Gamida Cell Reports Full Year 2019 Financial Results and Provides Company Update

February 25, 2020

– Completed patient enrollment in Phase 3 clinical study of omidubicel; Topline data expected in the second quarter of 2020 –

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

BOSTON--(BUSINESS WIRE)--Feb. 25, 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 full year ended December 31, 2019. The company also highlighted continued progress in advancing its clinical development candidates: omidubicel, an advanced cell therapy in Phase 3 clinical development as a potential 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.

"2019 was a key year for Gamida Cell that moved us closer to our goal of developing next-generation cell therapies with the potential to redefine standards of care for patients with blood cancers and rare, serious hematologic diseases," stated Julian Adams, Ph.D., chief executive officer of Gamida Cell. "In December, we completed patient enrollment in our multi-center, randomized Phase 3 study of omidubicel, the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA). We look forward to reporting topline data from the study in the second quarter of 2020. Positive data would enable us to file a biologics license application for omidubicel with the FDA in the fourth quarter of the year, representing an important step toward bringing potentially curative medicines to patients."

"We also continued to advance GDA-201, our second cell therapy program, which has shown early promise for the treatment of non-Hodgkin lymphoma. We will report additional data from this study in the first half of 2020 and are progressing toward an investigational new drug submission to the FDA by the end of the year," Dr. Adams continued.

Additional Company Highlights

- **Completed patient enrollment in Phase 3 clinical study of omidubicel**: In December 2019, Gamida Cell completed patient enrollment in the Phase 3 study of omidubicel in patients with high-risk hematologic malignancies. The international, randomized, multi-center study is designed to evaluate the safety and efficacy of omidubicel compared to standard umbilical cord blood for allogeneic bone marrow transplant in approximately 120 patients. Topline data from the study are expected in the second quarter of 2020. Assuming positive data, the company expects to submit a biologics license application to the FDA in the fourth quarter of 2020.

- **Presented research on mechanism of action for the NAM technology platform at the Transplantation & Cellular Therapy (TCT) Annual Meeting:** In February 2020, Gamida Cell reported research on the mechanism of action of its NAM cell expansion platform, which is designed to enhance the number and functionality of allogeneic donor cells. These data provide further scientific rationale for the favorable stem cell engraftment and patient outcomes observed in the Phase 1/2 clinical study of omidubicel.

- **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.

- **Progressed enrollment in the Phase 1/2 study of omidubicel in patients with severe aplastic anemia:** Enrollment is ongoing in a Phase 1/2 clinical study of omidubicel in patients with severe aplastic anemia, a rare, life-threatening bone marrow failure disease. Gamida Cell plans to report additional data from the study in the second half of 2020.

- **Presented data from Phase 1 clinical study of GDA-201 at 61st Annual Meeting of the American Society of Hematology (ASH):** In December, additional data were presented from the ongoing Phase 1 study of GDA-201. Results from 22 patients showed that GDA-201 in combination with monoclonal antibodies was generally well tolerated and demonstrated early evidence of clinical activity in heavily pre-treated patients, including five complete responses observed among nine patients with NHL.

- **Continued to prepare for the next clinical study of GDA-201:** Based on the data from the ongoing Phase 1 study of GDA-201, 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, multi-dose Phase 1/2 clinical study in patients with NHL.

- **Further strengthened executive team:** In January, Gamida Cell announced the appointment of Jas Uppal, Ph.D. to the newly created role of chief regulatory and quality officer. Dr. Uppal brings more than 25 years of global experience in the

pharmaceutical industry, including expertise in hematology, immunology and neurology. During her career, she has played key roles in building regulatory organizations and leading multiple successful product launches.

