



Equillium Announces Positive Interim Data of Itolizumab in the First-line Treatment of Acute Graft-Versus-Host Disease

November 6, 2020

100% overall response rate in dose cohort 3 and 80% overall response rate across all cohorts to date

Complete response observed in seven of eight responding patients

EQUATE Phase 1b topline data expected during first half 2021

LA JOLLA, Calif., Nov. 06, 2020 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders, today announced positive interim data from the third cohort of the Phase 1b open label, dose escalation study of itolizumab in the first-line treatment of acute graft-versus-host disease (aGVHD). The EQUATE trial is evaluating itolizumab in severe aGVHD patients concomitant with standard of care, which is typically comprised of high dose corticosteroids, as no other therapeutics are currently approved for this indication. Equillium anticipates reporting topline data across all cohorts from the Phase 1b portion of the EQUATE trial during the first half of 2021 and is accelerating plans for further development of itolizumab in graft-versus-host disease.

In the EQUATE trial, the overall response rate across the first three dose cohorts was 80%, and seven of eight patients responding achieved a complete response (CR) and one patient achieved a very good partial response (VGPR) by Day 29 (VGPR approximates the clinical benefit of CR). Responses observed have been rapid, with most patients achieving a CR within the first 15 days, and durable as patients in the first two cohorts have maintained responses through Day 57. To date, adverse events reported with the EQUATE trial have been consistent with the safety profile previously reported for itolizumab and those common in the aGVHD patient population. In review of the totality of safety, efficacy and pharmacodynamic data, the independent data monitoring committee has recommended to expand cohort 3 (1.6 mg/kg dose) and proceed forward with enrollment.

"We continue to accrue compelling data in the EQUATE trial – the rapid and durable response rates in patients treated with itolizumab meaningfully exceeds what has been observed in patients with severe aGVHD treated with steroids alone," said Bruce Steel, chief executive officer of Equillium. "We plan to engage the U.S. Food and Drug Administration (FDA) to explore expedited regulatory pathways to advance itolizumab for the first-line treatment of aGVHD. Further, this data suggests opportunities to expand the potential therapeutic application of itolizumab for patients with chronic GVHD and as a potential preventative treatment for patients who have undergone hematopoietic stem cell transplantation. We believe itolizumab has the potential to be a life-saving medicine for aGVHD patients, a severe and life-threatening illness for which there are currently no approved therapeutics."

EQUATE Study Results: Itolizumab Response Rates at Day 29 in First-line aGVHD						
Cohort	Itolizumab Dose (mg/kg)	Number of Patients	Number with CR / VGPR / PR	CR or VGPR Rate	Number with Any Response	Overall Response Rate
1	0.4	4	2 / 0 / 0	50%	2	50%
2	0.8	3	3 / 0 / 0	100%	3	100%
3	1.6	3	2 / 1 / 0	100%	3	100%
Total		10	7 / 1 / 0	80%	8	80%
Complete response (CR), very good partial response (VGPR) - approximates the clinical benefit of a complete response, partial response (PR)						

Equillium has received fast track designation from the FDA for the treatment of itolizumab in patients with aGVHD and orphan drug designations from the FDA for both the prevention and treatment of aGVHD. Equillium plans to provide additional updates on the program at its upcoming analyst day on December 4, 2020.

About Graft-Versus-Host Disease

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 severe aGVHD (Grades III and IV) 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 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. Itolizumab is currently being evaluated in multiple clinical trials in patients with severe diseases, including aGVHD, lupus nephritis, uncontrolled asthma, and will soon be evaluated in a clinical trial of patients with COVID-19. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon Limited. Itolizumab is marketed in India under the trade name "ALZUMAb-L" for the treatment of chronic plaque psoriasis and has received emergency use approval in India to treat cytokine release syndrome in COVID-19 patients with moderate to severe acute respiratory distress syndrome.

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 COVID-19, aGVHD, 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, the potential benefit of treating 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 completion of the EQUATE study and initiating a clinical trial in patients with COVID-19, the potential for interim data results to be consistent with final results, once available, the potential benefits of itolizumab, the potential for any of Equillium's ongoing or planned clinical trials to show safety or efficacy, and the impact of the COVID-19 pandemic. 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; uncertainties related to Equillium's capital requirements; Equillium's plans and product development, including the initiation, restarting and completion of clinical trials; uncertainties related to the actual impacts and length of such impacts caused by the COVID-19 pandemic; 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; 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" 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

Christine Zedelmayer, Chief Operating Officer
+1-858-412-5302
ir@equilliumbio.com

Media Contact

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