



Equillium Granted U.S. FDA Orphan Drug Designations for EQ001 (itolizumab) for both the Prevention and Treatment of Acute Graft-Versus-Host Disease

February 7, 2019

LA JOLLA, Calif., Feb. 07, 2019 (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 Orphan Drug designations for EQ001 for both the prevention and treatment of acute graft-versus-host disease (aGVHD).

The FDA's Orphan Drug designation program provides incentives to companies developing therapeutics for the safe and effective treatment, diagnosis or prevention of rare diseases and disorders that affect fewer than 200,000 people in the United States. As a result of EQ001's Orphan Drug designations, Equillium is eligible for an additional seven years of market exclusivity if the drug is approved, tax credits for qualified clinical research costs and a waiver of the Prescription Drug User Fee paid at the time of submission of a marketing application to FDA.

"Acute GVHD is a life-threatening condition faced by up to 50 percent of those who have undergone a hematopoietic stem cell transplant, and there are currently no approved therapies for either the prevention or treatment of aGVHD," said Stephen Connelly, Ph.D., chief scientific officer of Equillium. "Receiving both FDA Orphan Drug designations for EQ001 underscores the grave need for new treatment options. We believe the unique mechanism of action of EQ001 in modulating both the activity and trafficking of pathogenic T cells is ideally suited for both the prevention and treatment of aGVHD."

Equillium plans to initiate the Phase 1b/2 EQUATE clinical trial ([NCT_03763318](https://clinicaltrials.gov/ct2/show/study/NCT03763318)) in early 2019, which will evaluate EQ001 in combination with corticosteroids for the initial treatment of patients presenting with aGVHD.

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, jaundice, difficulty breathing, 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 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. CD6 plays a central role in modulating the activation, proliferation, differentiation and trafficking of T_{eff} cells that drive a number of immuno-inflammatory diseases. Itoizumab is a clinically-validated therapeutic that has demonstrated a favorable safety and tolerability profile. Equillium acquired rights to EQ001 through an exclusive collaboration and license agreement with Biocon Limited. Equillium believes that EQ001 has the potential to be a best-in-class disease modifying therapeutic and is advancing EQ001 into clinical development in multiple immuno-inflammatory indications with high unmet medical need. 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 Orphan Drug designations 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 Chokey, Ph.D.

Canale Communications

+1-619-203-5391

heidi@canalecomm.com