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

Omidubicel

- Report topline data from the Phase 3 study in the second quarter of 2020
- Present data from the Phase 3 study at a medical meeting in the second half of 2020
- Submit the biologics license application to the FDA in the fourth quarter of 2020, assuming positive data
- 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 first 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

Full Year 2019 Financial Results:

- Research and development (R&D) expenses in 2019 were $31.5 million, compared to $22.0 million in 2018. The increase was mainly due to clinical activities relating to the advancement of omidubicel and GDA-201 as well as additional headcount within the R&D organization.

- The commercial organization was established in 2019, and commercial expenses for the year were $4.7 million. These expenses were mainly due to $2.4 million of cash and non-cash expenses related to hiring and establishing the commercial organization as well as $2.3 million related to professional services and other expenses.

- General and administrative expenses were $12.1 million in 2019, compared to $11.6 million in 2018. The increase was mainly due to a $1.0 million increase in professional services expenses associated with being a publicly traded company and a $1.3 million increase in rent and other expenses, offset by a $1.8 million decrease related to establishing the commercial organization.

- Finance income, net, was $13.8 million in 2019, compared to finance expenses, net, of $19.2 million in 2018. The increase was primarily due to non-cash income resulting from revaluation of warrants, offset by non-cash expenses of the Israeli Innovation Authority royalty-bearing grant liability and the implementation of the new IFRS 16 accounting standard.

- Net loss for 2019 was $34.4 million, compared to a net loss of $52.9 million for 2018.

- At December 31, 2019, Gamida Cell had total cash, cash equivalents and available-for-sale securities of $55.4 million, compared to $60.7 million at December 31, 2018.

2020 Financial Guidance
Gamida Cell expects cash used for ongoing operating activities for the first six months of 2020 to range from $30-$35 million, primarily reflecting anticipated expenditures to advance the company's clinical programs. The company expects to provide full year financial guidance following the availability of topline Phase 3 data for omidubicel.

Gamida Cell expects that its current cash, cash equivalents and available-for-sale securities will support the company's ongoing operating activities into the fourth quarter of 2020. This cash runway guidance is based on the company's current operational plans, including the assumption that Gamida Cell will continue to advance all of its clinical programs and excludes any additional funding that may be received or business development activities that may be undertaken.

Conference Call Information
Gamida Cell will host a conference call today, February 25, 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 7886498. 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 a Phase 1/2 clinical study, omidubicel demonstrated rapid and durable time to engraftment and was generally well-tolerated.[1] A Phase 3 study evaluating omidubicel in patients with leukemia and lymphoma is ongoing in the U.S., South America, Europe and Asia.[2] Omidubicel is also being evaluated in a Phase 1/2 clinical study in patients with severe aplastic anemia.[3] The aplastic anemia investigational new drug application is currently filed with the FDA under the brand name Cordln®, 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.[4]

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. For additional information, please visit https://www.gamida-cell.com.

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 the patient enrolment in and timing of initiation and progress of and data reported from the clinical trials of Gamida Cell's product candidates, anticipated regulatory filings, 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 25, 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

	December 31,	
	2019	**2018**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 41,838	$ 40,272
Marketable securities	13,559	20,417
Prepaid expenses and other current assets	1,306	1,502
Total current assets	56,703	62,191
NON-CURRENT ASSETS:		
Property and equipment, net	6,298	2,311
Right-of-use assets	5,133	-

Other assets	641	662
Total non-current assets	12,072	2,973
Total assets	$ 68,775	$ 65,164
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 1,164	$ 1,985
Employees and payroll accruals	3,443	2,888
Current maturities of lease liabilities	1,870	-
Accrued expenses and other payables	4,918	1,832
	11,395	6,705
NON-CURRENT LIABILITIES:		
Liabilities presented at fair value	5,221	24,049
Employee benefit liabilities, net	773	183
Lease liability	4,101	-
Liability to Israel Innovation Authority (IIA)	12,302	9,540
	22,397	33,772
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Share capital	92	67
Share premium	238,992	193,953
Capital reserve due to actuarial loss	(541)	(77)
Reserve from financial assets measured at FVOCI	4	(43)
Accumulated deficit	(203,564)	(169,213)
Total shareholders' equity	34,983	24,687

