



## Equillium Announces Oral Presentation Highlighting Positive Data from the EQUATE Study in Acute Graft-Versus-Host Disease at the EHA2021 Virtual Congress of the European Hematology Association

May 13, 2021

LA JOLLA, Calif., May 13, 2021 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced that an abstract highlighting positive data from the EQUATE study of itolizumab in acute graft-versus-host disease (aGVHD) has been accepted for oral presentation at EHA2021 Virtual Congress. The annual meeting of the European Hematology Association will be held virtually June 9 – 17, 2021.

The abstract describes results from the ongoing Phase 1b EQUATE study of itolizumab in combination with steroids for the first-line treatment of patients with aGVHD. The primary cohorts enrolled 10 patients with Grade III-IV aGVHD that received itolizumab within 72 hours of first steroid dose, whereas the expansion cohorts also include subjects with Grade II aGVHD and an Ann Arbor Score of 2 or 3 that received itolizumab within 7 days of first steroid dose. The company will present data on all patient cohorts in the EQUATE study. The benefit-risk profile observed support continued evaluation in future randomized controlled trials.

**Title:** Interim results from the EQUATE Study: Preliminary safety and efficacy of itolizumab, a novel targeted anti-CD6 therapy, newly diagnosed acute graft-versus-host disease

**First Author:** John Koreth – Dana Farber Cancer Institute, Harvard Medical School

**Presentation Session:** Stem cell transplantation - GvHD

**Date and Time:** Friday, June 11, 3:00 am ET

**Abstract Code:** S238

### About Graft-Versus-Host Disease (GVHD)

GVHD is a multisystem disorder that is a common complication of allogeneic hematopoietic stem cell transplants (allo-HSCT) caused by the transplanted immune system recognizing and attacking the recipient's body. Symptoms of GVHD include rash, itching, skin discoloration, nausea, vomiting, diarrhea, and jaundice, as well as eye dryness and irritation.

GVHD is the leading cause of non-relapse mortality in cancer patients receiving allo-HSCT, and its risk limits the number and type of patients receiving HSCT. GVHD results in high morbidity and mortality, with five-year survival of approximately 53% in patients who respond to steroid treatment and mortality as high as 95% in patients who do not respond to steroids. There are no approved treatments for first-line aGVHD. Published literature (MacMillan et al., 2015) describes background response rates to high-dose steroid administration in severe high-risk patients as 43% overall response rate and 27% complete response.

### About the EQUATE Study

The EQUATE study is a Phase 1b/2 trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and clinical activity of itolizumab for first-line treatment in patients who present with aGVHD ([NCT 03763318](#)). The Phase 1b part of the trial is an open-label dose escalation study in adult patients who present with high-risk aGVHD and typically respond poorly to steroids. The Phase 1b data will inform selection of the dose to be used in the next phase of development for the program.

### About Itolizumab

Itolizumab is a clinical-stage, first-in-class anti-CD6 monoclonal antibody that selectively targets the CD6-ALCAM pathway. This pathway plays a central role in modulating the activity and trafficking of T cells that drive a number of immuno-inflammatory diseases. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon Limited.

### About Equillium

Equillium is a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop novel products to treat severe autoimmune and inflammatory disorders with high unmet medical need. Equillium is developing itolizumab for multiple severe immuno-inflammatory diseases, including acute graft-versus-host-disease (aGVHD), lupus/lupus nephritis and uncontrolled asthma.

For more information, visit [www.equilliumbio.com](http://www.equilliumbio.com).

### Forward Looking Statements

*Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to statements regarding the potential benefit of treating patients with aGVHD, uncontrolled asthma, or lupus/lupus nephritis with itolizumab, Equillium's plans and expected timing for developing itolizumab including the expected timing of initiating, completing and announcing further results from the EQUATE, EQUIP, and EQUALISE studies, the potential for any of Equillium's ongoing or planned clinical studies to show safety or efficacy, statements regarding the impact of new leadership team members, Equillium's anticipated timing of regulatory review and feedback, Equillium's cash runway, and Equillium's plans and expected timing for developing itolizumab and potential benefits of itolizumab. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties related to the abilities of new leadership team members to integrate and perform as expected; Equillium's ability to execute its plans and strategies; risks related to performing clinical studies; the risk that interim results of a clinical study do not necessarily predict*

*final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; potential delays in the commencement, enrollment and completion of clinical studies and the reporting of data therefrom; the risk that studies will not be completed as planned; Equillium's plans and product development, including the initiation and completion of clinical studies and the reporting of data therefrom; whether the results from clinical studies will validate and support the safety and efficacy of itolizumab; changes in the competitive landscape; uncertainties related to Equillium's capital requirements; and having to use cash in ways or on timing other than expected and the impact of market volatility on cash reserves. These and other risks and uncertainties are described more fully under the caption "Risk Factors" in Equillium's Annual Report on Form 10-K for the year ended December 31, 2020, and elsewhere in Equillium's filings and reports with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Equillium undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.*

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