

## **- Top-Line Data from Phase 2 EMPHASIS Trial in Relapsing-Remitting Multiple Sclerosis Expected in Third Quarter 2020 -**

## **- Cash of \$29.4 Million Provides Funding Through Key 2020 Inflection Points**

NEW YORK, March 16, 2020 /PRNewswire/ -- **Immunic, Inc. (Nasdaq: IMUX)**, a clinical-stage biopharmaceutical company focused on developing best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, today announced financial results for the year ended December 31, 2019 and highlighted recent achievements.

"In addition to the closing of our stock-for-stock exchange transaction with Vital Therapies, Inc., which provided our Nasdaq listing and a significant capital infusion, 2019 was punctuated by the attainment of other important milestones," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Most notably, we completed enrollment for our phase 2 EMPHASIS trial of our lead compound, IMU-838, for patients with relapsing-remitting multiple sclerosis (RRMS), roughly nine months ahead of our initial plan. With preclinical data showing a solidly superior profile compared to DHODH inhibitor, teriflunomide, IMU-838 holds promise as an important new, best-in-class oral therapy for RRMS and other underserved immunologic diseases. We anticipate reporting top-line results in the third quarter of this year and believe that positive data could allow us to move quickly into a pivotal phase 3 trial.

"We also reported progress for IMU-838 in moderate-to-severe ulcerative colitis (UC) and primary sclerosing cholangitis (PSC), with a positive phase 2 interim dosing analysis in UC and the initiation of our investigator-sponsored, phase 2 trial in PSC, led by the Mayo Clinic. Given that the interim dosing analysis from the CALDOSE-1 study in patients with UC showed that it was likely not ineffective at the lowest 10 mg dose and that none of the three dose levels revealed unacceptable intolerance, the trial was expanded to 240 patients and top-line data is expected in the fourth quarter of 2021."

Dr. Vitt continued, "Our earlier stage programs have also advanced, with the dosing of healthy volunteers in several dose cohorts in our phase 1 trial of IMU-935, a potentially best-in-class inverse agonist of ROR $\gamma$ t. Additionally, we plan to complete the preclinical and manufacturing activities required in order to initiate phase 1 clinical studies of IMU-856, during the first half of this year, having just announced in January 2020 the exercise of our option for the exclusive worldwide license to IMU-856 from Daiichi Sankyo, Co., Ltd. We are highly encouraged by the data we have generated thus far for our programs, most especially for IMU-838, and look forward to additional success in 2020."

### **Recent Highlights**

- January 2020: Exercised option from Daiichi Sankyo Co., Ltd. for the exclusive worldwide license to a group of compounds, designated by Immunic as IMU-856, aimed at restoring intestinal barrier function.
- December 2019: Presented data, for the first time, on IMU-856, at the Crohn's and Colitis Foundation IBD Innovate Conference. The presentation highlighted preclinical data indicating that the compound potentially restores intestinal barrier function without impairing the immune system. This represents a new and possibly disruptive approach for the treatment of intestinal diseases.
- November 2019: Expanded the Board of Directors to seven members with the appointment of biotechnology executive Barclay "Buck" A. Phillips.
- October 2019: Expanded the Board of Directors to six members with the appointment of industry veteran Tamar Howson.
- October 2019: Announced early completion of patient enrollment (nine months ahead of initial schedule) for the phase 2 EMPHASIS trial of IMU-838, for the treatment of RRMS.

### **Upcoming Anticipated Clinical Milestones**

- Top-line data from the phase 2 EMPHASIS trial in RRMS is expected to be available in the third quarter of 2020.
- Completion of the preclinical and manufacturing activities that are necessary for the initiation of phase 1 clinical studies of IMU-856 is expected during the first half of 2020.
- The current, single ascending dose trial of IMU-935 is planned to be followed by a phase 1 multiple ascending dose trial in healthy volunteers and a phase 1 trial in patients with mild-to-moderate psoriasis; both are expected to start during the first half of this year.
- Top-line data from the phase 2 CALDOSE-1 trial in UC is expected to be available during the fourth

quarter of 2021.

