Yumanity Therapeutics Provides Update on Its Lead Parkinson’s Disease Clinical Program, YTX-7739

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Results reported of the single ascending dose study in healthy volunteers

Enrollment completed of the multiple ascending dose study in healthy volunteers; results expected by end of Q1 2021

Dosing initiated in a Phase 1b trial in patients with Parkinson’s Disease; preliminary results expected by mid-year 2021

BOSTON, Feb. 10, 2021 (GLOBE NEWSWIRE) -- Yumanity Therapeutics (NASDAQ: YMTX), a clinical-stage biopharmaceutical company focused on the discovery and development of innovative, disease-modifying therapies for neurodegenerative diseases, today provided several updates on its lead clinical-stage program, YTX-7739, in development for the treatment of Parkinson’s Disease.

“Recent advances in our understanding of the pathological processes underlying neurodegenerative diseases are providing the opportunities for innovative companies such as Yumanity to address this challenge with therapies that attack known disease pathways,” said Robert Scannevin, Ph.D., Head of Discovery at Yumanity Therapeutics. “Multiple lines of evidence indicate that misfolded alpha-synuclein is a strong risk factor for Parkinson’s disease. However, rather than targeting alpha-synuclein directly, we discovered that inhibiting the enzyme stearoyl-CoA desaturase (SCD) could overcome alpha-synuclein toxicity, suggesting its potential as a therapeutic target.”

Brigitte Robertson, M.D., Chief Medical Officer at Yumanity Therapeutics, added, “YTX-7739 is a novel small molecule SCD inhibitor, which can be administered orally and was shown to be brain penetrant in preclinical models. We have completed the single ascending dose (SAD) study in healthy volunteers, which provides early evidence of the drug candidate’s safety and tolerability profile. We look forward to reporting on the data from the ongoing Multiple Ascending dose (MAD) study in healthy volunteers and the preliminary results of our first clinical trial in patients with Parkinson’s disease, later this year. We wish to also thank our investigators, their staff, study volunteers and patients for their dedication in continuing this important research through the challenges of the COVID-19 pandemic.”

Results from the single ascending dose study in healthy volunteers: This was a Phase 1, single-ascending dose study of YTX-7739, a novel SCD inhibitor being developed for the treatment of Parkinson’s disease. Fifty-six healthy volunteers (aged 19-39 years of age; 22 males; 34 females) were administered single oral doses of YTX-7739, from 5 mg to 400 mg. Forty subjects participated in the placebo controlled, randomized, double blind part of the study which included 7 cohorts of 8 subjects each, randomized to treatment or placebo in a 6:2 ratio. Sixteen of these subjects also participated in 2 cohorts where YTX-7739 was administered with food. In addition, 2 cohorts of 8 subjects each (16 subjects) were conducted in an open label fashion to further inform dose selection for the MAD study. There were no safety concerns identified and YTX-7739 was found to be well tolerated with most adverse events being mild or moderate in severity. The half-life of YTX-7739 combined with a favorable dose-proportional pharmacokinetic (PK) profile, in the fed state, supports that low daily doses administered with food will sustain the target range of exposure. Drug plasma concentrations in the study exceeded levels of exposure estimated to be sufficient for target engagement based on pharmacodynamic modeling. Consistent with preclinical data, YTX-7739 also demonstrated clinically relevant drug concentrations in the cerebral spinal fluid (CSF). The results of this SAD study supported progression to the multiple ascending dose study.

Completion of enrollment in the multiple ascending dose study (MAD) in healthy volunteers: This is a Phase 1, placebo-controlled, randomized, double-blind study, investigating the safety, tolerability, and pharmacokinetics of once daily oral administration of 2 doses of YTX-7739 (15 mg and 25 mg) for 14 to 28 days in 16 healthy male and female volunteers. The study includes 2 cohorts of 8 subjects each, randomized to treatment or placebo in a 6:2 ratio. The study is also exploring plasma and CSF biomarker measures of pharmacodynamic activity. The company expects to report the results of this MAD study by the end of the current quarter. Detailed clinical data from these Phase 1 studies in healthy volunteers with YTX-7739 will be presented at a future medical conference.

Dosing initiated in a Phase 1b study in Parkinson’s disease patients: The company also announced the start of a placebo controlled, randomized double blind, MAD Phase 1b study of YTX-7739 in patients with Parkinson’s disease. This study is expected to enroll 30 subjects and will collect safety, tolerability, pharmacokinetic and pharmacodynamic parameters including potential biomarkers of SCD activity and target engagement in the CSF, plasma, and other fluids or tissues. Preliminary results are expected by mid-year 2021.

