



## Innovate Biopharmaceuticals Reports Second Quarter 2019 Results and Corporate Updates

August 8, 2019

*Company is exploring potential strategic opportunities and non-dilutive sources of capital, and partnerships*

*Continued activities of the first Phase 3 clinical trial for celiac disease including the screening and monitoring of potential subjects*

RALEIGH, N.C., Aug. 08, 2019 (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 2019 financial results and corporate updates.

### Recent Developments

#### *Clinical*

- The screening and monitoring of patients in the first Phase 3 celiac disease trial continues
- Company has secured an initial set of 17 active clinical testing sites

#### *Research and development*

- Research collaboration with Institut Gustave Roussy continues to study regulation of intestinal permeability and the gut microbiota using larazotide in immuno-oncology checkpoint inhibitor failure preclinical models
- Data analysis from pre-clinical models in NASH advances from studying larazotide in both *ex vivo* and animal models
- Progression of research collaboration with Dr. Jay Luther and Dr. Raymond Chung at the Gastroenterology Division at Massachusetts General Hospital to research the effects of larazotide on certain forms of alcoholic liver disease, such as ASH
- Presented 3 posters at DDW 2019 in May
- Acceptance of poster at 2019 World Congress of Gastroenterology in September

### Second Quarter 2019 Financial Results

Net loss for the three months ended June 30, 2019 was \$4.5 million or \$0.13 per share. Research and development expenses were \$3.1 million and general and administrative expenses were \$3.0 million for the three months ended June 30, 2019, respectively. Cash and cash equivalents were \$13.3 million at June 30, 2019, compared to \$5.7 million at December 31, 2018.

Sandeep Laumas, M.D., Innovate's Executive Chairman and Chief Executive Officer, noted, "The second quarter of 2019 was focused on the start of the first Phase 3 clinical trial for celiac disease. Given the nature of celiac disease, the design of our screening and enrollment procedures are particular. We look forward to continuing to update our investors on our progress." Dr. Laumas continued, "The board and management of Innovate strongly believe that our novel therapeutics have significant clinical and economic potential in providing treatment where none exists. We are excited for the progress of the Phase 3 trial for celiac disease and expect to continue to explore various potential non-dilutive financing options and other strategic opportunities that we believe could bring value to our stockholders."

### 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.

### Forward Looking Statements

This press release includes forward-looking statements including, but not limited to, statements related to succession planning and our management team, the development of drug candidates, our operations and business strategy, capital raising, our expected financial results, and corporate updates. 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 identify, recruit and retain key talent, obtain additional capital on favorable terms to us, or at all, including, without limitation, to fund our current and future preclinical studies and clinical trials, including, without limitation, raising additional funds for our phase 3 trial for INN-202, and the success, timing and cost of our drug development program and our ongoing or future preclinical studies and clinical trials, including, without limitation, the possibility of unfavorable new clinical and preclinical data and additional analyses of existing data, uncertainties with respect to evaluating strategic options and completing strategic transactions, as well as the risks that prior clinical and preclinical results may not be replicated. These risks and uncertainties include, but may not be limited to, those described in our Form 10-K for the year ended December 31, 2018, our Form 10-Q for the quarter ended June 30, 2019, 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.

SOURCE: Innovate Biopharmaceuticals, Inc.

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