Gamida Cell Reports First Quarter 2020 Financial Results and Provides Company Update

May 21, 2020

– Primary endpoint achieved in global, randomized, Phase 3 study of omidubicel; Initiation of BLA submission planned for fourth quarter of 2020 —

– Additional data from GDA-201 program expected in second half of 2020 –

– $60 million follow-on offering expected to close today –

– Company to host conference call at 8:30 a.m. ET today –

BOSTON--(BUSINESS WIRE)--May 21, 2020-- Gamida Cell Ltd. (Nasdaq: GMDA), an advanced cell therapy company committed to finding cures for blood cancers and serious blood diseases, today reported financial results for the quarter ended March 31, 2020. The company also highlighted continued progress in advancing its clinical development candidates: omidubicel, an advanced cell therapy in Phase 3 clinical development as a potentially life-saving treatment option for patients in need of bone marrow transplant, and GDA-201, an investigational, natural killer (NK) cell-based cancer immunotherapy in Phase 1 development in patients with non-Hodgkin lymphoma (NHL) and multiple myeloma.

“Last week, we were extraordinarily pleased to report that our Phase 3 study of omidubicel met its primary endpoint of demonstrating a significant reduction in time to neutrophil engraftment, a key milestone in recovery from a bone marrow transplant. Shortening the time to engraftment is clinically meaningful, as it can reduce a patient’s time in the hospital and decrease likelihood of infection. These positive study results represent an important step forward for Gamida Cell and the transplant community,” stated Julian Adams, Ph.D., chief executive officer of Gamida Cell. “Omidubicel is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. FDA and has the potential to be the first FDA-approved bone marrow transplant graft. Our dedicated team is working hard to begin submitting the biologics license application for omidubicel to the FDA on a rolling basis in the fourth quarter.”

“Our Phase 3 omidubicel data underscore the potential of our proprietary NAM technology platform, and we’re very encouraged by the data in the ongoing Phase 1 study of our second development candidate, GDA-201, an investigational natural killer cell therapy. Natural killer cells have attracted significant attention as a potential breakthrough approach to treat cancer, and we are proud to be at the forefront of advancing this field. We anticipate reporting additional data on GDA-201 in the second half of 2020 and are working to initiate a multi-center Phase 1/2 clinical study in patients with lymphoma next year,” Dr. Adams continued.

Company Highlights

- **Reported positive topline data from Phase 3 study of omidubicel**: Last week, Gamida Cell announced positive topline data from its international, randomized Phase 3 study of omidubicel. The study was designed to evaluate the safety and efficacy of omidubicel in 125 patients with high-risk hematologic malignancies undergoing a bone marrow transplant compared to a comparator group of patients who received a standard umbilical cord blood transplant. The primary endpoint was time to neutrophil engraftment.

  The study achieved its primary endpoint ($p<0.001$). In the intent-to-treat analysis, the median time to neutrophil engraftment was significantly shorter for patients who were randomized to omidubicel (12 days; 95% CI: 10-15 days) compared to the comparator group (22 days; 95% CI: 19-25 days). Omidubicel was generally well tolerated. Among patients who were transplanted per protocol, 96 percent of patients who received omidubicel achieved successful neutrophil engraftment, compared to 88 percent of patients in the comparator group.

  The study included patients aged 12–65 years with high-risk hematologic malignancies and was conducted at more than 50 clinical centers in the United States, Latin America, Europe and Asia. The demographics and baseline characteristics were well-balanced across the two study groups.

  Gamida Cell expects to present the full Phase 3 data set at a medical meeting later this year and submit a rolling biologics license application to the FDA in the fourth quarter of 2020.

- **Announced $60 million public offering:** On May 18, Gamida cell announced the pricing of an underwritten public offering of 13,333,334 ordinary shares at a public offering price of $4.50 per share for aggregate gross proceeds of approximately $60 million, before deducting underwriting discounts and commissions and estimated offering expenses. In addition, Gamida Cell granted the underwriters a 30-day option to purchase up to an additional 2,000,000 ordinary shares at the public offering price, less the underwriting discounts and commissions. The offering is expected to close today, subject to satisfaction of customary closing conditions.

