, Japan, United Kingdom, Germany, France, Italy or Spain. To achieve the full value of the CVR, such regulatory approval must occur by December 31, 2024. If such regulatory approval occurs after December 31, 2024, the value of the CVR will be reduced by approximately 8.3 cents per month until December 1, 2028 (at which point the CVR will expire). There can be no assurance any payments will be made with respect to the CVR. The transaction is not subject to any financing condition and is expected to close in the first quarter of 2021, subject to customary closing conditions, including receipt of required regulatory approvals and the tender of a majority of the outstanding shares of Prevail's common stock. Following the successful closing of the tender offer, Lilly will acquire any shares of Prevail that are not tendered in the tender offer through a second-step merger at the same consideration as paid in the tender offer.

The purchase price payable at closing represents a premium of approximately 117 percent to the 60-day volume-weighted average trading price of Prevail's common stock ended on December 14, 2020, the last trading day before the announcement of the transaction. Prevail's Board of Directors unanimously recommends that Prevail's stockholders tender their shares in the tender offer. Additionally, certain Prevail stockholders, beneficially owning approximately 51 percent of Prevail's outstanding common stock, have (subject to certain terms and conditions) agreed to tender their shares in the tender offer.

Upon closing, the impact of this transaction will be reflected in Lilly's 2021 financial results according to Generally Accepted Accounting Principles (GAAP). There will be no change required to Lilly's 2021 financial guidance being issued today for research and development expense or non-GAAP earnings per share as a result of this transaction.

For Lilly, Lazard is acting as sole financial advisor and Weil, Gotshal & Manges LLP is acting as legal counsel. For Prevail, Centerview Partners LLC is acting as sole financial advisor, Ropes & Gray LLP is acting as legal counsel, and Cooley LLP also provided legal counsel.

Prevail Therapeutics Pipeline

- PR001 is being developed as a potentially disease-modifying, single-dose AAV9-based gene therapy for patients with Parkinson's disease with *GBA1* mutations (PD-GBA) and neuronopathic Gaucher disease (nGD), delivered by intra-cisterna magna injection. The PROPEL trial, a Phase 1/2 clinical trial of PR001 for the treatment of PD-GBA patients, is ongoing. The PROVIDE trial, a Phase 1/2 clinical trial of PR001 for the treatment of Type 2 Gaucher disease patients, is now recruiting. The U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for PR001 for the treatment of PD-GBA and for the treatment of nGD. It has also granted Orphan Drug Designation for PR001 for the treatment of Gaucher disease, and Rare Pediatric Disease Designation for the treatment of nGD.
- PR006 is being developed as a potentially disease-modifying, single-dose AAV9-based gene therapy for patients with frontotemporal dementia with GRN mutations (FTD-GRN), also delivered by intra-cisterna magna injection. The PROCLAIM trial, a Phase 1/2 clinical trial of PR006 for the treatment of FTD-GRN patients, is currently ongoing and the first patient was dosed in December 2020. The FDA and the European Commission have granted orphan designation for PR006 for the treatment of FTD, and the FDA has granted Fast Track Designation for PR006 for FTD-GRN.
- PR004 is a gene therapy in preclinical development for patients with certain synucleinopathies. PR004 utilizes an AAV9 vector to deliver the *GBA1* gene, which encodes glucocerebrosidase (GCase), and a molecule that suppresses expression of α-Synuclein.
- Prevail is developing a broad pipeline of additional AAV gene therapies for the treatment of Alzheimer's disease, ALS, Parkinson's disease, and other neurodegenerative disorders. Preclinical development of these potential therapies is currently ongoing.

About Prevail Therapeutics
Prevail is a gene therapy company leveraging breakthroughs in human genetics with the goal of developing and commercializing disease-modifying AAV-based gene therapies for patients with neurodegenerative diseases. Prevail is developing PR001 for patients with Parkinson's disease with *GBA1* mutations (PD-GBA) and neuronopathic Gaucher disease (nGD); PR006 for patients with frontotemporal dementia with *GRN* mutations (FTD-GRN); and PR004 for patients with certain synucleinopathies.

Prevail was founded by Dr. Asa Abeliovich in 2017, through a collaborative effort with The Silverstein Foundation for Parkinson's with GBA, and OrbiMed, and is headquartered in New York, NY.

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com. C-LLY

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements about Lilly's proposed acquisition of Prevail Therapeutics Inc. ("Prevail"), regarding potential contingent consideration amounts and terms, regarding the anticipated occurrence, manner and timing of closing of the proposed transaction, regarding Prevail's product candidates and ongoing preclinical development, regarding Lilly's development of a potential gene therapy program, and regarding Lilly's expected 2021 financial guidance and the impact of the proposed acquisition on research and development expense and non-GAAP earnings per share. It reflects current beliefs and expectations; however, as with any such undertaking, there are substantial risks and uncertainties in consummating the proposed transaction, in drug research, development and commercialization, and in Lilly's evaluation of its estimated financial results for 2021 and the impact of the proposed acquisition. Actual results could differ materially due to various factors, risks and uncertainties. Among other things, there can be no guarantee that the proposed transaction will be completed in the anticipated timeframe or at all, that the conditions required to complete the proposed transaction will be met, that Lilly will realize the expected benefits of the proposed transaction, that product candidates will be approved on anticipated timelines or at all, that Lilly will be successful in building a gene therapy program, that any products, if approved, will be commercially successful, that all or any of the contingent consideration will become payable on the terms described herein or at all, that Lilly's financial results will be consistent with its expected 2021 guidance or that Lilly can reliably predict the impact of the proposed acquisition on its 2021 financial guidance and results. For further discussion of these and other risks and uncertainties, see Lilly's and Prevail's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission (the "SEC"). Except as required by law, neither Prevail nor Lilly undertakes any duty to update forward-looking statements to reflect events after the date of this press release.

Additional Information about the Acquisition and Where to Find It

The tender offer for the outstanding shares of Prevail referenced in this communication has not yet commenced. This announcement is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell shares of Prevail, nor is it a substitute for the tender offer materials that Lilly and its acquisition subsidiary will file with the SEC upon commencement of the tender offer. At the time the tender offer is commenced, Lilly and its acquisition subsidiary will file tender offer materials on Schedule TO, and thereafter Prevail will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT WILL CONTAIN IMPORTANT INFORMATION. HOLDERS OF SHARES OF PREVAIL ARE URGED TO READ THESE DOCUMENTS CAREFULLY WHEN THEY BECOME AVAILABLE (AS EACH MAY BE AMENDED OR SUPPLEMENTED FROM TIME TO TIME) BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT HOLDERS OF PREVAIL SHARES SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING TENDERING THEIR SHARES. The Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, will be made available to all holders of shares of Prevail at no expense to them. The tender offer materials and the Solicitation/Recommendation Statement will be made available for free at the SEC's web site at www.sec.gov.

In addition to the Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the

Solicitation/Recommendation Statement, Lilly and Prevail file annual, quarterly and special reports and other information with the SEC. You may read and copy any reports or other information filed by Lilly or Prevail at the SEC public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. Lilly's and Prevail's filings with the SEC are also available to the public from commercial document-retrieval services and at the website maintained by the SEC at www.sec.gov.

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