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

August 11, 2020

– Secondary endpoints from positive Phase 3 study of omidubicel and initiation of BLA submission expected in the fourth quarter of 2020; Expanded access program for omidubicel now underway; Initial data from research collaboration with CIBMTR to be presented in September –

– Additional data from GDA-201, an investigational NK cell immunotherapy, expected in the fourth quarter of 2020; Company provides updated guidance for IND submission –

– Company expands executive team –

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

BOSTON--(BUSINESS WIRE)--Aug. 11, 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 June 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).

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

During the quarter, Gamida Cell reported that its Phase 3 study of omidubicel met its primary endpoint, demonstrating a highly statistically significant reduction ($p < 0.001$) in time to neutrophil engraftment, a key milestone in recovery from a bone marrow transplant. Omidubicel is the first bone marrow transplant product to receive Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA).

"The primary endpoint data for omidubicel underscore its potential to become an important treatment option for patients by providing a reliable graft source that can enable rapid neutrophil engraftment, which has been linked to other important outcomes such as fewer infections and hospitalizations," stated Julian Adams, Ph.D., chief executive officer of Gamida Cell. "We look forward to reporting secondary endpoints from the study and to initiating the biologics license application, or BLA, for omidubicel to the FDA on a rolling basis, both in the fourth quarter of this year."

Program highlights for omidubicel:

- **Initial data from collaboration with CIBMTR to be presented:** Next month, Gamida Cell will report initial data from an observational study that includes data contemporaneous to the Phase 3 study of omidubicel. This study utilizes data from the CIBMTR registry, which consists of clinical outcomes data on more than 500,000 stem cell transplants, to analyze long-term safety and efficacy data for patients with hematologic malignancies who underwent a bone marrow transplant with an alternative donor source following myeloablative conditioning. The criteria for inclusion of patients and the outcomes evaluated in the analyses are consistent with those in the Phase 3 study of omidubicel. These data will be highlighted in a poster presentation at the Cord Blood Connect Meeting, which is being held virtually on September 10 and September 17.

- **Initiated expanded access program for omidubicel:** Gamida Cell today announced that it has initiated an open-label, single-arm study to provide access to omidubicel for patients with high-risk hematologic malignancies who are in need of a bone marrow transplant and meet protocol criteria. This study is currently open at three sites in the U.S., and additional sites are expected to open in the coming months.

- **Reported positive Phase 3 data for omidubicel:** In May, Gamida Cell announced that the international, randomized Phase 3 study of omidubicel achieved its primary endpoint of time to neutrophil engraftment. 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. In the intent-to-treat analysis, the median time to neutrophil engraftment was 12 days (95% CI: 10-15 days) for patients who were randomized to omidubicel compared to 22 days (95% CI: 19-25 days) for the comparator group ($p<0.001$). 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.

  Gamida Cell expects to present the full data set, including secondary endpoint data, at a medical meeting in the fourth quarter of 2020. The company also expects to begin submitting the biologics license application for omidubicel to the FDA on a rolling basis in the fourth quarter of 2020.

- **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.

GDA-201, an innate NK cell immunotherapy

"We are encouraged by data from the Phase 1 study of GDA-201, which has shown a high complete response rate in patients with non-Hodgkin lymphoma," stated Dr. Adams. "NK cell immunotherapies offer tremendous potential for transforming the care of hematologic malignancies. We are pleased to be pioneering a novel approach that harnesses the power of our cell expansion technology, which uniquely improves antibody-dependent cytotoxicity (ADCC), cytotoxic killing and the in vivo homing potential of GDA-201 to address potential limitations of NK cells."

Program highlights for GDA-201

- **Continued advancing Phase 1 study of GDA-201:** Earlier this year, Gamida Cell reported data from the first 25 patients in its ongoing Phase 1 study in patients with NHL and multiple myeloma, which 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. Gamida Cell expects to provide updated data from the study at a medical conference in the fourth quarter of 2020.

- **Responded to COVID-19 pandemic:** Gamida Cell has implemented additional safety measures designed to comply with applicable government guidelines, including shift work to allow for appropriate social distancing. The company now expects to submit an investigational new drug (IND) application for GDA-201 to the FDA 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.