Total liabilities and shareholders' equity	$ 68,775	$ 65,164

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Year ended December 31,		
	2019	**2018**	**2017**
Operating expenses:			
Research and development expenses, net	$ 31,462	$ 22,045	$ 15,018
Commercial activities	4,692	-	-
General and administrative expenses	12,091	11,599	4,472
Operating loss	48,245	33,644	19,490
Financial expenses	3,325	20,259	718
Financial income	(17,149)	(1,042)	(1,197)
Loss before taxes on income	34,421	52,861	19,011
Taxes on income	(70)	70	-
Net loss	34,351	52,931	19,011
Net loss per share:			

Basic net loss per share	$ 1.17	$ 10.53	$ 27.56
Diluted net loss per share	$ 1.69	$ 10.53	$ 27.56

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,		
	2019	**2018**	**2017**
Cash flows from operating activities:			
Net loss	$ (34,351)	$ (52,931)	$ (19,011)
Adjustments to reconcile net loss to net cash used in operating activities:			
Adjustments to the profit or loss items:			
Depreciation of property, plant and equipment and right-of-use assets	2,143	269	162
Financial income, net	(775)	(858)	(330)
Cost of share-based compensation	4,868	3,575	2,208
Change in employee benefit liabilities, net	126	(15)	26
Amortization of premium on marketable securities	184	272	28
Revaluation of financial derivatives	(15,904)	17,600	(1,061)
Revaluation of liability to IIA	2,531	2,037	631

	(6,827)	22,880	1,664
Changes in asset and liability items:			
Increase (decrease) in other receivables, prepaid expenses and other assets	(150)	942	(2,210)
Increase (decrease) in trade payables	(821)	(405)	1,464
Increase in accrued expenses and other payables	2,807	2,296	1,214
	1,836	2,833	468
Cash received during the year for:			
Interest received	1,546	792	330
Interest paid	(134)	-	-
Net cash used in operating activities	(37,930)	(26,426)	(16,549)
Cash flows from investing activities:			
Purchase of property and equipment	(3,055)	(1,645)	(402)
Purchase of marketable securities	(32,021)	(10,905)	(14,820)
Proceeds from bank deposits	-	5,000	(5,000)
Investment in restricted bank deposits	-	(150)	-
Proceed from maturity of marketable securities	38,742	-	-
Proceed from sale of marketable securities	-	4,949	-
Net cash provided by (used in) investing activities	3,666	(2,751)	(20,222)

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,		
	2019	**2018**	**2017**
Cash flows from financing activities:			
Proceeds from secondary offering, net	37,140	-	-
Proceeds from issuance of financial derivatives	-	-	10,900
Receipt of grants from the IIA	224	612	272
Proceeds from issuance of shares, initial public offering (payment of issuance expenses), net	(238)	47,479	-
Proceeds from issuance of shares, net	-	-	28,865
Payment of lease liabilities	(1,529)	-	-
Exercise of options	132	2	-
Net cash provided by financing activities	35,729	48,093	40,037
Exchange differences on balances of cash and cash equivalents	101	31	-
Increase in cash and cash equivalents	1,566	18,947	3,266
Cash and cash equivalents at beginning of year	40,272	21,325	18,059
Cash and cash equivalents at end of year	$ 41,838	$ 40,272	$ 21,325

The accompanying notes are an integral part of the consolidated financial statements.

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[1]Horwitz M.E., Wease S., Blackwell B., Valcarcel D. et al. Phase I/II study of stem-cell transplantation using a single cord blood unit expanded ex vivo with nicotinamide. *J Clin Oncol.* 2019 Feb 10;37(5):367-374.

[2] ClinicalTrials.gov identifier NCT02730299.

[3] ClinicalTrials.gov identifier NCT03173937.

[4] ClinicalTrials.gov identifier NCT03019666.

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