Novus Therapeutics Announces First Patient Enrolled in Phase 2a Clinical Trial of Anti-CD40L Antibody AT-1501 in Amyotrophic Lateral Sclerosis

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IRVINE, Calif.--(BUSINESS WIRE)--Nov. 2, 2020-- Novus Therapeutics, Inc. (“Novus”) (NASDAQ: NVUS), a clinical stage biopharmaceutical company focused on developing life-changing, targeted medicines for patients undergoing organ or cellular transplantation, as well as those living with immunological diseases, today announced that the first subject has been enrolled in the Phase 2a clinical trial evaluating AT-1501, the Company’s lead product candidate, in adults with amyotrophic lateral sclerosis (ALS). AT-1501 blocks the activation of the CD40L pathway, which has been shown to improve muscle function, slow disease progression, and improve survival in a pre-clinical animal model of ALS. AT-1501 previously received orphan drug designation from the U.S. Food and Drug Administration for the treatment of ALS.

“Novus is committed to providing people living with ALS and their families with a therapeutic solution to treat this progressive and devastating disease as expeditiously as possible,” said Steven Perrin, Ph.D., President and Chief Scientific Officer of Novus. “We look forward to the safety and biomarker insights from this study and we anticipate top-line data from this important trial in 2022.”

"There is strong evidence that the reduction of peripheral neuroinflammation has the capacity to influence disease progression in ALS,” said Dr. Merit Cudkowicz, Director of the Sean M. Healey & AMG Center for ALS, and Chief of Neurology at Massachusetts General Hospital, Boston. “I am excited to see the clinical advancement of AT-1501, which targets a key signaling pathway in the generation of pro-inflammatory responses."

The AT-1501 Phase 2a trial in ALS is a 12-week, open label, dose escalating, safety and biomarker study. The endpoints of the study are safety and tolerability, and changes in pro-inflammatory biomarkers as well as neurofilament light chain. Exploratory clinical endpoints will also be assessed.

"We are in urgent need of new therapies for people living with ALS,” said Dr. Michael Rivner, Charbonnier Professor of Neurology and Director of the ALS Clinic at Georgia Regents Medical Center, Augusta. “AT-1501 and the CD40/CD40L pathway represent a highly promising approach to treating this disease.”

Novus Therapeutics has completed a Phase 1a/1b single ascending dose trial in healthy volunteers and adults living with ALS. In that trial, AT-1501 was well tolerated at all doses tested and demonstrated a good safety profile. AT-1501 also demonstrated linear dose proportionality across the dose range and a half-life of up to 26 days.

About AT-1501

AT-1501 is a humanized IgG1 anti-CD40L antibody with high affinity for CD40L, a well-validated target with broad therapeutic potential. The CD40/CD40L pathway plays a central role in generating pro-inflammatory responses in autoimmune disease, allograft transplant rejection, and neuroinflammation. In a Phase 1 safety study of healthy volunteers and adults with ALS, AT-1501 was well tolerated at all doses tested.

The discovery and early development of AT-1501 for ALS received support from The ALS Therapy Development Institute, Augie’s Quest, The Muscular Dystrophy Association, The ALS Association, ALS One, ALS Finding a Cure, and The ALS Ice Bucket Challenge.

About Novus Therapeutics

Novus Therapeutics, Inc. is a clinical stage biotechnology company using its expertise in targeting the CD40L pathway to develop potential treatments for people requiring an organ or cell-based transplant, and for people with autoimmune and neurodegenerative disease. Novus is headquartered in Irvine, California. For more information, please visit the company’s website at www.novustherapeutics.com.

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Forward-Looking Statements

This press release contains forward-looking statements that involves substantial risks and uncertainties. Any statements about the company’s future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, and other statements containing the words “believes,” “anticipates,” “plans,” “expects,” “estimates,” “intends,” “predicts,” “projects,” “targets,” “looks forward,” “could,” “may,” and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, although not all forward-looking statements include such identifying words. Forward-looking statements include, but are not limited to statements regarding: risks related to market conditions; expectations regarding the timing for the commencement of future clinical trials; expectations regarding the success of clinical trials; the rate and degree of market acceptance and clinical utility of the company’s products; the company’s estimates regarding expenses and cash runway; and the impact of the ongoing coronavirus pandemic. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors. These risks and uncertainties, as well as other risks and uncertainties that could cause the company’s actual results to differ significantly from the forward-looking statements contained herein, are discussed in our quarterly 10-Q, annual 10-K, and other filings with the SEC, which can be found at www.sec.gov. Any forward-looking statements contained in this press release speak only as of the date hereof and not of any future date, and the company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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