Corporate Highlights

- **Executed a public offering:** In May, Gamida Cell executed an underwritten public offering resulting in the sale of 15.3 million shares of common stock at $4.50 per share. Aggregate gross proceeds to the company were approximately $69 million before deducting underwriting discounts, commissions and offering expenses.

- **Appointed Matthew Metivier as vice president, human resources:** Today Gamida Cell announced the appointment of Matthew Metivier to the role of vice president, human resources. Mr. Metivier brings more than 20 years of human resources experience, primarily in the life sciences industry. Mr. Metivier brings over 20 years of experience in human resources. Prior to joining Gamida Cell, Mr. Metivier worked at Sage Therapeutics, Inc., most recently as the vice president of human resources, where he helped develop and lead the company's global human resources strategy. Before joining Sage, Mr. Metivier spent almost a decade at Infinity Pharmaceuticals in multiple human resource roles. He has also held prior human resource positions at various healthcare and high-tech companies, including Idenix Pharmaceuticals (acquired by Merck & Co) and Therion Biologics Corp. Mr. Metivier holds a B.A. in Political Science and Business Studies from Providence College and an MBA from Suffolk University.

- **Appointed Michele Korfin as chief operating and chief commercial officer:** In July, Gamida Cell appointed Michele Korfin to the role of chief operating and chief commercial officer. Ms. Korfin brings over 20 years of experience in oncology, focused on business operations and commercialization of novel therapies, including cell therapy experience as vice president of market access at Kite Pharma, where she oversaw the market access strategy, including payer relations, reimbursement and government affairs for Yescarta®, the first approved CAR-T therapy in lymphoma.

- **Appointed David Fox to Gamida Cell's board of directors:** In July, Gamida Cell appointed David Fox to its board of directors as an independent member. Mr. Fox was most recently a partner at Kirkland & Ellis LLP and served as a member of its Global Executive Management Committee.

Second Quarter 2020 Financial Results

- Research and development expenses in the second quarter of 2020 were $9.3 million, compared to $7.3 million for the same period in 2019. The increase was mainly due to clinical activities relating to the advancement of GDA-201 and a decrease in grants received from the Israel Innovation Authority.

- Commercial expenses in the second quarter of 2020 were $1.0 million compared to $1.1 million for the same period in 2019. The decrease was mainly attributed to non-cash compensation offset by omidubicel commercial readiness activities.

- General and administrative expenses were $2.5 million for the second quarter of 2020 and for the second quarter of 2019.

- Finance expense, net, was $2.2 million for the second quarter of 2020, compared to finance income, net, of $16.8 million in the same period in 2019. The increase was primarily due to noncash expenses resulting from revaluation of warrants owned by the company's shareholders.

- Net loss for the second quarter of 2020 was $15.1 million, compared to a net income of $6.0 million in the same period in 2019.
- As of June 30, 2020, Gamida Cell had total cash, cash equivalents and available-for-sale securities of $88.6 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 $70 million.

Gamida Cell expects that 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 that closed in May 2020 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
- Launch omidubicel in 2021, contingent upon FDA approval

GDA-201

- Present additional data from the Phase 1 study in the fourth quarter of 2020
- 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, August 11, 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 8888903. 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 (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 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 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.

INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

U.S. dollars in thousands

	June 30		December 31,
	2020	2019	2019
	Unaudited		
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$ 88,638	$37,078	$ 41,838
Available-for-sale financial assets	-	4,618	13,559
Prepaid expenses and other current assets	2,241	886	1,306
Total current assets	90,879	42,582	56,703
NON-CURRENT ASSETS:			
Property, plant and equipment, net	14,204	3,437	6,298
Right-of-use assets	7,490	6,157	5,133
Other assets	642	1,355	641
Total non-current assets	22,336	10,949	12,072
Total assets	$113,215	$53,531	$ 68,775
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Trade payables	$ 2,738	$ 2,121	$ 1,164
Employees and payroll accruals	3,187	2,753	3,443
Current maturities of lease liabilities	2,145	1,945	1,870
Accrued expenses and other payables	5,509	2,699	4,918
Total current liabilities	13,579	9,518	11,395
NON-CURRENT LIABILITIES:			
Liabilities presented at fair value	4,551	7,654	5,221
Employee benefit liabilities, net	773	274	773
Lease liabilities	5,946	4,627	4,101
Liability to Israel Innovation Authority (IIA)	13,816	10,906	12,302
Total non-current liabilities	25,086	23,461	22,397
SHAREHOLDERS' EQUITY:	74,550	20,552	34,983
Total liabilities and shareholders' equity	$113,215	$53,531	$ 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)