About YTX-7739

YTX-7739 is Yumanity Therapeutics’ proprietary lead small molecule investigational therapy designed to penetrate the blood-brain barrier and inhibit the activity of a novel target, stearoyl-CoA desaturase (SCD), that plays an important and previously unrecognized role in modulating neurotoxicity arising from the alpha-synuclein protein, a major driver of Parkinson’s disease and related neurodegenerative disorders. Misfolding and aggregation of alpha-synuclein triggers a cascade of events, ultimately resulting in neurotoxicity and the subsequent dysregulation of movement and cognition that afflicts patients living with these diseases. Through inhibition of SCD, YTX-7739 modulates an upstream process in the alpha-synuclein pathological cascade and has been shown to rescue or prevent toxicity in preclinical models. The company is assessing the potential utility of YTX-7739 in Parkinson’s disease.

About SCD

SCD is an enzyme that catalyzes fatty acid desaturation, the products of which are incorporated into phospholipids, triglycerides, or cholesterol esters. These lipid-related molecules regulate multiple diverse cellular properties and processes, including membrane structure and function, vesicle trafficking, intracellular signaling and inflammation. SCD expression is regulated by a transcription factor known as SREBF1, which has been identified in human genome-wide association studies as a risk factor for Parkinson’s disease. In preclinical models, SCD inhibition appears to normalize the dynamic interaction of pathological alpha-synuclein with membranes, which improves neuronal function and reduces toxicity, leading to enhanced neuronal survival. Alpha-synuclein-dependent disruption of membrane-related biological pathways, such as vesicle trafficking, is closely linked to the formation of Lewy body protein/membrane aggregations, a hallmark pathological feature of Parkinson’s disease.
About Yumanity Therapeutics

Yumanity Therapeutics is a clinical-stage biopharmaceutical company dedicated to accelerating the revolution in the treatment of neurodegenerative diseases through its scientific foundation and drug discovery platform. The Company’s most advanced product candidate, YTX-7739, is currently in Phase 1 clinical development for Parkinson’s disease. Yumanity’s drug discovery platform is designed to enable the Company to rapidly screen for potential disease-modifying therapies by overcoming toxicity of misfolded proteins in neurogenerative diseases. Yumanity’s pipeline consists of additional programs focused on Lewy body dementia, multi-system atrophy, amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), frontotemporal lobar dementia (FTLD), and Alzheimer’s disease. For more information, please visit www.yumanity.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words and phrases such as “aims,” “anticipates,” “believes,” “could,” “designed to,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “seeks,” “will,” and variations of these words and phrases or similar expressions that are intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements regarding our business strategy for and the potential therapeutic benefits of our prospective product candidates, results of preclinical studies, the design, commencement, enrollment and timing of ongoing or planned clinical trials, clinical trial results, product approvals and regulatory pathways, and the anticipated benefits of our drug discovery platform. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Results in preclinical or early-stage clinical trials may not be indicative of results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented.

Any forward-looking statements in this press release are based on Yumanity Therapeutics’ current expectations, estimates and projections about our industry as well as management’s current beliefs and expectations of future events only as of today and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that any one or more of our product candidates will not be successfully developed or commercialized; the risk of cessation or delay of any ongoing or planned clinical trials of Yumanity Therapeutics or our collaborators, the risk that Yumanity Therapeutics may not successfully recruit or enroll a sufficient number of patients for our clinical trials, the risk that Yumanity Therapeutics may not realize the intended benefits of its drug discovery platform, the risk that our product candidates will not have the safety or efficacy profile that we anticipate, the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or trials involving Yumanity Therapeutics’ product candidates, the risk that we will be unable to obtain and maintain regulatory approval for our product candidates, the risk that the size and growth potential of the market for our product candidates will not materialize as expected, risks associated with our dependence on third-party suppliers and manufacturers, risks regarding the accuracy of our estimates of expenses and future revenue, risks relating to our capital requirements and needs for additional financing, risks relating to clinical trial and business interruptions resulting from the COVID-19 outbreak or similar public health crises, including that such interruptions may materially delay our enrollment and development timelines and/or increase our development costs or that data collection efforts may be impaired or otherwise impacted by such crises, and risks relating to our ability to obtain and maintain intellectual property protection for our product candidates. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Yumanity Therapeutics’ actual results to differ materially and adversely from those contained in the forward-looking statements, see the section entitled “Risk Factors” in the definitive proxy statement/prospectus/information statement filed with the Securities and Exchange Commission on November 12, 2020, as well as discussions of potential risks, uncertainties, and other important factors in Yumanity Therapeutics’ subsequent filings with the Securities and Exchange Commission. Yumanity Therapeutics explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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