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

– Primary and secondary endpoints were met in Phase 3 study of omidubicel in patients with hematologic malignancies who underwent a bone marrow transplant –

– Full data from Phase 3 study of omidubicel in patients with hematologic malignancies anticipated this quarter; Initiation of BLA submission for omidubicel expected to begin on a rolling basis by year-end –

– Updated data from Phase 1 study of GDA-201 in patients with non-Hodgkin lymphoma and Phase 1 study of omidubicel in patients with severe aplastic anemia to be presented at 62nd ASH Annual Meeting –

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

BOSTON--(BUSINESS WIRE)-- 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 September 30, 2020. The company also highlighted progress with 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, a natural killer (NK) cell immunotherapy in Phase 1 development in patients with non-Hodgkin lymphoma (NHL).

“Gamida Cell continued to make strong progress during the quarter. Most importantly, we recently announced that our Phase 3 study of omidubicel met all three secondary endpoints, further underscoring the potential clinical benefit of this novel graft source for bone marrow transplant,” stated Julian Adams, Ph.D., chief executive officer of Gamida Cell. “We look forward to reporting the data in further detail and to initiating the biologics license application (BLA) for omidubicel to the FDA on a rolling basis, both in the fourth quarter of this year.”

“Our second program, GDA-201, a natural killer cell therapy, is also advancing. NK cell immunotherapies offer tremendous potential for transforming the care of hematologic malignancies. Last week, we announced that updated data from the Phase 1 study in patients with non-Hodgkin lymphoma will be presented next month in an oral session at the American Society for Hematology (ASH) annual meeting. The data continue to be compelling, with multiple complete responses and a favorable tolerability profile reported in patients with advanced disease,” Dr. Adams continued.

Omidubicel, an investigational advanced cell therapy for allogeneic bone marrow transplant

During the quarter, Gamida Cell continued to advance its Phase 3 product candidate, omidubicel, which is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and which has the potential to be the first FDA-approved engineered bone marrow transplant graft.

Last month, Gamida Cell announced that all three pre-specified secondary endpoints in the company’s Phase 3 study of omidubicel demonstrated a statistically significant improvement among patients who received omidubicel compared to the comparator group (who received standard umbilical cord blood). These secondary endpoints were platelet engraftment, infections and hospitalization.

In May, Gamida Cell reported that omidubicel achieved its primary endpoint, demonstrating a statistically significant reduction in time to neutrophil engraftment, a key milestone in recovery from a bone marrow transplant. The international, multi-center, randomized Phase 3 study was designed to evaluate the safety and efficacy of omidubicel in patients with hematologic malignancies undergoing a bone marrow transplant compared to a comparator group of patients who received a standard umbilical cord blood transplant. Gamida Cell expects to report the full data set later in the fourth quarter of 2020.

Additional omidubicel highlights:

- **New Phase 1 data from study of omidubicel in patients with severe aplastic anemia to be presented at ASH:** Gamida Cell is evaluating omidubicel in an investigator-sponsored, Phase 1/2 study in patients with severe aplastic anemia and will present new data from the ongoing study at the 62nd ASH Annual Meeting.

Data from the abstract published in *Blood* showed that omidubicel was generally well tolerated and could result in rapid engraftment and achieve sustained hematopoiesis in heavily transfused patients with severe aplastic anemia, a rare and life-threatening blood disorder. The poster presentation, “Rapid Engraftment, Immune Recovery, and Resolution of Transfusion Dependence in Treatment-Refractory Severe Aplastic Anemia Following Transplantation with Ex Vivo Expanded Umbilical Cord Blood (Omidubicel)” (Abstract #1531) will take place on Saturday, December 5, 2020, 7:00 a.m. – 3:30 p.m. PT (10:00 a.m. – 6:30 p.m. ET).

