



Equillium Presents Positive Interim Clinical Data of Itolizumab in First-line Treatment of Acute Graft-Versus-Host Disease at the 2021 Transplantation and Cellular Therapy Meetings Digital Experience

February 12, 2021

Higher dose cohorts demonstrated 100% overall response rate, resulting in substantial reduction in baseline corticosteroid use

Dose-dependent reduction of CD6 expression on CD4+ and CD8+ T cells is consistent with itolizumab mechanism of action

LA JOLLA, Calif., Feb. 12, 2021 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, presented interim data from the EQUATE clinical trial supporting itolizumab's potential as a first-line treatment for acute graft-versus-host disease (aGVHD). The study, described in the late-breaking oral presentation titled "Preliminary Safety and Efficacy of Itolizumab, A Novel Targeted Anti-CD6 Therapy, in Newly Diagnosed Severe Acute Graft-Versus-Host Disease: Interim Results from Equate Study," was presented earlier today by John Koreth, MBBS, DPhil, Associate Professor of Medicine, Harvard Medical School, Director of Translational Research – Stem Cell Transplantation, Dana-Farber Cancer Institute, at the 2021 TCT Meetings Digital Experience.

"Itolizumab's favorable safety and tolerability profile, combined with preliminary efficacy results and the ability to reduce corticosteroid use, bodes very well for treating aGVHD patients in the first-line setting," said Dr. Koreth. "There is a critical need for new treatments for aGVHD, and this study supports further evaluation of itolizumab as a novel immunomodulatory treatment for this life-threatening condition."

Key Highlights, Summary and Conclusions from Oral Presentation:

- The CD6-ALCAM pathway modulates both the activity and trafficking of pathogenic CD6^{high} T effector cells, which play an important role in the immuno-inflammatory cascade
- Itolizumab causes antigenic modulation of CD6, yielding hyporesponsive T cells
- Itolizumab was generally well tolerated across all doses in high-risk aGVHD patients
- Key findings for itolizumab:
 - Dose-dependent reduction of CD6 expression on CD4+ and CD8+ T cells is consistent with proposed mechanism of action
 - Strong response for higher dose level cohorts (0.8 and 1.6 mg/kg) with overall response rate (ORR) of 100% (N=6) at Day 29; 5 patients demonstrated complete responses (CR) and one patient, a very good partial response (VGPR)
 - Clinical responses have been sustained through Day 57
 - Reduction in baseline corticosteroid use at Day 29 was ~40 - 80%
 - Dose-dependent reduction in the pharmacodynamic marker of CD6 expression on effector T cells was observed as early as 24 hours after treatment

"The data highlighted in the presentation underscore itolizumab's potential as a first-line treatment in patients with acute GVHD, as well as a reduction in steroid use by as much as eighty percent in the first four weeks. Building on favorable safety data and durable response rates demonstrated so far, we look forward to the topline data results of the EQUATE study towards the middle of the year," said Stephen Connelly, Ph.D., chief scientific officer of Equillium.

Full text of the abstract can be found on the [conference website](#) and [the presentation is available](#) on the Publications page, under the Our Science section of Equillium's website.

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 the risk of GVHD limits the number and type of patients receiving HSCT. GVHD results in very 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. In the first-line aGVHD setting, published literature (MacMillan et al., 2015) describes background response rates to high-dose steroid administration in less severe standard risk patients as 69% overall response rate (ORR) and 48% CR, whereas in more severe high-risk patients response rates observed were 43% ORR and 27% CR.

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.

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 with itolizumab, the ability of Equillium to transition to later-stage development, the expected timing of further results from the EQUATE study, 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: Equillium's ability to execute its plans and strategies; risks related to performing clinical trials; the risk that interim results of a clinical trial 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 trials 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 trials and the reporting of data therefrom; whether the results from clinical trials will validate and support the safety and efficacy of itolizumab; and changes in the competitive landscape. These and other risks and uncertainties are described more fully under the caption "Risk Factors" 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.

Investor Contact

Michael Moore
Vice President, Investor Relations & Corporate Communications
+1-619-302-4431
ir@equilliumbio.com

Media Contact

Katherine Carlyle Smith
Senior Account Associate
Canale Communications
+1-805-907-2497
katherine.smith@canalecomm.com