## Financial and Operating Results

- **Research and Development (R&D) Expenses** were \$22.5 million for the year ended December 31, 2019, compared to \$9.6 million for the same period during 2018, an increase of \$12.9 million. The increase is primarily due to (i) higher external development costs for the company's IMU-838 program for the phase 2 clinical trial in patients with RRMS and UC and preparation costs related to the phase 2 clinical trial for patients with Crohn's disease totaling \$8.3 million, (ii) an increase of drug supply costs to support clinical trials of IMU-838 totaling \$1.5 million, (iii) a contingent payment under the asset purchase agreement with 4SC AG settled in stock valued at \$1.5 million, (iv) external R&D costs related to the company's IMU-856 program of \$1.1 million and (v) \$0.5 million related to increases across numerous categories.
- **General and Administrative (G&A) Expenses** were \$14.5 million for the year ended December 31, 2019, compared to \$2.4 million for the same period during 2018, an increase of \$12.1 million. The increase is primarily due to (i) one-time costs related to the stock-for-stock exchange transaction completed on April 12, 2019 with Vital Therapies, including \$6.4 million of stock-based compensation for executives, key employees and members of the board and \$1.7 million of investment banking and legal fees, (ii) \$2.6 million related to becoming a public company, including directors and officers liability insurance, audit and legal fees and personnel costs for executives and staff in the U.S. corporate headquarters, (iii) \$0.5 million related to travel and (iv) \$0.9 million related to increases across numerous categories.
- **Other Income** for the year ended December 31, 2019 was \$2.1 million compared to \$450,000 for the same period of 2018, an increase of \$1.6 million. The increase is primarily attributable to a \$0.9 million year-over-year increase in reimbursement of research and development expenses in connection with the option and license agreement with Daiichi Sankyo Co., Ltd., the \$0.3 million as a result of the sale of certain of Vital Therapies' clinical development-related assets and related intellectual property, \$0.3 million related to research and development tax incentives for clinical trials in Australia and \$0.1 million related to interest income.
- **Net Loss** for year ended December 31, 2019 was approximately \$34.9 million, or \$4.52 per basic and diluted share, based on 7,722,269 weighted average common shares outstanding, compared to a net loss of approximately \$11.5 million, or \$13.63 per basic and diluted share, based on 846,953 weighted average common shares outstanding for the year ended December 31, 2018. Substantially all of the company's operating losses resulted from expenses incurred in connection with its R&D programs and from G&A costs associated with operations.
- **Cash and Cash Equivalents**, as of December 31, 2019, of \$29.4 million, is expected to fund the company's operations into the first quarter of 2021.

## About Immunic, Inc.

Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, including relapsing-remitting multiple sclerosis, ulcerative colitis, Crohn's disease, and psoriasis. The company is developing three small molecule products: IMU-838 is a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH; IMU-935 is an inverse agonist of ROR $\gamma$ t; and IMU-856 targets the restoration of the intestinal barrier function. Immunic's lead development program, IMU-838, is in phase 2 clinical development for relapsing-remitting multiple sclerosis and ulcerative colitis, with an additional phase 2 trial considered in Crohn's disease. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is ongoing at the Mayo Clinic. For further information, please visit: [www.imux.com](http://www.imux.com).

## Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to Immunic's three development programs and the targeted diseases; the potential for IMU-838, IMU-935 and IMU-856 to safely and effectively target diseases; preclinical data for IMU-856; the timing of future clinical trials; the nature, strategy and focus of the company; and the development and commercial potential of any product candidates of the company. Immunic may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, risks and uncertainties associated

with the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability of sufficient resources to meet business objectives and operational requirements, the fact that the results of earlier studies and trials may not be predictive of future clinical trial results, the protection and market exclusivity provided by Immunic's intellectual property, risks related to the drug development and the regulatory approval process and the impact of competitive products and technological changes. A further list and descriptions of these risks, uncertainties and other factors can be found in the section captioned "Risk Factors," in the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 16, 2020, and in the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov) or [ir.immunic-therapeutics.com/sec-filings](http://ir.immunic-therapeutics.com/sec-filings) and on request from Immunic. Any forward-looking statement made in this release speaks only as of the date of this release. Immunic disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances that exist after the date on which they were made. Immunic expressly disclaims all liability in respect to actions taken or not taken based on any or all the contents of this press release.

