



## Innovate Biopharmaceuticals Reports Second Quarter 2018 Earnings and Key Corporate Highlights

August 15, 2018

- Added as a member of the broad-market Russell 3000®, 2000® and Microcap® Indexes
- Innovate plans to host a *Clinical and Scientific Update* on September 6, 2018, in New York City
- Multiple research collaborations with academic partners for potential new indications

RALEIGH, N.C., Aug. 15, 2018 (GLOBE NEWSWIRE) -- Innovate Biopharmaceuticals, Inc. (Nasdaq: INNT), a clinical stage biotechnology company focused on developing novel therapeutics for autoimmune and inflammatory diseases, today reported its second quarter 2018 financial results and key highlights.

### Recent Achievements and Upcoming Milestones

#### Upcoming Milestones

- Phase 3 celiac disease trial startup preparations underway with clinical site evaluations and patient dosing targeted before year end
- Pre-clinical studies for non-alcoholic steatohepatitis (NASH) expected to readout in late Q3
- Innovate plans to host a *Clinical and Scientific Update* on Thursday, September 6, 2018, from 8:15am-11:00am at the Omni Hotel (52<sup>nd</sup> St. & Madison Ave.) in New York City

#### Corporate

- Innovate Biopharmaceuticals Inc. was added as a member of the broad-market Russell 3000®, 2000® and Microcap® Indexes effective June 25, 2018, as part of the 2018 Russell indexes reconstitution
- Innovate intends to present at the 20th Annual Rodman & Renshaw Global Investment Conference on September 5, 2018, at 12:05pm at the St. Regis in New York City

#### Research

- Presented two posters in collaboration with North Carolina State University at the Digestive Disease Week medical conference 2018 highlighting larazotide's novel mechanism of action and pharmacology
- Continued collaboration with Anthony Blikslager, DVM, PhD, DACVS, AGAF, of NC State to understand and characterize the mechanism of action and dose response of larazotide
- Initiated collaboration with O. Colin Stine, PhD, of the University of Maryland, Baltimore to study larazotide's corrective effect on the dysfunctional intestinal barrier and the dysfunctional microbiome (see press release from June 28, 2018)
- Initiated collaboration with James Nataro, MD, PhD, MBA, of University of Virginia to study larazotide's effect on improving the microbiome of children with environmental enteric dysfunction (EED) (see press release from July 31, 2018)

Christopher Prior, Ph.D., CEO of Innovate, said, "The second quarter of 2018 marked continued progress for Innovate as we continued to advance the startup activities for our celiac disease Phase 3 trials and progress our NASH program. We are also excited about our ongoing and new research collaborations with various partners to leverage our mechanism of action to address unmet medical needs."

### Second Quarter 2018 Financial Results

Net loss for the three months ended June 30, 2018, was \$4.2 million, or \$(0.16) per basic and diluted share, compared to net loss of \$2.8 million, or \$(0.23) per basic and diluted share for the same period ended June 30, 2017.

Research and development expenses were \$1.2 million for the three months ended June 30, 2018, an increase of \$0.1 million, compared to \$1.1 million for the same period ended June 30, 2017.

General and administrative expenses were \$2.1 million for the three months ended June 30, 2018, an increase of \$0.6 million, compared to \$1.5 million for the same period ended June 30, 2017.

At June 30, 2018, Innovate had \$10.7 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 autoimmune and 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 nonalcoholic steatohepatitis (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 its 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, targeted to commence 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 Quarterly Report on Form 10-Q filed with the SEC on August 14, 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.

#### **Innovate Biopharmaceuticals, Inc.**

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