- **Expanded collaboration with Be The Match BioTherapies®:** In October, Gamida Cell and Be The Match BioTherapies®announced an expansion of their existing strategic collaboration for omidubicel. The original partnership agreement between the organizations focused on the omidubicel development program and leveraged a wide range of Be The Match BioTherapies’ capabilities and services. In building upon the collaboration, Gamida Cell will work with Be The Match BioTherapies for the ordering and supply of cord blood units, which serve as the starting material for omidubicel. The expanded agreement is designed to provide a smooth process for the supply of cord blood units throughout the supply chain to deliver omidubicel to patients.

- **Presented initial observational data from collaboration with CIBMTR:** In September,Gamida Cell reported initial data from an observational study that includes data contemporaneous to the Phase 3 study of omidubicel. The study was the result of a research agreement between Gamida Cell and the CIBMTR® (Center for International Blood and Marrow Transplant Research®) designed to collect and analyze health outcomes data in patients with hematologic malignancies who receive a hematopoietic stem cell transplant or cellular therapy infusion, including bone marrow transplant graft from various donor sources. The study evaluated clinical outcomes for 660 patients in the CIBMTR registry who underwent a bone marrow transplant with a matched unrelated, mismatched unrelated or haploidentical graft source contemporaneous to the Phase 3 study of omidubicel. The study data demonstratd that key clinical outcomes, including time to neutrophil engraftment and overall survival, were improved for patients with donors under the age of 30.

- **Continued 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.

GDA-201, an innate NK cell immunotherapy

- **Updated Phase 1 data to be presented at the 62nd ASH Annual Meeting:** Last week, Gamida Cell announced that updated data from the ongoing Phase 1 study of GDA-201 in patients with non-Hodgkin lymphoma and multiple myeloma will be presented at the ASH Annual Meeting. Data from the abstract published in *Blood* demonstrated that GDA-201 in combination with a monoclonal antibody was generally well tolerated and clinically active. Among 15 patients with NHL, there were 10 complete responses and 1 partial response. Additional details will be presented in an oral session, “Results of a Phase 1 Trial of GDA-201, Nicotinamide-Expanded Allogeneic Natural Killer (NK) Cells in Patients with Refractory Non-Hodgkin Lymphoma (NHL) and Multiple Myeloma” (Abstract #63) on Saturday, December 5, at 7:30 a.m. PT (10:30 a.m. ET).

- **Continued advancing Phase 1 study of GDA-201:** Gamida Cell continues to advance activities to enable the submission of an investigational new drug (IND) application for GDA-201 in the first half of 2021. The company continues to be on track to initiate a multi-center, Phase 1/2 clinical study in patients with NHL next year. Gamida Cell is pioneering a novel approach that harnesses the power of its cell expansion technology, which uniquely improves antibody-dependent cellular cytotoxicity (ADCC) and tumor targeting of NK cells.

Corporate Highlights

- **Responded to COVID-19 pandemic:** Gamida Cell is committed to the health and safety of its employees while continuing to advance its business, including regularon-site testing.

- **Expanded team with key appointments in information technologies and market access:** Today, Gamida Cell announced the appointment of Stephen Jamieson to the newly created role of senior vice president, information technologies. Mr. Jamieson brings 25 years of information technologies experience, primarily in the life sciences industry. Prior to joining Gamida Cell, Mr. Jamieson served as chief information officer and head of commercial operations at Verastem Oncology. He also held prior information technologies roles at several life sciences companies, including Infinity Pharmaceuticals, Inc., ARIAD Pharmaceuticals, Inc. and OSI Pharmaceuticals, Inc. (acquired by Astellas Pharma, Inc.). Mr. Jamieson holds a B.S. in Computer

Science/Mathematics from Widener University.

Today, the company also announced the appointment of Rocio Manghani to the role of senior vice president, market access. Ms. Manghani has nearly 20 years of experience in market access and patient support roles. In this role, she will lead the strategic planning and implementation of Gamida Cell's market access initiatives. Ms. Manghani joins the company from Tricida, Inc., where she served as senior vice president, market access. Prior to Tricida, she worked in various commercial positions with increasing responsibility, including roles at Kite Pharma, Inc. (acquired by Gilead Sciences, Inc.), Celgene (acquired by Bristol-Myers Squibb), Abraxis Oncology and Roche Laboratories. Ms. Manghani holds a M.P.H. from Emory University and a B.S. in Sociology, Healthcare and Social Issues from University of California, San Diego.