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## Financials

### Immunic, Inc. Consolidated Statements of Operations

(In thousands, except share and per share amounts)

|   | Years Ended December 31, |                    |
|---|--------------------------|--------------------|
|   | 2019                     | 2018               |
| Operating expenses:   |                          |                    |
| Research and development                                      | \$ 22,512                | \$ 9,595           |
| General and administrative                                    | 14,520                   | 2,402              |
| Total operating expenses                                      | <u>37,032</u>            | <u>11,997</u>      |
| Loss from operations  | (37,032)                 | (11,997)           |
| Other income (expense):                                       |                          |                    |
| Interest income (expense)                                     | 107                      | (1)                |
| Other income, net   | 1,992                    | 456                |
| Total other income  | <u>2,099</u>             | <u>455</u>         |
| Net loss  | <u>\$ (34,933)</u>       | <u>\$ (11,542)</u> |
| Net loss per share, basic and diluted                         | <u>\$ (4.52)</u>         | <u>\$ (13.63)</u>  |
| Weighted-average common shares outstanding, basic and diluted | <u>7,722,269</u>         | <u>846,953</u>     |

### Immunic, Inc. Consolidated Balance Sheets

(In thousands, except share and per share amounts)

|                 | December 31, |      |
|-----------------|--------------|------|
|                 | 2019         | 2018 |
| <b>Assets</b>   |              |      |
| Current assets: |              |      |

|  |                  |                  |
|--|------------------|------------------|
| Cash and cash equivalents  | \$ 29,369        | \$ 13,072        |
| Other current assets and prepaid expenses  | 2,861            | 259              |
| Total current assets   | 32,230           | 13,331           |
| Property and equipment, net  | 80               | 40               |
| Goodwill   | 32,970           | —                |
| Right of use asset, net  | 633              | —                |
| Other long-term assets   | 42               | —                |
| Total assets   | <u>\$ 65,955</u> | <u>\$ 13,371</u> |
| <b>Liabilities, Preferred Stock and Stockholders' Equity (Deficit)</b>   |                  |                  |
| Current liabilities:   |                  |                  |
| Accounts payable   | \$ 2,423         | \$ 1,400         |
| Accrued expenses   | 3,298            | 416              |
| Other current liabilities  | 1,351            | 104              |
| Total current liabilities  | 7,072            | 1,920            |
| Long-term liabilities:   |                  |                  |
| Operating lease liabilities  | 520              | —                |
| Total long-term liabilities  | 520              | —                |
| Total liabilities  | 7,592            | 1,920            |
| Commitments and contingencies (note 6)   |                  |                  |
| Series A-2 Convertible preferred stock, €1.00 par value, 299,456 shares authorized, issued and outstanding at December 31, 2018  | —                | 34,313           |
| Series A-1 Convertible preferred stock, €1.00 par value, 13,541 shares authorized, issued and outstanding at December 31, 2018   | —                | 2,879            |
| Stockholders' equity (deficit):  |                  |                  |
| Preferred stock, \$0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at December 31, 2019 and 2018   | —                | —                |
| Common stock, \$0.0001 par value; 130,000,000 and 846,953 shares authorized and 10,744,806 and 846,953 shares issued and outstanding at December 31, 2019 and 2018, respectively | 1                | —                |
| Additional paid-in capital   | 119,646          | 56               |
| Accumulated other comprehensive loss   | (1,373)          | (819)            |
| Accumulated deficit  | (59,911)         | (24,978)         |
| Total stockholders' equity (deficit)   | 58,363           | (25,741)         |
| Total liabilities, preferred stock and stockholders' equity (deficit)  | <u>\$ 65,955</u> | <u>\$ 13,371</u> |

SOURCE Immunic, Inc.

<https://ir.imux.com/2020-03-16-Immunic-Inc-Reports-Year-End-2019-Financial-Results-and-Highlights-Recent-Achievements>