Equillium Announces Data from Phase 1b EQUIP Study in Patients with Uncontrolled Asthma

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Study achieved primary objective of safety and tolerability

Itolizumab demonstrated rapid and sustained reduction in levels of cell surface CD6

LA JOLLA, Calif.--(BUSINESS WIRE)-- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company developing itolizumab to treat severe autoimmune and inflammatory disorders with high unmet medical need, today announced that the Phase 1b EQUIP study of itolizumab in patients with uncontrolled asthma met its primary objective of safety and tolerability and demonstrated on-target peak and sustained reduction of CD6 at Day 85 (one month following last dose). Itolizumab is a first-in-class anti-CD6 monoclonal antibody that targets the CD6-ALCAM signaling pathway to selectively inhibit pathogenic T effector cells.

The data, collected from a total of 18 patients, shows that subcutaneous delivery of itolizumab was generally safe and well tolerated at 0.8 mg/kg (Cohort 1, n=7 treatment and n=2 placebo) and 1.6 mg/kg (Cohort 2, n=7 treatment and n=2 placebo). All subjects (0.8 mg/kg, 1.6 mg/kg, and placebo) reported at least one adverse event. Most subjects (83%) had adverse events that were mild or moderate in severity. The most reported adverse events for subjects treated across all doses with itolizumab were transient lymphopenia (79%), a known drug effect, and injection site reaction or rash (57%; all mild in severity). There was one SAE (peripheral artery thrombosis) reported in the 1.6 mg/kg dosing cohort, which resolved without sequelae.

Pharmacodynamic data demonstrated significant and comparable reductions in cell surface CD6 at both dose levels of 0.8 and 1.6 mg/kg compared to placebo. The loss of cell surface CD6 was rapid, observed on the first evaluation at Day 8, and durable with levels remaining suppressed through Day 85, 28 days after the last dose (Day 57). The reductions in CD6 were similar to those observed in the EQUALISE study where subcutaneous dosing of systemic lupus erythematosus patients showed maximal loss of CD6 between 0.8 and 1.6mg/kg. The study was completed after Cohort 2 as no further pharmacodynamic effects were anticipated at higher doses. Asthma control questionnaire (ACQ-6) scores, used to measure

the adequacy and change in asthma control resulting from treatment, improved (numerically declined) from baseline across all treated subjects from 2.18 to 1.34 at Day 85, the end of the study. FEV-1, or forced expiratory volume, a measure of lung function, improved in Cohort 1, declined in Cohort 2, and was variable at different time points. Overall, there were 4 subjects with a total of 5 asthma exacerbations (defined as requiring systemic corticosteroids), including one patient in the treatment arm of Cohort 1 and 3 patients in the treatment arm of Cohort 2. Additional detail on ACQ-6, FEV-1, and CD6 values can be found in table 1 below.

“EQUIP was designed as a safety study and has met its primary objective, demonstrating that repeat dosing of subcutaneous itolizumab was generally well tolerated in patients with uncontrolled asthma,” said Dolca Thomas, M.D., executive vice president of research and development and chief medical officer of Equillium. “Based on the critical mass of pharmacodynamic data we have collected from EQUIP and our other studies that confirms our optimal dosing range, we decided to end the study after two Cohorts. While we are encouraged by our first placebo-controlled pharmacodynamic data, the small sample size has not enabled us to make any meaningful observations regarding changes in FEV, ACQ, or other outcomes. As a result of the ongoing pandemic and associated challenges conducting asthma trials, we will be prioritizing our clinical development efforts on our pivotal study in acute graft-versus-host disease and our ongoing lupus nephritis program, and reassessing our potential future development strategy in asthma.”

Table 1

	Cohort 1 Treatment (N=7)	Cohort 1 Placebo (N=2)	Cohort 2 Treatment (N=6)	Cohort 2 Placebo (N=2)	Pooled Treatment (N=13)	Pooled Placebo (N=4)
ACQ-6 mean (SD)						
Baseline	2.54 (0.65)	2.42 (0.12)	1.75 (0.50)	2.08 (0.35)	2.18 (0.70)	2.23 (0.30)
D85	1.34 (0.99)	1.85 (0.21)	1.34 (0.92) N=5	0.85 (0.21)	1.34 (0.92) N=12	1.35 (0.60)
FEV1, L mean (SD)						
Baseline	1.94 (0.61)	2.84 (0.04)	1.90 (0.75)	1.42 (0.47)	1.92 (0.65)	2.13 (0.86)
D85	2.12 (0.84)	3.15 (0.01)	1.42 (0.46) N=5	1.40 (0.24)	1.83 (0.77) N=12	2.28 (1.02)
Pharmacodynamic Response % of Baseline Cell Surface CD6*, mean (SD)	(N=6)	(N=2)	(N=5)	(N=2)	(N=11)	(N=4)
Day 15	34.9 (12.4)	118.5 (18.8)	32.2 (7.8)	129.1 (55.1)	33.7 (10.7)	123.8 (41.5)
Day 29	37.1 (24.4)	106.7 (24.0)	28.1 (5.1)	129.2 (8.3)	33.8 (20.2)	117.9 (21.2)
Day 85	33.5 (18.1)	91.1 (4.9)	31.2 (4.0)	125.0 (26.0)	32.7 (15.0)	108.1 (25.3)

*geometric mean fluorescent intensity of CD6 staining on CD4 T cells at each timepoint as assessed by flow cytometry was normalized to the baseline (Day 1) value to calculate the % of baseline value; the resulting % value indicates how much CD6 is expressed in comparison to baseline.

About Uncontrolled Asthma

Asthma is a complex and highly prevalent inflammatory lung disease, characterized by reversible airway obstruction and chronic inflammation that, in severe cases, can significantly impact patient quality of life. Asthma is estimated to affect approximately 26 million people in the United States – with a subset of that population exhibiting eosinophilic and non-eosinophilic asthma (Th2 or non-Th2, respectively), which impacts distinct phenotypes and disease severity. Preclinical data has demonstrated that modulating the CD6-ALCAM pathway has the potential to inhibit the activation and trafficking of both Th2 and Th17 effector T cells.

About EQUIP

The EQUIP study is a Phase 1b randomized, double-blind, placebo-controlled study in patients with uncontrolled moderate to severe asthma. In this 12-week multiple ascending dose study, patients receive either itolizumab or placebo administered subcutaneously every two weeks, for a total of 5 doses, with 4 weeks of follow-up. The primary endpoints of the study are safety and tolerability of itolizumab in patients with uncontrolled moderate to severe asthma. The secondary endpoints include characterizing pharmacokinetics (PK), pharmacodynamics (PD), PK/PD relationship and clinical activity of itolizumab.

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 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 acute graft-versus-host-disease (aGVHD), lupus/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, 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 with the SEC. 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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