Third Quarter 2020 Financial Results

- Research and development expenses in the third quarter of 2020 were $10.5 million, compared to $7.5 million for the same period in 2019. The increase was mainly due to BLA readiness preparation, increased clinical activities relating to the advancement of GDA-201, and the initiation of the omidubicel expanded access study.
- Commercial expenses in the third quarter of 2020 were $1.9 million compared to $1.7 million for the same period in 2019. The increase was mainly attributed to commercial readiness activities for omidubicel.
- General and administrative expenses were $2.7 million for the third quarter of 2020 and compared to $2.8 million for the same period in 2019. The decrease was mainly due to reduced travel expenses.
- Finance income, net, was $0.3 million for the third quarter of 2020, compared to finance income, net, of $1.7 million for the third quarter of 2019. The decrease was primarily due to noncash income resulting from revaluation of warrants owned by certain shareholders.
- Net loss for the third quarter of 2020 was $14.8 million, compared to a net loss of $10.1 million for the same period in 2019.
- As of September 30, 2020, Gamida Cell had total cash and cash equivalents of $73.3 million, compared to $55.4 million as of December 31, 2019.

2020 Financial Guidance

Gamida Cell expects cash used for ongoing operating activities in 2020 to range from $60 million to $65 million.

Gamida Cell expects that its current cash and cash equivalents 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 and any business development activities that may be undertaken.

Expected 2020-2021 Milestones

Gamida Cell plans to achieve the following milestones during 2020-2021:

Omidubicel

- Present data from the Phase 3 study at a medical meeting in the fourth quarter of 2020
- Initiate the submission of the BLA 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 fourth quarter of 2020
- Commercial launch of omidubicel in the second half of 2021, contingent upon FDA approval

GDA-201

- Present additional data from the Phase 1 study at the ASH Annual Meeting
- Submit company-sponsored IND application to the FDA in the first half of 2021
- Initiate a Phase 1/2 clinical study in patients with NHL in 2021

Conference Call Information

Gamida Cell will host a conference call today, November 10, 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 & Media" 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 9998754. 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 FDA and has also received Orphan Drug Designation in the U.S. and EU. In both Phase 1/2 and Phase 3 clinical studies (NCT01816230 and NCT02730299), 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 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 ongoing operating activities 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 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 Reports on Form 6-K filed with the SEC on May 18, 2020, and August 11, 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.

About Gamida Cell

Gamida Cell is an advanced cell therapy company committed to cures for patients with 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 www.gamida-cell.com, or follow Gamida Cell on LinkedIn or Twitter at @GamidaCellTx.

INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

U.S. dollars in thousands

	September 30,		December 31,
	2020	2019	2019
	Audited		Audited
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$73,311	$39,573	$ 41,838
Available-for-sale financial assets	-	28,544	13,559
Prepaid expenses and other current assets	1,734	1,134	1,306
Total current assets	75,045	69,251	56,703
NON-CURRENT ASSETS:			
Property, plant and equipment, net	15,838	4,209	6,298
Right-of-use assets	7,023	5,568	5,133
Other assets	802	651	641
Total non-current assets	23,663	10,428	12,072
Total assets	$98,708	$79,679	$ 68,775
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Trade payables	$ 2,704	$ 2,105	$ 1,164
Employees and payroll accruals	3,872	3,096	3,443
Current maturities of lease liabilities	2,345	1,926	1,870
Accrued expenses and other payables	5,005	1,979	4,918
Total current liabilities	13,926	9,106	11,395
NON-CURRENT LIABILITIES:			
Liabilities presented at fair value	3,252	5,434	5,221
Employee benefit liabilities, net	773	280	773
Lease liabilities	5,460	4,342	4,101
Liability to Israel Innovation Authority (IIA)	14,729	11,594	12,302
Total non-current liabilities	24,214	21,650	22,397
SHAREHOLDERS' EQUITY:	60,568	48,923	34,983
Total liabilities and shareholders' equity	$98,708	$79,679	$ 68,775

