# Equillium Reports First Quarter 2019 Financial Results and Recent Highlights

May 13, 2019

*EQUATE Phase 1b/2 trial in acute graft-versus-host disease (aGVHD) ongoing with data expected in 1Q 2020*

*On track to initiate Phase 1b proof-of-concept trials of itolizumab (EQ001) in uncontrolled asthma and lupus nephritis this year*

LA JOLLA, Calif., May 13, 2019 (GLOBE NEWSWIRE) -- Equillium, Inc. (Nasdaq: EQ), a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop products to treat severe autoimmune and inflammatory disorders with high unmet medical need, today announced financial results for the first quarter 2019, and recent business highlights.

"We achieved a significant milestone during the first quarter of 2019 with the initiation of the open label Phase 1b portion of our EQUATE trial evaluating itolizumab in acute GVHD, our initial indication," stated Daniel Bradbury, chairman and chief executive officer of Equillium. "In parallel, we continue to advance plans to initiate two additional trials this year – uncontrolled asthma and lupus nephritis – all of which we believe set the stage for multiple opportunities to demonstrate the value of itolizumab in treating severe immuno-inflammatory diseases. The body of evidence implicating the CD6-ALCAM pathway in immuno-inflammatory diseases continues to grow. Itolizumab's unique mechanism of action, which selectively targets CD6 and downregulates cellular pathways that modulate both the activity and trafficking of effector T cells, represents an entirely new approach to treating these serious diseases. We look forward to data from these important proof-of-concept trials."

**Business Highlights:**

- Initiated the open label Phase 1b portion of the EQUATE trial for the first-line treatment of aGVHD
- Received FDA Orphan Drug and Fast Track designations for itolizumab for both the prevention and treatment of aGVHD
- Announced plans to develop itolizumab for the treatment of lupus nephritis

**Upcoming Milestones:**

- Initiation of the Phase 1b EQUIP proof-of-concept trial evaluating itolizumab for the treatment of uncontrolled moderate to severe asthma expected during the second quarter of 2019
- Initiation of a Phase 1b proof-of-concept trial of itolizumab for the treatment of lupus nephritis expected during the second half of 2019
- Data from the EQUATE aGVHD trial expected during the first quarter of 2020, approximately 12 months following initiation

**First Quarter 2019 Financial Results**

**Research and development (R&D) expenses.** Total R&D expenses for the three months ended March 31, 2019 were $3.8 million, compared with $0.7 million for the same period in 2018. The increase in R&D expenses was primarily driven by additional costs related to increased headcount and the ramp up in regulatory and clinical activity including initiation of the Phase 1b portion of the clinical trial of itolizumab in aGVHD, and preclinical research activities to support Equillium's clinical development program.

**General and administrative (G&A) expenses.** Total G&A expenses for the three months ended March 31, 2019 were $2.6 million, compared with $0.4 million for the same period in 2018. The increase in G&A expenses was primarily driven by additional costs related to increased headcount, legal and other professional fees and costs associated with being a public company.

**Net loss.** Net loss for the three months ended March 31, 2019 was $6.0 million, or $(0.34) per basic and diluted share, compared with a net loss of approximately $1.6 million, or $(0.15) per basic and diluted share, for the same period in 2018.

**Cash and cash equivalents.** As of March 31, 2019, Equillium reported total cash, cash equivalents and short-term investments of $61.6 million, compared to $65.9 million as of December 31, 2018.

**About Equillium**

Equillium is a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop products to treat severe autoimmune and inflammatory, or immuno-inflammatory, disorders with high unmet medical need.

Equillium's initial product candidate, itolizumab (EQ001), 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 activity and trafficking of T cells that drive a number of immuno-inflammatory diseases. Itolizumab is a clinically-validated therapeutic that has demonstrated a favorable safety and tolerability profile. Equillium acquired rights to itolizumab through an exclusive partnership with Biocon Limited. Equillium believes that itolizumab has the potential to be a best-in-class disease modifying therapeutic and is advancing itolizumab 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 Company's business strategy, the Company's plans and expected timing for developing itolizumab, including the expected timing of clinical trial initiation and timing of results, and the potential benefits of itolizumab. Risks that contribute to the uncertain nature of the forward-looking statements include: uncertainties related to the Company's plans and product development, including the initiation and completion of clinical trials and whether the results from clinical trials will validate and support the safety and efficacy of itolizumab. 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

**Equillium, Inc.**
**Condensed Consolidated Balance Sheets**
**(In thousands)**

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| | (Unaudited) | |
| Cash, cash equivalents and short-term investments | $ 61,607 | $ 65,913 |
| Prepaid expenses and other assets | 1,120 | 1,250 |
| Total assets | $ 62,727 | $ 67,163 |
| Current liabilities | 3,052 | 2,028 |
| Non-current liabilities | 181 | 200 |
| Total stockholders' equity | 59,494 | 64,935 |
| Total liabilities and stockholders' equity | $ 62,727 | $ 67,163 |

**Equillium, Inc.**
**Condensed Consolidated Statements of Operations and Comprehensive Loss**
**(In thousands, except share and per share data)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| | (Unaudited) | |
| Operating expenses: | | |
| Research and development | $ 3,759 | $ 663 |
| General and administrative | 2,589 | 374 |
| Total operating expenses | 6,348 | 1,037 |
| Loss from operations | (6,348) | (1,037) |
| Other income (expense), net | 398 | (540) |
| Net loss | $ (5,950) | $ (1,577) |
| Unrealized gain on available-for-sale securities, net | 44 | - |
| Comprehensive loss | $ (5,906) | $ (1,577) |

| | | |
|---|---|---|
| Net loss per common share, basic and diluted | $ (0.34) | $ (0.15) |
| Weighted-average common shares outstanding, basic and diluted | 17,376,236 | 10,708,074 |