Replimune Reports Fiscal Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update

June 3, 2020

WOBURN, Mass., June 03, 2020 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a biotechnology company developing a series of oncolytic immuno-gene therapies derived from its Immulytic™ platform, today announced financial results for the fiscal fourth quarter and year ended March 31, 2020 and provided a business update.

"I am very pleased with our continued progress developing our pipeline of oncolytic immuno-gene therapies. Today we released additional data with RP1 in our lead indications of cutaneous squamous cell carcinoma (CSCC) and anti-PD1 refractory cutaneous melanoma that we believe point to a high probability of success in our registration-directed clinical trial in CSCC and our potentially registrational cohort of patients currently being enrolled with anti-PD1 refractory melanoma. We also today announced plans to initiate clinical development of RP1 in anti-PD1 refractory patients with non-small cell lung cancer (NSCLC)," said Philip Astley-Sparke, CEO of Replimune. "We look forward to presenting further clinical updates from our skin cancer programs later in the year, together with single agent safety and efficacy data and initial data in combination with Opdivo® from our ongoing Phase 1 clinical trial with our second product candidate, RP2. We believe we have established clinical proof of principle with RP1 in immune-responsive tumor types and that we now have a solid foundation to further establish our product candidates more universally as the second cornerstone of immune-oncology."

Recent Events and Corporate Highlights

- **Presented new interim clinical data from the Phase 2 portion of the Phase 1/2 clinical trial of RP1 in combination with Opdivo in non-melanoma and melanoma skin cancers that continue to support clinical programs in both CSCC and anti-PD1 refractory melanoma.** A link to the data presented can be found here.
    - New interim data for patients with CSCC treated with RP1 continued to strengthen since the last update provided at the 2019 Society for the Immunotherapy of Cancer (SITC). Overall four of seven evaluable patients have ongoing complete responses (CRs) and six of seven have an ongoing CR or partial response (PR) as compared to the data presented at SITC in November 2019, where one out of five patients had a CR and two out of five had a PR. Importantly, we believe that the number of CRs seen to date in advanced CSCC patients with aggressive disease treated with RP1 in combination with anti-PD1 provides clear differentiation for RP1 versus anti-PD1 therapy alone. Overall, the data continues to demonstrate that RP1 in combination with Opdivo is well tolerated, demonstrates immune activation, continues to drive deep and durable responses in patients with CSCC, and provides what we believe to be strong validation of the Company's clinical development plan.
    - Early interim data of RP1 in combination with Opdivo in 16 patients with anti-PD1 refractory cutaneous melanoma demonstrated clear activity, including in patients with extensive visceral disease. Five of 16 patients have so far met the formal criteria of a response, including four of whom had previously failed both anti-PD1 and anti-CTLA4 therapies, providing for a minimum final response rate from this cohort of 31%. With a majority of melanoma patients having primary or acquired resistance to checkpoint blockade, we believe that the initial efficacy seen represents a potential new therapeutic option for these patients.
    - Additional promising data with RP1 combined with Opdivo in patients with anti-PD1 naïve cutaneous melanoma, mucosal melanoma and uveal melanoma were presented. Uveal and mucosal represent difficult to treat melanoma sub-types and the patients enrolled include responding patients who have already failed both anti-PD1 and anti-CTLA4 therapies.
- **Announced plans to enroll a new 30 patient cohort in anti-PD1 refractory NSCLC into the Phase 2 portion of the clinical trial of RP1 combined with Opdivo and terminate further enrollment of the 30 patient cohort in metastatic bladder cancer.** Anti-PD1 refractory NSCLC represents an area of considerable unmet need. RP1 in combination with Opdivo has demonstrated the ability to shrink lung metastases of other tumor types, including in patients with anti-PD1 refractory disease, where administration of RP1 via imaging guidance has been demonstrated to be both feasible and generally well tolerated in the patients treated so far. Additionally, as a result of a new emerging standard of care in metastatic bladder cancer, the Company has elected to terminate enrollment of this cohort.
- **Manufacturing.** The Company has completed construction of and equipped its 63,000 square feet state of the art commercial capacity manufacturing facility in Framingham MA and successfully completed technology transfer activities. The facility has been designed to allow us to produce enough material to cover full global commercialization of all our current product candidates.
- **Intellectual Property.** The Company has made significant progress in developing its intellectual property portfolio during

the year, including through the grant of US patents covering its core technology. These include US patent number 10,612,005, which protects the use of an oncolytic virus expressing an inserted gene encoding a fusogenic glycoprotein (thereby intended to increase the extent and immunogenicity of tumor cell death) together with a gene encoding an immune stimulating protein, and US 10,570,377 which protects the use of the Company's novel strains of herpes simplex virus (HSV) which were identified through an extensive screen of clinical isolates of HSV to identify strains with the greatest ability to kill human tumor cells.