- **Continued to focus on activities required to successfully bring omidubicel to patients:** Gamida Cell is continuing to

advance key activities required to bring omidubicel to patients in a commercial setting, including building out manufacturing infrastructure, assembling an experienced commercial team with expertise in cell therapy and transplant, establishing hospital services and patient assistance programs, and exploring coverage and reimbursement models to enable access.

- **Published updated data for GDA-201:** In February 2020, updated data from the ongoing Phase 1 clinical study of GDA-201 in patients with non-Hodgkin lymphoma (NHL) and multiple myeloma (MM) was reported in an abstract published in advance of the 46th European Society for Blood Marrow Transplantation (EBMT) Annual Meeting, which was subsequently postponed due to COVID-19. The data from the first 25 patients demonstrated that GDA-201 was clinically active and generally well tolerated. Among the eleven patients with NHL, seven patients achieved a complete response and one patient achieved a partial response. Among the patients with MM, one patient achieved a complete response, and four patients achieved stable disease. Gamida Cell expects to provide updated data from the study at a medical conference in the second half of 2020.

- **Continued preparations for the next clinical study of GDA-201:** Based on the data from the ongoing Phase 1 study of GDA-201 previously presented, Gamida Cell expects to submit an investigational new drug application to the FDA in the fourth quarter of 2020 to enable the initiation of a multi-center Phase 1/2 clinical study in patients with NHL.

COVID-19 Operational Impact

Gamida Cell has taken important steps to help ensure the safety of employees and their families and to reduce the spread of COVID-19. In early March, Gamida Cell established a work-from-home policy for all employees, other than those performing or supporting business-critical laboratory-based experiments and manufacturing-related activities. For those employees, the company has implemented stringent safety measures designed to comply with applicable government guidelines instituted in response to the COVID-19 pandemic. Gamida Cell has maintained frequent communication with its business partners and clinical sites as the COVID-19 situation has progressed.

"We are proud of the resilience of our employees and are thankful for the continued dedication and support of our clinical study investigators and participating patients. COVID-19 has slightly slowed the cadence of new patient enrollment in the ongoing clinical study of GDA-201 and changed how we conduct our day-to-day business. However, we anticipate that COVID-19 will have limited overall impact on our clinical development programs, timing of regulatory submission for omidubicel, or manufacturing readiness for the potential launch of omidubicel in 2021," said Dr. Ronit Simantov, chief medical officer at Gamida Cell.

Expected 2020-2021 Milestones

Gamida Cell targets achieving the following milestones during 2020-2021:

Omidubicel

- Present data from the Phase 3 study at a medical meeting in the second half of 2020
- Initiate the submission of the biologics license application to the FDA, on a rolling basis, in the fourth quarter of 2020
- Report additional data from the Phase 1/2 study in patients with severe aplastic anemia in the second half of 2020
- Launch omidubicel in 2021, contingent upon FDA approval

GDA-201

- Present additional data from the Phase 1 study in the second half of 2020
- Submit company-sponsored investigational new drug application to FDA in the fourth quarter of 2020
- Initiate a Phase 1/2 clinical study in patients with NHL in 2021

First Quarter 2020 Financial Results

- Research and development expenses in the first quarter of 2020 were $7.9 million, compared to $7.3 million for the same period in 2019. The increase was mainly due to clinical activities relating to the advancement GDA-201, offset by grants received from the Israel Innovation Authority.

- Commercial expenses in the first quarter of 2020 were $1.5 million compared to $1.0 million for the same period in 2019. The increase was mainly attributed to commercial readiness activities for omidubicel.

- General and administrative expenses were $3.0 million for the first quarter of 2020, compared to $2.8 million in the same period in 2019. The increase was due mainly to expenses associated with being a publicly traded company.

- Finance income, net, were $1.7 million for the three months ended March 31, 2020, compared finance expenses, net of $4.4 million in the same period in 2019. The increase was primarily due to noncash expenses resulting from revaluation of warrants.

- Net loss for the first quarter of 2020 was $10.6 million, compared to a net loss of $15.5 million in the same period in 2019.