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

INTERIM CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

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

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2020	2019	2020	2019	2019
	Audited				Audited
Operating expenses:					

Research and development, net	$ 27,652	$ 22,009	$ 10,454	$ 7,473	$ 31,462
Commercial activities	4,413	3,805	1,916	1,715	4,692
General and administrative	8,180	8,063	2,690	2,796	12,091
Operating loss	40,245	33,877	15,060	11,984	48,245
Finance expense	2,367	2,499	1,001	895	3,325
Finance income	(2,203)	(16,665)	(1,309)	(2,613)	(17,149)
Loss before taxes on income	40,409	19,711	14,752	10,266	34,421
Taxes on income (benefit)	-	(70)	-	(170)	(70)
Net loss (income)	40,409	19,641	14,752	10,096	34,351
Net loss (income) per share:					
Basic loss (income) per share	$ 0.98	$ 0.70	$ 0.30	$ 0.30	$ 1.17
Diluted loss per share	$ 0.98	$ 1.24	$ 0.30	$ 0.30	$ 1.69

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

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2020	2019	2020	2019	2019
	Audited				Audited
Cash flows from operating activities:					
Net (loss) income	$(40,409)	$(19,641)	$(14,752)	$(10,096)	$ (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	1,716	1,792	610	547	2,143
Financial income, net	(169)	(768)	91	(199)	(775)
Cost of share-based compensation	1,969	3,731	748	1,321	4,868
Change in employee benefit liabilities, net	-	14	-	6	126
Amortization of premium on available-for-sale financial assets	4	150	-	49	184
Revaluation of financial derivatives	(1,969)	(15,691)	(1,299)	(2,220)	(15,904)
Revaluation of liability to IIA	2,227	1,852	912	653	2,531
Changes in asset and liability items:	3,778	(8,920)	1,062	157	(6,827)
Decrease (increase) in prepaid expenses, other current assets and other assets	(718)	113	347	(4)	(150)
Increase (decrease) in trade payables	1,535	120	(39)	(124)	(821)
Increase (decrease) in accrued expenses and other payables	516	680	1,141	518	2,807

	1,333	913	1,449	390	1,836
Cash received during the period for:					
Interest received	359	1,132	2	302	1,546
Interest paid	(120)	(92)	(40)	(41)	(134)
	239	1,040	(38)	261	1,412
Net cash used in operating activities	(35,059)	(26,608)	(12,279)	(9,288)	(37,930)
Cash flows from investing activities:					
Purchase of property, plant and equipment	(9,792)	(2,139)	(2,683)	(1,261)	(3,055)
Purchase of marketable securities	-	(32,021)	-	(32,021)	(32,021)
Proceeds from sale of marketable securities	13,551	23,789		8,049	
Proceed from maturity of marketable securities	-	-	-	-	38,742
Net cash provided by (used in) investing activities	3,759	(10,371)	(2,683)	(25,233)	3,666

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2020	2019	2020	2019	2019
	Audited				Audited
Cash flows from financing activities:					
Receipt of grants from the IIA	200	202		35	$ 224
Proceeds from secondary offering, net	63,860	37,235	-	37,343	37,140
Proceeds from issuance of shares, initial public offering (payment of issuance expenses), net	-	(238)	-	-	(238)
Payment of lease liabilities	(1,539)	(1,144)	(417)	(380)	(1,529)
Exercise of options	169	120	21	3	132
Net cash (used in) provided by financing activities	62,690	36,175	(396)	37,001	35,729
Exchange differences on balances of cash and cash equivalents	83	105	31	15	101
Increase (decrease) in cash and cash equivalents	31,473	(699)	(15,327)	2,495	1,566
Cash and cash equivalents at beginning of period	41,838	40,272	88,638	37,078	40,272
Cash and cash equivalents at end of period	$73,311	$39,573	$ 73,311	$39,573	$ 41,838

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

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