Equillium Granted U.S. FDA Fast Track Designation for EQ001 for the Treatment of Acute Graft-Versus-Host Disease

December 19, 2018

Company plans to initiate Phase 1b/2 EQUATE clinical trial in early 2019

LA JOLLA, Calif., Dec. 19, 2018 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a biotechnology company developing treatments for severe immuno-inflammatory disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for EQ001 for the treatment of acute graft-versus-host disease (aGVHD). The Company is planning to initiate a Phase 1b/2 clinical trial in early 2019, called the EQUATE trial, which will evaluate EQ001 for the treatment of patients presenting with aGVHD.

The FDA's Fast Track program is designed to facilitate the development of new treatments for serious or life-threatening conditions for which there is a significant unmet medical need. Companies with investigational drugs that receive Fast Track designation benefit from more frequent meetings or communications with the FDA to discuss the drug's development plan and may be eligible for Accelerated Approval and Priority Review.

"FDA Fast Track designation of EQ001 highlights the significant need for novel approaches for the first line treatment of aGVHD in combination with corticosteroids and positions Equillium to rapidly advance a promising treatment to patients suffering with this common complication after hematopoietic stem cell transplant," said Krishna Polu, M.D., chief medical officer of Equillium. "We are excited about this important achievement and believe the opportunity for more frequent dialog with the FDA will benefit the efficient development of EQ001 in aGVHD. Our team is working closely with investigators and trial sites to rapidly prepare for dosing of the first patients in the EQUATE trial early next year."

"Graft-versus-host disease is a very serious immuno-inflammatory condition that is the leading cause of non-relapse related mortality in patients undergoing allogeneic hematopoietic stem cell transplantation and aGVHD is an area of major unmet clinical need," said John Koreth, M.D., director of Translational Research for Stem Cell Transplantation at Dana-Farber Cancer Institute, who is the lead investigator of the EQUATE clinical trial. "Safe and effective therapies are needed for the treatment of this life-threatening complication. We are very excited to participate in the EQUATE trial for the treatment of aGHVD with EQ001, which carries forward some of the pioneering work conducted at the Dana-Farber by Drs. Jerome Ritz and Robert Soiffer that elucidated the role of CD6+ T effector cells in the development of aGVHD. An anti-CD6 targeted approach has the potential to improve outcomes in patients who develop aGVHD and I look forward to leading the EQUATE trial to evaluate the safety and activity of EQ001 in these patients."

The EQUATE trial is a Phase 1b/2 clinical trial that will enroll approximately 84 patients to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and clinical activity of EQ001 for the initial treatment of aGVHD in combination with corticosteroids (NCT 03763318). The Phase 1b component is an open-label dose escalation trial and will be followed by the Phase 2 component, which is a randomized, double-blind, placebo-controlled trial in which subjects will receive either EQ001 or placebo in combination with corticosteroids over a two-month period.

About Graft-Versus-Host Disease
Both aGVHD and chronic graft-versus-host disease (cGVHD) are multisystem disorders that are common complications of allogeneic hematopoietic stem cell transplants (HSCT). Graft-versus-host disease (GVHD) is 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 allogeneic HSCT, and the risk of GVHD limits the number and type of patients receiving HSCT. Approximately 50 percent of HSCT recipients develop aGVHD, resulting in very high morbidity and mortality, with five-year survival of approximately 53 percent in patients who respond to corticosteroid treatment, and mortality as high as 95 percent in patients who do not respond to corticosteroids.

GVHD is predominantly driven by T effector cells (T_{eff}). Prior clinical studies have implicated T_{eff} cells that express high levels of CD6 in the development of GVHD, providing evidence that CD6 is a highly relevant target in this disease.

About EQ001
EQ001 (itolizumab) is a clinical-stage, first-in-class monoclonal antibody that selectively targets CD6, a novel immune checkpoint pathway. CD6 plays a central role in the modulation of T_{eff} cell activity and trafficking. Activated T_{eff} cells drive a number of immuno-inflammatory diseases across therapeutic areas, including transplantation science, pulmonary, neurologic, gastrointestinal, renal, vascular, ophthalmic and dermatologic inflammatory disorders. Based on its broad upstream multi-modal mechanism of action, EQ001 may have potential to treat multiple severe immuno-inflammatory diseases, including those that are resistant or refractory to existing therapies.

About Equillium
Equillium is a biotechnology company leveraging deep understanding of immunobiology to develop products to treat severe autoimmune and inflammatory disorders with high unmet medical need. Equillium's initial product candidate, EQ001 (itolizumab), is a clinical-stage, first-in-class monoclonal antibody that selectively targets the novel immune checkpoint receptor CD6 to modulate T cells that drive immuno-inflammation. Itolizumab is a clinically-validated therapeutic with a favorable safety and tolerability profile. Equillium plans to advance EQ001 into clinical

development in multiple immuno-inflammatory indications with high unmet medical need and believes that EQ001 has the potential to be a best-in-class disease modifying therapeutic. 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 timing for initiating Equillium's Phase 1b/2 clinical trial and plans for such clinical trial, expected benefits to be received from Fast Track designation and potential impact of EQ001. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties related to the initiation and completion of clinical trials, action on the part of the FDA and whether the final results from the Phase 1b/2 clinical trial will validate and support the safety and efficacy of EQ001. 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
+1-858-412-5302
ir@equilliumbio.com

Media Contact
Heidi Chokeir, Ph.D.
Canale Communications
+1-619-203-5391
heidi@canalecomm.com