- **Announced new appointments to the Board.** In April the Company announced the appointment of Dieter Weinand as Chairman of the Board of Directors and the appointment of Paolo Pucci as a new member of the Board of Directors. Mr. Weinand succeeds Philip Astley-Sparke who in January transitioned from part time Executive Chairman to full time Chief Executive Officer. The appointments bring international experience within commercial, operational, and strategic functions in the pharmaceutical industry along with extensive experience in the field of oncology.

- **Amendment of debt facility.** On June 1st the Company closed an expansion of its debt facility with Hercules Growth Capital from $30m to $40m and extension of the interest only period. Combined with various cost containment measures, this should allow the Company to fund operations through 2022.

Program Highlights

Replimune is currently developing three oncolytic immuno-gene therapies derived from its Immulytic platform. RP1 is Replimune's first clinical product candidate and is based on a proprietary new strain of herpes simplex virus armed with a gene encoding a potent fusogenic protein (GALV-GP-R), intended to enhance tumor killing potency, immunogenic cell death and the activation of systemic anti-tumor immune responses, and with a gene encoding the cytokine GM-CSF. RP2 is a version of RP1 that in addition to expressing GALV-GP-R and GM-CSF also expresses a genetically encoded anti-CTLA-4 antibody-like molecule intended to block the inhibition of the initiation of immune response caused by CTLA-4. RP3 is a further armed oncolytic immuno-gene therapy which additionally expresses two immune co-stimulatory activating ligands – CD40L and 4-1BBL – together with anti-CTLA-4 and GALV-GP-R. CD40L activates CD40, with the goal of achieving broad activation of both innate and adaptive immunity, and 4-1BBL activates 4-1BB (CD137), intended to promote the expansion of cellular and memory immune responses.

- **RP1 in combination with Libtayo® in CSCC:** Enrollment in the 240-patient registration-directed Phase 2, randomized, controlled clinical trial is ongoing and is expected to take approximately 18 to 24 months with enrollment intended in the US, Australia, Canada, and European countries including the United Kingdom.

- **RP1 in combination with Opdivo in melanoma, non-melanoma skin cancers, and MSI-H/dMMR tumors:** The melanoma cohort has completed accrual and preliminary results were presented on June 3, together with updated data from the enrolling non-melanoma skin cancer (NMSC) cohort. The NMSC cohort is expected to be fully accrued by the end of 2020, representing a delay partially relating to COVID-19 disruptions. Similarly, it is likely that accumulating sufficient data to inform a decision as to whether to pursue MSI-H/dMMR tumors into registration-directed development will be delayed into 2021.

- **RP1 in combination with Opdivo in anti-PD-1 refractory melanoma patients:** In February 2020, the Company initiated recruitment into a new registration-directed 125-patient cohort in the Phase 2 clinical trial of RP1 in combination with Opdivo.

- **RP1 as monotherapy in solid organ transplant recipients with CSCC:** In May 2020, the Company initiated enrollment into a 30 patient Phase 1/2 clinical trial to assess the safety and efficacy of RP1 in liver and kidney transplant recipients with recurrent CSCC.

- **RP2 alone and in combination with Opdivo:** The ongoing Phase 1 clinical trial evaluating the safety, tolerability, and optimal dose for further development of RP2 alone and in combination with Opdivo remains on track, with initial safety and efficacy data from the single agent RP2 part of the clinical trial together with initial data in combination with Opdivo expected to be presented by the end of 2020.

- **RP3 alone and in combination with anti-PD-1 therapy:** The Phase 1 clinical trial of RP3 alone and in combination with anti-PD-1 therapy remains on track to initiate in 2020.

Financial Highlights

- **Cash Position:** As of March 31, 2020, cash, cash equivalents and short-term investments were $168.6 million, as compared to $134.8 million as of March 31, 2019. This increase was primarily related to $99.7 million in net proceeds from financing activities offset by an increase in cash utilized for capital investments associated with our new manufacturing facility and advancing our expanded clinical development plan.

  Based on our current operating plan, we believe that our existing cash and cash equivalents and short-term investments along with our debt commitments will enable us to fund our operating expenses and capital expenditure requirements through 2022.

- **R&D Expenses:** Research and development expenses were $11.2 million for the fourth quarter and $38.8 million for the fiscal year ended March 31, 2020, as compared to $5.4 million for the fourth quarter and $22.2 million for the fiscal year ended March 31, 2019. This increase was primarily due to increased clinical and manufacturing expenses driven by the Company's lead programs and increased personnel expenses. Research and development expenses included $0.7 million in stock-based compensation expenses for the fourth quarter and $3.7 million in stock-based compensation expenses for the fiscal year ended March 31, 2020.

- **G&A Expenses:** General and administrative expenses were $5.2 million for the fourth quarter and $17.4 million for the fiscal year ended March 31, 2020, as compared to $2.4 million for the fourth quarter and $8.8 million for the year ended March 31, 2019. The increase was primarily driven by personnel related costs, professional fees, and facility expansion. General and administrative expenses included $1.0 million in stock-based compensation expenses for the fourth quarter and $4.1 million in stock-based compensation expenses for the fiscal year ended March 31, 2020.

