Equillium Announces Two Oral Presentations at the Annual Meeting of the European Society for Blood and Marrow Transplantation

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Response at Day 29 was associated with 72% overall survival at 12 months and high rates of progression-free survival

7 9% of responders maintained or achieved a complete response through at least 6 months

Responders were able to taper corticosteroids by 73% at Day 29 and 96% at 6 months

Clinical efficacy of itolizumab associated with higher itolizumab serum concentrations after a single dose

LA JOLLA, Calif.--(BUSINESS WIRE)-- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company focused on developing novel therapeutics to treat severe autoimmune and inflammatory disorders with high unmet medical need, today announced two oral presentations at the 48th Annual Meeting of the European Society for Blood and Marrow Transplantation. The presentations include new findings demonstrating durability of clinical response out to one year for patients with high-risk acute graft-versus-host disease (aGVHD) that were treated with itolizumab in the EQUATE study. Clinical data were presented by Corey Cutler, M.D., associate professor of medicine, Dana Farber Cancer Institute, Harvard Medical School.

“These extended twelve-month findings add to the critical mass of data indicating the potential clinical value of itolizumab for patients with high-risk aGVHD initiating therapy with corticosteroids,” said Dr. Cutler. “In addition to these rapid and durable responses, I’m particularly encouraged by a clinically meaningful reduction in the use of corticosteroids and that response at Day 29 was associated with 72 percent overall survival at 12 months, as well as high rates of progression free survival.”

Data demonstrated that across all dose cohorts Day 29 complete response (CR) rate was 52%, overall response rate (ORR) was 64% and that the highest Day 29 CR rate of 61% was achieved in subjects treated with itolizumab within 72 hours of starting systemic corticosteroids. Patients who responded to itolizumab treatment had clinically meaningful reductions in steroid administration during the evaluation period with a median reduction in steroid use of 73% by Day 29 and 96% by 6 months.

“As we continue to collect data from the EQUATE study, we see more evidence of the association between itolizumab treatment and rapid and durable decreases in cell surface CD6, supporting itolizumab’s mechanism of action,” said Steve Connelly, chief scientific officer at Equillium. “For the first time, we are now able to report that the clinical efficacy of itolizumab is associated with higher itolizumab serum concentrations after just one dose, highlighting the importance of achieving high initial itolizumab concentrations early in the treatment period to maximize pharmacodynamic effect. These findings are promising, and we are optimistic about itolizumab’s potential as we launch EQUATOR, our Phase 3 study in the first-line treatment of aGVHD patients.”

Itolizumab is a first-in-class anti-CD6 monoclonal antibody that selectively targets the CD6-ALCAM pathway, which plays a central role in modulating the activity and trafficking of the pathogenic T cells driving a number of immuno-inflammatory diseases.

Details of Itolizumab Data Presented at EBMT 2022

Title: Updated Interim Results from the EQUATE Study: Preliminary Safety and Efficacy of Itolizumab, a Novel Targeted Anti-CD6 Therapy, in Newly Diagnosed Acute Graft-Versus-Host Disease

Presenting Author: Corey Cutler, M.D., associate professor of medicine, Dana Farber Cancer Institute, Harvard Medical School

Session Name: Oral session 10: GVHD I, clinical

Presentation Number: OS10-04

Key Highlights, Summary and Conclusions from Oral Presentation:

- First-line itolizumab treatment resulted in rapid and durable response in high-risk aGVHD
- Itolizumab treatment was associated with high rates of overall clinical response
- At Day 29, CR was 52% and ORR was 64% across all doses
- The highest Day 29 CR of 61% was achieved in subjects treated with itolizumab within 72 hours of starting systemic corticosteroids
- Responses were durable, with 79% of Day 29 responders maintaining response through 6 months and 50% through 12 months
- Responders were able to taper corticosteroids by 73% at Day 29 and 96% at Day 169
- Response at Day 29 was associated with 72% overall survival at 12 months and improved progression-free survival
- Itolizumab was well tolerated across all doses, in the context of a severe aGVHD population
- Itolizumab offers a favorable benefit-risk profile that supports evaluation in a pivotal Phase 3 study which has been initiated for the first-line treatment of aGVHD (NCT05263999)

Title: Itolizumab, a Novel Targeted Anti-CD6 Therapy, Induces Cleavage of Cell Surface CD6 and Rapid Onset of Efficacy in Subjects with Newly Diagnosed Acute Graft-Versus-Host Disease

Presenting Author: Stephen Connelly, Ph.D., co-founder and chief scientific officer of Equillium

Session Name: Oral session 10: GVHD I, clinical

Presentation Number: OS10-02

Key Highlights, Summary and Conclusions from Oral Presentation:

- Itolizumab was associated with rapid and durable decreases in cell surface CD6
- Treatment led to an increase in the ratio of T regulatory to T effector cells
- Clinical efficacy of itolizumab was associated with higher itolizumab serum concentrations after a single dose, highlighting the importance of achieving high initial itolizumab concentrations early in the treatment period to maximize PD effect and efficacy

Both presentations are available on the Publications & Presentations page on 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 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 and 27% complete response.

About the EQUATE Study

EQUATE is a Phase 1b open-label dose escalation study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and clinical activity of itolizumab for first-line treatment in adult patients who present with high-risk aGVHD (NCT 03763318).

About Itolizumab

Itolizumab is a clinical-stage, first-in-class anti-CD6 monoclonal antibody that selectively targets the CD6-ALCAM signaling pathway to selectively downregulate pathogenic T effector cells while preserving T regulatory cells critical for maintaining a balanced immune response. 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 a deep understanding of immunobiology to develop novel therapeutics to treat severe autoimmune and inflammatory disorders with high unmet medical need. The company's pipeline consists of the following novel immunomodulatory assets targeting immuno-inflammatory pathways. Itolizumab, a first-in-class monoclonal antibody that targets the CD6-ALCAM signaling pathway which plays a central role in the modulation of effector T cells, is currently in a Phase 3 study for patients with acute graft-versus-host disease (aGVHD) and is in a Phase 1b study for patients with lupus/lupus nephritis. EQ101, a first-in-class tri-specific cytokine inhibitor that selectively targets IL-2, IL-9, and IL-15, is Phase 2 ready and expected to begin enrolling patients in an alopecia areata study in the second half of 2022. EQ102, a bi-specific cytokine inhibitor that selectively targets IL-15 and IL-21, is ready for clinical development and expected to begin enrolling patients in a Phase 1 study to include patients with celiac disease in the second half of 2022.

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. Forward-looking statements may be identified by the use of words such as "anticipate", "believe", “could”, “continue”, "expect", "estimate", “may”, “promise”, "plan", "outlook", “future” and "project" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Because such statements are subject to risks and uncertainties, many of which are outside of the Company's control, 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, Equillium's plans and expected timing for developing itolizumab including the expected timing of initiating, completing and announcing further results from the EQUATE and EQUATOR studies, the potential for any of Equillium's ongoing or planned clinical studies to show safety or efficacy, Equillium's anticipated timing of regulatory review and feedback, and Equillium's plans and expected timing for developing its product candidates and potential benefits of its product candidates. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties related to the abilities of the leadership team to 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 Equillium's product candidates; 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" and elsewhere in Equillium's filings and reports, which may be accessed for free by visiting EDGAR on the SEC web site at http://www.sec.gov and on the Company's website under the heading “Investors.” Investors should take such risks into account and should not

rely on forward-looking statements when making investment decisions. 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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