



resTORbio Announces Initiation of Phase 3 Clinical Program of RTB101 in Clinically Symptomatic Respiratory Illness

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Top-line data from both PROTECTOR Phase 3 studies expected in mid-2020

BOSTON, May 09, 2019 (GLOBE NEWSWIRE) -- resTORbio, Inc. (Nasdaq: TORC), today announced the initiation of PROTECTOR 1, the first Phase 3 trial of RTB101, an orally administered, small molecule, potent inhibitor of target of rapamycin complex 1 (TORC1). The two PROTECTOR Phase 3 trials are designed to evaluate the safety and efficacy of RTB101 for decreasing the percent of elderly subjects with clinically symptomatic respiratory illness, defined as illness associated with a respiratory tract infection (RTI) based on prespecified diagnostic criteria, with or without laboratory-confirmation of a pathogen.

"The launch of our PROTECTOR Phase 3 program is an important milestone for resTORbio and for the elderly population, as RTB101 has the potential to be the first immunotherapy for reducing the incidence of illness associated with RTIs, regardless of the causative pathogen," said Chen Schor, Co-Founder, President and CEO of resTORbio. "The majority of RTIs are caused by viruses, and the results of our Phase 2 trials suggest that upregulation of innate antiviral gene expression is a mechanism underlying the reduced incidence of RTIs observed in elderly subjects treated with RTB101 compared to placebo. We plan to enroll approximately 2,600 subjects in our Phase 3 trials, and believe this program will provide us with sufficient clinical data to support the submission of a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for RTB101."

The PROTECTOR Phase 3 program includes two randomized, double-blinded, placebo-controlled clinical trials that will evaluate the safety and efficacy of RTB101 10mg given once daily for 16 weeks during winter cold and flu season to subjects 65 years of age and older, excluding current smokers and chronic obstructive pulmonary disease patients. The primary endpoint is the reduction in the percentage of subjects with clinically symptomatic respiratory illness with or without laboratory-confirmation of a pathogen.

The PROTECTOR program incorporates feedback from both the FDA and the European Medicines Agency on key elements of the Phase 3 trial design. PROTECTOR 1, initiated in the southern hemisphere, is expected to enroll approximately 1,000 subjects. PROTECTOR 2, the second Phase 3 clinical trial, is expected to begin in the northern hemisphere in the fourth quarter of 2019 and to enroll approximately 1,600 subjects. Based on current enrollment expectations for the Phase 3 program, resTORbio expects top-line data in mid-2020.

About Respiratory Tract Infections in the Elderly

As part of the aging process, the immune system weakens and becomes less effective at detecting and fighting infections such as RTIs. As a result, RTIs are more likely to be of greater severity, prolonged duration, and are more likely to be associated with medical complications in people age 65 years and older as compared to younger adults. In the U.S., RTIs are the fourth leading cause of hospitalization and seventh leading cause of death in people aged 65 and older. Given that RTIs are caused by many different types of viruses, most of which lack effective therapies, there remains a significant unmet medical need for an immunotherapy that enhances the ability of the immune system to fight multiple viruses to reduce illness associated with RTIs in the elderly.

About RTB101

RTB101 is an oral, selective, and potent TORC1 inhibitor product candidate. TORC1 inhibition has been shown to be of therapeutic benefit in multiple aging-related conditions in preclinical species including immunosenescence (aging-related decline in immune function). In two Phase 2 clinical trials enrolling over 900 elderly people, RTB101 was observed to improve immune function by upregulation of antiviral gene expression and to reduce the incidence of RTIs.

About resTORbio

resTORbio, Inc. is a clinical-stage biopharmaceutical company developing innovative medicines that target the biology of aging to prevent or treat aging-related diseases. resTORbio's lead program selectively inhibits TORC1, an evolutionarily conserved pathway that contributes to the decline in function of multiple organ systems, including the immune, cardiovascular and central nervous systems. Learn more about resTORbio, Inc. at www.resTORbio.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, express or implied statements or guidance regarding our proposed timing and trial design for our PROTECTOR Phase 3 clinical program of RTB101, including timing and anticipated results of this clinical trial, our future plans to develop RTB101 alone or in combination with rapalogs, such as everolimus or sirolimus, including the therapeutic potential and clinical benefits thereof and the potential patient populations that may be addressed by our product candidates, our ongoing and future clinical trials for RTB101, including the timing of the initiation and anticipated results of these trials, the continued expansion of our pipeline into Parkinson's disease and UTIs, the intended regulatory path for our product candidates and interactions with regulatory authorities, our ability to replicate results achieved in our clinical trials in any future trials, our cash position and expected cash runway, and our ability to fund operations through 2020 constitute forward-looking statements identified by words like "believe," "expect," "may," "will," "should," "seek," "anticipate," or "could" and similar expressions.

Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, risks associated with: our PROTECTOR Phase 3 program; our planned Phase 3 clinical trials in RTIs and/or development of RTB101, either alone or in combination with a rapalog, such as everolimus or sirolimus; our ability to successfully demonstrate the

efficacy and safety of our lead product candidate; the clinical results for our lead product candidate which may not support further development of additional indications; uncertainties related to the results of our clinical trials predictive of future results in connection with future trials, including our Phase 3 clinical trials; the timing and outcome of our planned interactions with regulatory authorities; and obtaining, maintaining and protecting our intellectual property; as well as those risks more fully discussed in the section entitled "Risk Factors" in the Annual Report on Form 10-K filed by resTORbio, Inc. with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent our views only as of today and should not be relied upon as representing its views as of any subsequent date. resTORbio explicitly disclaims any obligation to update any forward-looking statements.

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