



## Equillium Presents Translational Data Demonstrating Impact of Itolizumab on Effector T Cell Function at the 2020 American Society of Hematology Annual Meeting and Exposition

December 7, 2020

### Studies further support itolizumab's potential as treatment for aGVHD patients

LA JOLLA, Calif., Dec. 07, 2020 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ) a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, presented data over the weekend demonstrating the impact of itolizumab on effector T cell function in graft-versus-host disease (GVHD). The data was presented virtually at the 2020 American Society of Hematology (ASH) Annual Meeting and Exposition being held December 5-8, 2020.

GVHD is a severe multisystem complication that frequently occurs after hematopoietic stem cell transplantation when there is an upregulation of activated proinflammatory effector T cells resulting in the transplanted immune system attacking and damaging host tissues. There are currently no approved therapies to treat acute GVHD (aGVHD) in the first-line setting. The CD6-ALCAM pathway promotes effector T cell activation, proliferation and trafficking, playing a central role in the autoimmune and inflammatory process. Itolizumab is an anti-CD6 monoclonal antibody that has been shown to potentially modulate T cell activity in GVHD.

The study described in the oral presentation titled, "Early Reconstitution of CD6+ T Cells after Hematopoietic Cell Transplantation Identifies a Suitable Target for Acute Graft Versus Host Disease Treatment Using Anti-CD6 Monoclonal Antibody Itolizumab", characterized CD6 expression levels and demonstrated the suppressive effect of itolizumab on the activity of CD4 and CD8 T cells from transplant patients with acute GVHD. Additional data presented in a poster reveals itolizumab's direct impact on activated Th1 and Th17 effector T cells shown through decreases of activation markers, cytokine release and CD6 surface expression.

"CD6 is a T cell costimulatory receptor that plays a key role in multiple autoimmune and inflammatory diseases, including aGVHD," said Jerome Ritz, M.D., executive director of the Connell and O'Reilly Families Cell Manipulation Core Facility at Dana-Farber Cancer Institute and professor of medicine at Harvard Medical School. "Expanding upon previous work, these findings underscore the important role of the CD6-ALCAM pathway in modulating effector T cell function and provide further validation for the use of itolizumab and the targeting of CD6 in aGVHD."

"Our findings demonstrate that the CD6-ALCAM pathway is crucial in modulating effector T cell function, and inhibition of CD6 signaling with itolizumab can modulate multiple effector T cell subsets," said Stephen Connelly, Ph.D., chief scientific officer of Equillium. "This translational research, combined with encouraging early readouts from our EQUATE Phase 1b study in aGVHD, underscore the therapeutic potential of itolizumab as a first-line treatment in combination with steroids for patients with aGVHD and potentially chronic GVHD. We presented additional details at our recent investor and analyst day last week and look forward to topline data from the study in the first half of next year."

Below are the abstract titles that were selected for poster and oral presentations. Full text of the abstracts can be found on the [conference website](#). The oral presentation and poster presentation with voice over are available on the [publications section](#) of the Equillium website.

#### **Oral Presentation**

**Title:** Early Reconstitution of CD6+ T Cells after Hematopoietic Cell Transplantation Identifies a Suitable Target for Acute Graft Versus Host Disease Treatment Using Anti-CD6 Monoclonal Antibody Itolizumab

**Presenter:** Benedetta Rambaldi, M.D., Research Fellow in Medicine, Dana-Farber Cancer Institute

**Session:** Clinical Allogeneic Transplantation: Acute and Chronic GvHD, Immune Reconstitution: Pathobiology and Predictive Biomarkers

**Publication Number:** 418

#### **Poster Presentation**

**Title:** Impact of Itolizumab on the Expression of CD6 and the Function of Effector T Cells

**Presenter:** Jeanette Ampudia, Scientist, Equillium, Inc.

**Session:** Lymphocytes, Lymphocyte Activation, and Immunodeficiency, including HIV and Other Infections: Poster I

**Publication Number:** 827

#### **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 standard risk patients, e.g. Grades II thru IV, of 69% overall response (OR) and 48% complete response (CR), whereas in high-risk patients, e.g. Grades III thru IV, response rates observed were 43% OR and 27% CR.

#### **About Itolizumab**

Itolizumab is a clinical-stage, first-in-class 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 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 or chronic GVHD patients, as well as patients who have undergone hematopoietic stem cell transplantation, with itolizumab, Equillium's business strategy, Equillium's plans and expected timing for developing itolizumab, including the expected timing of further results from the EQUATE study, the potential for interim data results to be consistent with final results, once available, the potential for the ongoing EQUATE trial to show safety or efficacy, and potential benefits of itolizumab. Risks that contribute to the uncertain nature of the forward-looking statements include: 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, restarting and completion of clinical trials and the reporting of data therefrom; uncertainties caused by the recent restarting of the EQUIP and EQUALISE clinical trials after a pause; whether the results from clinical trials will validate and support the safety and efficacy of itolizumab; changes in the competitive landscape; and uncertainties 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" and elsewhere in Equillium's filings and reports with the United States Securities and Exchange Commission. 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](mailto:ir@equilliumbio.com)

### **Media Contact**

Katherine Carlyle Smith  
Senior Account Associate  
Canale Communications  
+1-805-907-2497  
[katherine.smith@canalecomm.com](mailto:katherine.smith@canalecomm.com)