



## Caladrius Biosciences Reports Interim Analysis for Phase 2 T-Rex Trial of CLBS03 for Type 1 Diabetes

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Treatment continues to be well-tolerated and deemed non-futile for therapeutic effect

BASKING RIDGE, N.J. (March 8, 2018) – Caladrius Biosciences, Inc. (Nasdaq:CLBS) (“Caladrius” or the “Company”), a development-stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiovascular indications, reports results from the predetermined interim analysis in The Sanford Project: T-Rex Study, a prospective, randomized, placebo-controlled, double-blind Phase 2 clinical trial of 110 patients to evaluate the safety and efficacy of the Company’s CLBS03 as a treatment for recent-onset type 1 diabetes (“T1D”).

The interim analysis was triggered by 50% of the targeted total number of subjects in the trial completing six months of follow-up. The interim analysis, conducted by independent statisticians, showed that CLBS03 continues to be well-tolerated and led to the conclusion that the study was non-futile as determined by pre-defined futility criteria for therapeutic effect.

CLBS03 is a personalized autologous cell therapy consisting of each patient’s own regulatory T cells (“Tregs”) which have been expanded in number and functionally enhanced by a proprietary method developed through a collaboration with Jeffrey Bluestone, Ph.D., and renowned researchers at the University of California, San Francisco. Caladrius holds exclusive rights to an international portfolio of issued and pending patents related to this product. CLBS03 as a treatment for T1D has U.S. Food and Drug Administration (“FDA”) Orphan Drug designation, European Medicine Agency Advanced Therapeutic Medicinal Product classification and FDA Fast Track designation, which represents the first T1D program to receive this distinction.

“The results of this interim analysis show that CLBS03 remains well-tolerated and that a positive outcome for therapeutic effect at the end of the trial remains a statistical possibility. Of course, we have long anticipated that an analysis of the complete data set at the end of the study would be necessary to fully understand the impact of CLBS03 treatment on patients with recently-diagnosed T1D,” stated David J. Mazzo, Ph.D., President and Chief Executive Officer of Caladrius. “We look forward to completing and reporting on the 12-month follow-up on all 110 patients in early 2019 and using the complete results to determine the next steps in our development plan.”

The Phase 2 T-Rex study is being conducted with support from Sanford Research, a Sanford Health subsidiary, a grant from the California Institute for Regenerative Medicine and a grant from the Juvenile Diabetes Research Foundation.

### About The Sanford Project: T Rex Study

The landmark T-Rex study, which is being conducted in collaboration with Sanford Research, a Sanford Health subsidiary, is a prospective, randomized, placebo-controlled, double-blind Phase 2 clinical trial to evaluate the safety and efficacy of CLBS03 as a treatment for T1D in approximately 110 subjects age 8 to 17 with recent-onset T1D. Subjects are randomized into one of three groups to receive, through a single administration, either a high dose of CLBS03, a low dose of CLBS03 or a placebo. Enrollment of the first cohort of 19 subjects, designated for a preliminary safety evaluation, was completed in August 2016. The evaluation of safety data from this group was satisfactory and the Company began enrollment of the second cohort of subjects in October 2016. The key endpoints for the trial are the standard medical and regulatory endpoints for a T1D trial and include preservation of C-peptide (an accepted measure for pancreatic beta cell function), insulin use, severe hypoglycemic episodes and glucose and hemoglobin A1c levels to be evaluated when all patients complete 12-month follow-up. For more information on The Sanford Project: T Rex Study, please visit <https://clinicaltrials.gov/ct2/show/NCT02691247>.

### About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical stage biopharmaceutical company with multiple technology platforms targeting autoimmune and select cardiovascular indications. The Company is investigating its lead product candidate, CLBS03, an ex vivo expanded polyclonal T regulatory cell therapy for the treatment of recent-onset type 1 diabetes, in an ongoing Phase 2 trial. CLBS14, CD34 cell therapy intended as a treatment for coronary microvascular dysfunction and refractory angina, is Caladrius’ proprietary and patent protected formulation of CD34 cells designed specifically to enhance the potency of the CD34 cells for repair and regeneration of cardiovascular tissue. Its companion product, CLBS12, is formulated specifically for intramuscular administration for the treatment of lower extremity ischemia. A phase 2 study of CLBS12 as a treatment for critical limb ischemia is enrolling in Japan, a successful outcome of which will qualify the program for consideration of early conditional approval based on discussions with the Japanese regulatory authorities as provided for under Japan’s progressive regenerative medicine regulations. For more information about Caladrius please visit [www.caladrius.com](http://www.caladrius.com).

### Safe Harbor for Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect management’s current expectations, as of the date of this press release, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this press release are forward-looking statements. The Company’s actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. Factors that could cause future results to materially differ from the recent results or those projected in forward-looking statements include the “Risk Factors” described in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”) on March 17, 2017, and in the Company’s other periodic filings with the SEC. The Company’s further development is highly dependent on, among other things, future medical and research developments and market acceptance, which are outside of its control. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Press Release. Caladrius does not intend, and disclaims any obligation, to update or revise any forward-looking information contained in this Press

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