- **Net Loss:** Net loss was $15.8 million for the fourth quarter and $52.6 million for the fiscal year ended March 31, 2020, as compared to a net loss of $6.7 million for the fourth quarter and $30.8 million for the fiscal year ended March 31, 2019.

About CSCC
CSCC is the second most common form of skin cancer and is estimated to be responsible for at least 7,000 deaths each year in the U.S. It currently accounts for approximately 20% of all skin cancers in the U.S., with the number of newly diagnosed cases expected to rise annually. When CSCC invades deeper layers of the skin or adjacent tissues, it is categorized as locally advanced. Once it spreads to other distant parts of the body, it is considered metastatic. Libtayo® is the only approved therapy in the United States and Brazil, and conditionally approved therapy in the European Union and Canada, for the treatment of locally advanced or metastatic CSCC.

About Melanoma
Melanoma is a form of skin cancer characterized by the uncontrolled growth of pigment-producing cells (melanocytes) located in the skin. Metastatic melanoma is the deadliest form of the disease and occurs when cancer spreads beyond the surface of the skin to other organs. The incidence of melanoma has been increasing steadily for the last 30 years. In the United States, 91,270 new diagnoses of melanoma and more than 9,320 related deaths are estimated for 2018. Globally, the World Health Organization estimates that by 2035, melanoma incidence will reach 424,102, with 94,308 related deaths. Melanoma is mostly curable when treated in its very early stages; however, survival rates are roughly halved if regional lymph nodes are involved.

About RP1
RP1 is Replimune's lead Immulytic™ product candidate and is based on a proprietary new strain of herpes simplex virus engineered to maximize tumor killing potency, the immunogenicity of tumor cell death and the activation of a systemic anti-tumor immune response.

About Replimune
Replimune Group, Inc., headquartered in Woburn, MA, was founded in 2015 to develop the next generation of oncolytic immune-gene therapies for the treatment of cancer. Replimune is developing novel, proprietary therapeutics intended to improve the direct cancer-killing effects of selective virus replication and the potency of the immune response to the tumor antigens released. Replimune's Immulytic ™ platform is designed to maximize systemic immune activation, in particular to tumor neoantigens, through robust viral-mediated immunogenic tumor cell killing and the delivery of optimal combinations of immune-activating proteins to the tumor and draining lymph nodes. The approach is expected to be highly synergistic with immune checkpoint blockade and other approaches to cancer treatment. Replimune intends to progress these therapies rapidly through clinical development in combination with other immuno-oncology products with complementary mechanisms of action. For more information, please visit www.replimune.com.

Forward Looking Statements

This press release contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding our expectations about our cash runway, advancement of our clinical trials, our plans to initiate new clinical trials, our goals to develop and commercialize our product candidates, our expectations regarding commercialization of our product candidates, our expectations regarding the size of the patient populations for our product candidates if approved for commercial use, patient enrollments in our existing and planned clinical trials and the timing thereof, our expectations with respect to our own in-house manufacturing capabilities, and other statements identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to generate positive clinical trial results for our product candidates, the costs of operating our in-house manufacturing facility, the timing and scope of regulatory approvals, changes in laws and regulations to which we are subject, competitive pressures, our ability to identify additional product candidates, political and global macro factors including the impact of the coronavirus as a global pandemic and related public health issues, and other risks as may be detailed from time to time in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other reports we file with the Securities and Exchange Commission. Our actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as

required by law, we undertake no obligation to update or revise these forward-looking statements.

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Replimune Group, Inc.
Condensed Consolidated Statements of Operations
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	Year Ended March 31,		
	2020	**2019**	**2018**
Operating expenses:			
Research and development	$ 38,761	$ 22,173	$ 13,516
General and administrative	17,437	8,773	5,713
Total operating expenses	56,198	30,946	19,229
Loss from operations	(56,198)	(30,946)	(19,229)
Other income:			
Research and development incentives	3,084	2,528	2,267
Investment income	2,424	2,585	288
Interest expense on finance lease liability	(1,185)	-	-
Interest expense on debt obligations	(734)	-	-
Change in fair value of warrant liability	-	(5,452)	(972)
Other income (expense), net	(16)	451	(2,056)
Total other income (expense), net	3,573	112	(473)
Net loss attributable to common stockholders	$ (52,625)	$ (30,834)	$ (19,702)
Net loss per share attributable to common stockholders—basic and diluted	$ (1.54)	$ (1.33)	$ (3.96)
Weighted average common shares outstanding— basic and diluted	34,261,548	23,198,400	4,978,539

Replimune Group, Inc.
Condensed Consolidated Balance Sheets
(Amounts In thousands, except share and per share amounts)
(Unaudited)

	March 31,	
	2020	**2019**
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 168,555	$ 134,811
Working capital	162,377	131,096
Total assets	234,097	154,326
Total stockholders' equity	183,718	137,856

Source: Replimune Group Inc