- As of March 31, 2020, Gamida Cell had total cash, cash equivalents and available-for-sale securities of $40.3 million,

compared to $ 55.4 million as of December 31, 2019. The March 31, 2020, cash position excludes approximately $56 of net proceeds after underwriting discounts and commission and offering-related expenses from the company's recent public follow-on offering.

2020 Financial Guidance

Gamida Cell expects cash used for ongoing operating activities in 2020 to range from $60 million to $70 million.

Gamida Cell expects that, after accounting for the completion of its public follow-on offering, its current cash, cash equivalents and available-for-sale securities will support the company's ongoing operating activities into the second half of 2021. This cash runway guidance is based on the company's current operational plans and excludes any additional funding beyond the follow-on offering, or business development activities that may be undertaken.

Conference Call Information

Gamida Cell will host a conference call today, May 21, 2020, at 8:30 a.m. ET to discuss these financial results and company updates. A live webcast of the conference call can be accessed in the "Investors" section of Gamida Cell's website at www.gamida-cell.com. To participate in the live call, please dial 866-930-5560 (domestic) or +1-409-216-0605 (international) and refer to conference ID number 8530548. A recording of the webcast will be available approximately two hours after the event, for approximately 30 days.

About Omidubicel

Omidubicel, the company's lead clinical program, is an advanced cell therapy under development as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant solution for patients with hematologic malignancies (blood cancers). Omidubicel is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. Food and Drug Administration and has also received Orphan Drug Designation in the U.S. and EU. In both Phase 1/2 and Phase 3 clinical studies, omidubicel demonstrated rapid and durable time to engraftment and was generally well tolerated. Omidubicel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia (NCT03173937). The aplastic anemia investigational new drug application is currently filed with the FDA under the brand name CordIn®, which is the same investigational development candidate as omidubicel. For more information on clinical trials of omidubicel, please visit www.clinicaltrials.gov.

About GDA-201

Gamida Cell applied the capabilities of its NAM-based cell expansion technology to develop GDA-201, an innate natural killer (NK) cell immunotherapy for the treatment of hematologic and solid tumors in combination with standard of care antibody therapies. GDA-201 addresses key limitations of NK cells by increasing the cytotoxicity and in vivo retention and proliferation in the bone marrow and lymphoid organs of NK cells expanded in culture. GDA-201 is in Phase 1 development through an investigator-sponsored study in patients with refractory non-Hodgkin lymphoma and multiple myeloma (NCT03019666).

Omidubicel and GDA-201 are investigational therapies, and their safety and efficacy have not been evaluated by the U.S. Food and Drug Administration or any other health authority.

About Gamida Cell

Gamida Cell is an advanced cell therapy company committed to finding cures for blood cancers and serious blood diseases. We harness our cell expansion platform to create therapies with the potential to redefine standards of care in areas of serious medical need.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, including with respect to timing of initiation and progress of and data reported from the clinical trials of Gamida Cell's product candidates, anticipated regulatory filings, commercialization efforts and Gamida Cell's expectations regarding its projected operating expenses and cash runway, which statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to the scope, progress and expansion of Gamida Cell's clinical trials and variability, and ramifications for the cost thereof; and clinical, scientific, regulatory and technical developments. In light of these risks and uncertainties, and other risks and uncertainties that are described in the Risk Factors section and other sections of Gamida Cell's Annual Report on Form 20-F, filed with the Securities and Exchange Commission (SEC) on February 26, 2020, its Report on Form 6-K filed with the SEC on May 18, 2020 and other filings that Gamida Cell makes with the SEC from time to time (which are available at http://www.sec.gov), the events and circumstances discussed in such forward-looking statements may not occur, and Gamida Cell's actual results could differ materially and adversely from those anticipated or implied thereby. Any forward-looking statements speak only as of the date of this press release and are based on information available to Gamida Cell as of the date of this release.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

U.S. dollars in thousands

	March 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 40,292	$ 41,838
Marketable securities	-	13,559
Prepaid expenses and other current assets	1,637	1,306
Total current assets	41,929	56,703

