Equillium Announces Initiation of the Phase 3 EQUATOR Study of Itolizumab in First-line Acute Graft-Versus-Host Disease

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Pivotal study to enroll up to 200 patients

Global study with sites expected in North America, Europe, Asia and Australia

Primary endpoint assessment of Complete Response at Day 29

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 the initiation of the EQUATOR study, a pivotal Phase 3 clinical study of itolizumab in patients with acute graft-versus-host disease (aGVHD). The randomized, double-blind study will assess the efficacy and safety of itolizumab versus placebo as a first-line therapy for aGVHD in combination with corticosteroids. The primary objective of the study is to achieve early disease response, with key secondary objectives to evaluate durability of response, corticosteroid use, survival outcomes, and chronic GVHD incidence. The primary endpoint assessment is complete response (CR) rate at Day 29, with key secondary endpoints of overall response rate (ORR) at Day 29 and durability of CR rate from Day 29 through Day 99.

“The initiation of this pivotal study marks a major milestone for Equillium to assess itolizumab’s potential as a life-changing advancement for patients suffering from acute GVHD,” said Bruce Steel, chief executive officer of Equillium**.** “Patients who do not respond to existing standard of care – high-dose corticosteroids – have very poor outcomes with high mortality rates. Our Phase 3 study is supported by the compelling results from our EQUATE study demonstrating rapid and durable complete responses in high-risk acute GVHD patients. Hematologists and transplantation specialists have highlighted their enthusiasm for itolizumab as a potential therapeutic option and we are optimistic for these patients as we launch the EQUATOR study.”

“Acute GVHD remains a potentially lethal condition,”said John Koreth, M.D., associate professor of Medicine, Harvard Medical School. “With no drugs approved for the first-line treatment setting, clinicians are eager for therapeutic options beyond standard-of-care high-dose systemic corticosteroids. Itolizumab demonstrated impressive complete response rates in the EQUATE study that were both rapid and durable, and which compared favorably to historical data with corticosteroid therapy

alone. If successful in the EQUATOR study, itolizumab could result in the first approval of a novel therapeutic in the first-line treatment of acute GVHD, potentially transformative in the field."

The Phase 3 EQUATOR study is supported by results generated in the EQUATE study of 25 high-risk aGVHD patients, where CR and ORR at Day 29 were 52% and 64% respectively, across all doses. When evaluating the subset of patients treated within 3 days of first corticosteroid administration (n=18), the treatment window as specified in the EQUATOR Phase 3 protocol, CR and ORR were 61% and 67%, respectively, across all dose cohorts. Responses observed were generally rapid – within 15 days – and durable through Day 29 and beyond, with 79% of responding patients maintaining a CR at six months. Adverse events reported were consistent with a hospitalized, high-risk aGVHD patient population. Itolizumab treatment resulted in a dose-dependent reduction of CD6 expression on CD4+ T cells and an increase in the ratio of regulatory to effector T cells in patients, consistent with the drug's mechanism of action.

Equillium has received fast track designation from the FDA for itolizumab for the treatment of patients with aGVHD and orphan drug designations from the FDA for both the prevention and treatment of aGVHD.

About the EQUATOR Study

The Phase 3, randomized, double-blind, placebo-controlled multicenter study (NCT05263999) will compare the efficacy and safety of IV administered itolizumab versus placebo (randomized 1:1) as a first-line therapy in up to 200 adult and adolescent patients with Grade III-IV aGVHD, or Grade II aGVHD with lower GI involvement, in combination with high doses of corticosteroids, the current standard of care. The primary study endpoint is complete response rate at Day 29; key secondary endpoints include overall response rate at Day 29 and durability of complete response rate from Day 29 through Day 99.

Per the study protocol, patients must receive itolizumab within 3-days of the first administration of high-dose corticosteroids with a treatment period from Days 1-99, and a follow-up period from Days 100-365. Approximately 200 eligible subjects who receive 2 mg/kg methylprednisolone or equivalent on Day 1 will be randomized in a 1:1 ratio to the following two treatment groups:

1. Group A: Itolizumab, 1.6 mg/kg initial dose followed by 6 doses of 0.8 mg/kg once every 2 weeks (q2w), plus systemic corticosteroids (100 subjects)
2. Group B: Placebo, 7 doses q2w, plus systemic corticosteroids (100 subjects)

An independent data monitoring committee will regularly review safety data, and an interim analysis is planned after approximately 100 subjects have completed Day 29 assessments for both futility and efficacy.

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 corticosteroid treatment and mortality as high as 95% in patients who do not respond to corticosteroids. There are no approved treatments for first-line aGVHD. Published literature (MacMillan et al., 2015) describes background response rates to high-dose corticosteroid administration in severe high-risk patients as 43% overall response and 27% complete response.

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 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. BNZ-1, 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. BNZ-2, 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”, "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, 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 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 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" 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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