Innovate Biopharmaceuticals Reports First Quarter 2018 Key Financial and Corporate Highlights

May 16, 2018

- *Further data on larazotide's mechanism of action, dose response and pharmacology expected at DDW (June 2-5) in Washington D.C.*
- *Addition to senior management of June Almenoff, M.D., PhD. as COO and CMO (former principal executive and CMO of Furiex Pharmaceuticals, Inc., which was acquired by Allergan plc in 2014)*
- *Completed a merger with a concurrent financing of $21 million, with our shares now trading on the Nasdaq Capital Market under the symbol "INNT"*

RALEIGH, N.C., May 16, 2018 (GLOBE NEWSWIRE) -- Innovate Biopharmaceuticals, Inc. (Nasdaq:INNT), a clinical stage biotechnology company focused on developing novel therapeutics for immuno-inflammatory diseases, today reported its first quarter 2018 financial results and key highlights.

Recent Achievements and Upcoming Milestones

Corporate

- Attendance at the Digestive Disease Week (DDW) conference; KOL/analyst event and 1-on-1 meetings with management planned for Monday, June 4
- Presentation at the BIO Convention planned for Tuesday, June 5 at 4:45PM ET in Theater 2 and 1-on-1 partnering meetings
- Attendance at the Gut-Liver Axis EASL Monothematic Conference in Leuven, Belgium, planned for June 8-9 (focused meeting on liver diseases due to a dysfunctional intestinal barrier)

Research

- As previously announced, presentation of two poster abstracts planned for June 2-3 at DDW highlighting larazotide's novel mechanism of action, dose response and pharmacology

CMC/Manufacturing

- Ongoing stability and testing of INN-202 for celiac disease; preparing for expected final release of drug product in the third quarter

Clinical

- Phase 3 celiac disease trial preparations underway
- World-renowned celiac Scientific Advisory Board in place: Ciaran Kelly, M.D. (Beth Israel/Harvard), Joseph Murray, M.D. (Mayo), Anthony DiMarino, M.D. (Jefferson), Peter Green, M.D. (Columbia), Markku Mäki, M.D, Ph.D. (Tampere (emeritus)), and Elena Verdu, M.D., Ph.D. (McMasters)
- Leading nonalcoholic steatohepatitis (NASH) experts Manal F. Abdelmalek, M.D. (Duke), Anna Mae Diehl, M.D. (Duke) and Stephen A. Harrison, M.D. joined our Scientific Advisory Board

Christopher Prior, Ph.D., CEO of Innovate, said, "To our knowledge, Innovate has the only oral therapeutic offering promise to restore intestinal barrier function and reduce the immuno-inflammatory responses that culminate in celiac disease and NASH. Based on what we believe to be a unique mechanism of action, we believe we are well positioned to build a robust pipeline of product candidates either as standalone therapies or in combination with other therapies working at different targets."

June Almenoff, M.D., Ph.D., COO and CMO of Innovate, added, "I've been delighted to become part of the Innovate team as we plan to initiate our Phase 3 trial for celiac disease. We believe our program will be the first Phase 3 trial for this unmet need."

First Quarter 2018 Financial Results

Net loss for the quarter ended March 31, 2018, was $16.2 million, or ($0.76) per share, compared to net loss of $4.0 million, or ($0.34) per share for the same period ended March 31, 2017.

Research and development expenses were $6.4 million for the quarter ended March 31, 2018, an increase of $5.0 million compared to $1.3 million for the same period ended March 31, 2017. The increase in research and development expenses was primarily attributable to a $4.9 million increase in non-cash, non-employee share-based compensation expense primarily due to the significant increase in the market value of our common stock. The remaining increase was primarily due to an increase of $0.1 million related to an increase in manufacturing, clinical and regulatory costs for the development of larazotide as we prepare for the Phase 3 clinical trial later in 2018. Share-based compensation expense, non-cash expense for the three months ended March 31, 2018 and 2017 was $5.8 million and $0.9 million, respectively.

General and administrative expenses were $6.2 million for the quarter ended March 31, 2018, an increase of $3.6 million compared to $2.6 million for the same period ended March 31, 2017. The increase was driven by approximately $1.2 million in share-based compensation, non-cash expense primarily due to the increase in the market value of our common stock. The additional $2.4 million increase in costs was primarily due to certain transaction and merger-related fees

and expenses, including legal, accounting and advisory fees and expenses, and an increase in personnel and salary costs. Share-based compensation, non-cash expense for the three months ended March 31, 2018 and 2017 was $2.6 million and $1.4 million, respectively.

At March 31, 2018, the company held $13.0 million in cash and cash equivalents, compared to $0.4 million at December 31, 2017.

About Innovate Biopharmaceuticals, Inc. (Nasdaq:INNT):
Innovate is a clinical stage biotechnology company focused on developing novel therapeutics for immuno-inflammatory diseases. Innovate's lead drug candidate, larazotide acetate, has a mechanism of action that renormalizes the dysfunctional intestinal barrier by decreasing intestinal permeability and reducing antigen trafficking, such as gliadin fragments in celiac disease, and bacterial toxins and immunogenic antigens in NASH. In several diseases, including celiac disease, NASH, Crohn's disease, ulcerative colitis, irritable bowel syndrome (IBS), type 1 diabetes mellitus (T1DM), chronic kidney disease (CKD), the intestinal barrier is dysfunctional with increased permeability.

In celiac disease, larazotide is the only drug which has successfully met the primary endpoint with statistical significance in a Phase 2b efficacy clinical trial (342 patients). Innovate successfully completed the End of Phase 2 Meeting with the FDA in 2017 and is preparing to begin Phase 3 registration clinical trials for celiac disease later in 2018. Larazotide has been exposed to more than 800 subjects in clinical trials demonstrating a favorable safety profile comparable to placebo for long-term chronic administration. Larazotide has received Fast Track designation from the FDA for celiac disease.

Forward Looking Statements
This press release includes forward-looking statements including, but not limited to, statements related to the potential for Innovate's drug development pipeline candidates in treating the diseases and conditions for which they are being developed, Innovate's start of clinical trials for celiac disease, NASH, Crohn's disease, and ulcerative colitis, and Innovate's ability to develop future collaborations. The forward-looking statements contained in this press release are based on management's current expectations and are subject to substantial risks, uncertainty and changes in circumstances. Actual results may differ materially from those expressed by these expectations due to risks and uncertainties, including, among others, those related to our ability to obtain additional capital on favorable terms to us, or at all, the success, timing and cost of our drug development program and our ongoing or future clinical trials, the lengthy and unpredictable nature of the drug approval process, and our ability to commercialize our product candidates if approved. These risks and uncertainties include, but may not be limited to, those described in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 14, 2018, our Quarterly Report on Form 10-Q filed with the SEC on May 15, 2018, and in any subsequent filings with the SEC. Forward-looking statements speak only as of the date of this press release, and we undertake no obligation to review or update any forward-looking statement except as may be required by applicable law.

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