NON-CURRENT ASSETS:		
Property and equipment, net	8,543	6,298
Right-of-use assets	5,820	5,133
Other assets	637	641
Total non-current assets	15,000	12,072
Total assets	$ 56,929	$ 68,775
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 3,098	$ 1,164
Employees and payroll accruals	2,549	3,443
Current maturities of lease liabilities	1,535	1,870
Accrued expenses and other payables	2,922	4,918
	10,104	11,395
NON-CURRENT LIABILITIES:		
Liabilities presented at fair value	2,773	5,221
Employee benefit liabilities, net	773	773
Lease liability	4,920	4,101
Liability to Israel Innovation Authority (IIA)	13,077	12,302
	21,543	22,397
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Share capital	92	92
Share premium	239,897	238,992
Share premium	(541)	(541)
Capital reserve due to actuarial gains	-	4
Available-for-sale reserve	(214,166)	(203,564)
Total shareholders' equity	25,282	34,983
Total liabilities and shareholders' equity	$ 56,929	$ 68,775

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

U.S. dollars in thousands (except share and per share data)

	Three months ended March 31,		Year ended December 31,
	2020	2019	2019
Operating expenses:			
Research and development, net	$ 7,879	$ 7,283	$ 31,462
Commercial activities	1,468	998	4,692
General and administrative	2,994	2,815	12,091
Operating loss	12,341	11,096	48,245
Finance expense	919	4,734	3,325
Finance income	(2,658)	(349)	(17,149)
Loss before taxes on income	10,602	15,481	34,421
Taxes on income	-	26	(70)
Net loss	10,602	15,507	34,351
Net loss per share:			
Basic loss per share	$ 0.31	$ 0.62	$ 1.17
Diluted loss per share	$ 0.31	$ 0.62	$ 1.69

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Three months ended March 31,		Year ended December 31,
	2020	2019	2019
Cash flows from operating activities:			
Net loss	$ (10,602)	$ (15,507)	$ (34,351)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Adjustments to the profit or loss items:			
Depreciation of property, equipment and right-of-use assets	550	542	2,143
Financial income, net	(132)	(191)	(775)
Cost of share-based compensation	899	1,091	4,868
Change in employee benefit liabilities, net	-	11	126
Amortization of premium on available-for-sale financial assets	4	50	184
Revaluation of financial derivatives	(2,448)	3,907	(15,904)
Revaluation of liability to IIA	722	568	2,531
	(405)	5,978	(6,827)
Changes in asset and liability items:			
Decrease (increase) in prepaid expenses, other current assets and other assets	(458)	409	(150)
Increase (decrease) in trade payables	1,934	(844)	(821)
Increase (decrease) in accrued expenses and other payables	(3,096)	21	2,807
	(1,620)	(414)	1,836
Cash received during the period for:			
Interest received	348	521	1,546
Interest paid	(47)	(28)	(134)
Net cash used in operating activities	(12,326)	(9,450)	(37,930)
Cash flows from investing activities:			
Purchase of property, plant and equipment	(2,119)	(350)	(3,055)
Purchase of marketable securities	-	-	(32,021)
Proceeds from maturity of marketable securities	-	-	38,742
Proceeds from sale of marketable securities	13,551	13,893	-
Net cash provided by investing activities	$ 11,432	$ 13,543	$ 3,666

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Three months ended March 31		Year ended December 31,
	2020	2019	2019
Cash flows from financing activities:			
Proceeds from secondary offering, net	-	-	37,140
Receipt of grants from the IIA	53	-	224
Proceeds from issuance of shares, initial public offering (payment of issuance expenses), net	-	(238)	(238)
Payment of lease liabilities	(787)	(440)	(1,529)
Exercise of options	6	-	132
Net cash (used in) provided by financing activities	(728)	(678)	35,729
Exchange differences on balances of cash and cash equivalents	76	62	101

Increase in cash and cash equivalents	1,546	3,477	1,566
Cash and cash equivalents at beginning of period	41,838	40,272	40,272
Cash and cash equivalents at end of period	$ 40,292	$ 43,749	$ 41,838

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