Six months ended June 30,	Three months ended June 30,	Year ended December 31,

	2020	2019	2020	2019	2019
	Unaudited				Audited
Operating expenses:					
Research and development, net	$17,198	$ 14,536	$ 9,319	$ 7,253	$ 31,462
Commercial activities	2,497	2,090	1,029	1,092	4,692
General and administrative	5,490	5,267	2,316	2,452	12,091
Operating loss	25,185	21,893	12,664	10,797	48,245
Finance expense	1,366	1,604	2,320	1,336	3,325
Finance income	(894)	(14,052)	(109)	(18,169)	(17,149)
Loss before taxes on income	25,657	9,445	14,875	(6,036)	34,421
Taxes on income (benefit)	-	100	-	74	(70)
Net loss (income)	25,657	9,545	14,875	(5,962)	34,351
Net loss (income) per share:					
Basic loss (income) per share	$ 0.69	$ 0.38	$ 0.37	$ (0.23)	$ 1.17
Diluted loss per share	$ 0.69	$ 0.87	$ 0.37	$ 0.44	$ 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

	Six months ended June 30,		Three months ended June 30,		Year ended December 31,
	2020	2019	2020	2019	2019
	Unaudited				Audited
Cash flows from operating activities:					
Net (loss) income	$(25,657)	$ (9,545)	$ (15,055)	$ 5,962	$ (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	1,106	1,245	556	703	2,143
Financial income, net	(260)	(569)	(128)	(378)	(775)
Cost of share-based compensation	1,221	2,410	322	1,319	4,868
Change in employee benefit liabilities, net	-	8	-	(3)	126
Amortization of premium on available-for-sale financial asses	4	101	-	51	184
Revaluation of financial derivatives	(670)	(13,471)	1,778	(17,378)	(15,904)
Revaluation of liability to IIA	1,315	1,199	593	631	2,531
	2,716	(9,077)	3,121	(15,055)	(6,827)
Changes in asset and liability items:					
Decrease (increase) in prepaid expenses, other current assets and other assets	(1,065)	117	(607)	(292)	(150)
Increase (decrease) in trade payables	1,574	244	(360)	1,088	(821)
Increase (decrease) in accrued expenses and other payables	(624)	162	2,472	141	2,807
	(115)	523	1,325	937	1,836
Cash received during the period for:					
Interest received	357	830	9	309	1,546

Interest paid	(80)	(51)	(33)	(23)	(134)
	277	779	(24)	286	1,412
Net cash used in operating activities	(22,779)	(17,320)	(10,453)	(7,870)	(37,930)
Cash flows from investing activities:					
Purchase of property, plant and equipment	(7,109)	(878)	(4,990)	(528)	(3,055)
Purchase of marketable securities	-	-	-	-	(32,021)
Proceed from sale of marketable securities	13,551	15,740	-	1,847	-
Proceed from maturity of marketable securities	-	-	-	-	38,742
Net cash provided by (used in) investing activities	$ 6,442	$ 14,862	$ (4,990)	$ 1,319	$ 3,666

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,		Year ended December 31,
	2020	2019	2020	2019	2019
	Unaudited				
Cash flows from financing activities:					
Receipt of grants from the IIA	$ 200	$ 167	$ 147	$ 167	$ 224
Proceeds from secondary offering, net	63,860	(346)	63,860	(108)	37,140
Proceeds from issuance of shares, initial public offering (payment of issuance expenses), net					(238)
Payment of lease liabilities	(1,122)	(764)	(335)	(324)	(1,529)
Exercise of options	147	117	141	117	132
Net cash (used in) provided by financing activities	63,085	(826)	63,813	(148)	35,729
Exchange differences on balances of cash and cash equivalents	52	90	(24)	28	101
Increase (decrease) in cash and cash equivalents	46,800	(3,194)	48,346	(6,671)	1,566
Cash and cash equivalents at beginning of period	41,838	40,272	40,292	43,749	40,272
Cash and cash equivalents at end of period	$88,638	$37,078	$ 88,638	$ 37,078	$ 41,838

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

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