Gamida Cell Reports Second Quarter 2019 Financial Results and Provides Company Update

August 6, 2019

– Successfully completed follow-on public offering raising approximately $40 million in gross proceeds –

– Patient enrollment in Phase 3 study of omidubicelexpected to be completed by year-end 2019; Topline data expected in first half of 2020 –

– Phase 1 clinical study of GDA-201 continues to progress, with additional data expected in the second half of 2019 –

BOSTON--(BUSINESS WIRE)--Aug. 6, 2019-- Gamida Cell Ltd. (Nasdaq: GMDA), a leading cellular and immune therapeutics company, today reported financial results for the quarter ended June 30, 2019. The company also highlighted continued progress in advancing its clinical development candidates: omidubicel, an investigational advanced cell therapy in Phase 3 clinical development designed to enhance the life-saving benefits of hematopoietic stem cell (bone marrow) transplant for patients with hematologic malignancies, and GDA-201, an investigational, natural killer (NK) cell-based cancer immunotherapy in Phase 1 development in patients with non-Hodgkin lymphoma and multiple myeloma.

“During the past quarter, Gamida Cell made important progress toward its goal of transforming the treatment landscape for patients with blood cancers and rare, serious hematologic diseases,” stated Julian Adams, Ph.D., chief executive officer of Gamida Cell. “We are continuing to progress our multi-center, randomized Phase 3 study of omidubicel to enable a topline data readout, which is expected in the first half of 2020. As we look ahead toward the potential submission of a biologics license application next year, we are advancing key activities required to bring omidubicel to patients in a commercial setting. To help ensure that we will have sufficient and reliable commercial supply, we established a commercial manufacturing supply agreement with Lonza and engaged Biopharmax, a biopharmaceutical design and construction firm, to initiate the construction of our own commercial manufacturing facility in Israel.”

“Our second cell therapy program, GDA-201, is also moving forward. We anticipate additional data from the ongoing Phase 1/2 clinical study in the second half of the year. We are also on track with our plans to develop a cryopreserved formulation of GDA-201 to enable a multi-center clinical study in patients with non-Hodgkin lymphoma,” Dr. Adams continued. “Both omidubicel and GDA-201 are based on our proprietary cell expansion platform, which has the potential to further expand our pipeline. In June, we appointed Dr. Tracey Lodie to our team as chief scientific officer to set our scientific strategy and lead new translational research to further elucidate the potential of our technology and clinical development programs.”

Program Highlights

- **Continued to advance the Phase 3 clinical study of omidubicel:** Patient enrollment continued to progress in the Gamida Cell’s 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 with no available matched donor. The company anticipates completing patient enrollment by the end of this year with topline data anticipated in first half of 2020.

- **Established agreements to support commercial manufacturing for omidubicel:** In June, Gamida Cell and Lonza announced that the companies entered into a strategic manufacturing agreementfor the future commercial production after potential FDA approval of omidubicel. This agreement follows a successful multi-year clinical manufacturing relationship and provides Gamida Cell with a path to commercial supply of omidubicel. Under this multi-year agreement, Lonza will construct and dedicate production suites at its Geleen, NL site for the anticipated commercial launch. Additionally, the agreement enables Gamida Cell to increase the number of dedicated production suites over time to ensure commercial supply. Gamida Cell also has the option of expanding further into Lonza's global cell and gene therapy manufacturing network. In August, Gamida Cell signed an agreement with Biopharmax for the construction of suites for the commercial manufacture of omidubicel after potential FDA approval of omidubicel at a Gamida Cell-operated facility in Israel.

- **Initiated enrollment for Cohort 2 in the Phase 1/2 study of omidubicel in patients with severe aplastic anemia:** In June, patient enrollment began in Cohort 2 of the investigator-sponsored, Phase 1/2 clinical study of omidubicel in patients with severe aplastic anemia, a rare and life-threatening blood disorder. Earlier this year, encouraging data from Cohort 1 were reported at the 2019 Transplantation & Cellular Therapy (TCT) Meeting. All three patients enrolled in Cohort 1 successfully underwent a bone marrow transplant consisting of omidubicel plus a haploidentical stem cell graft. The rapid engraftment, sustained hematopoiesis and accelerated immune recovery observed in these patients enabled the initiation of Cohort 2, where patients will be treated with omidubicel as a stand-alone graft.

- **Demonstrated continued progress with GDA-201 clinical development program:** Gamida Cell continued to make progress with the GDA-201 clinical development program. The investigator-sponsored, Phase 1/2 clinical study of GDA-201 in patient with non-Hodgkin lymphoma and multiple myeloma is ongoing, with additional data expected in the second half of 2019. The company is developing a cryopreserved formulation of GDA-201 to enable a multi-center, multi-dose Phase

1/2 clinical study in patients with non-Hodgkin lymphoma, which is expected to begin next year.

Corporate Highlights

- **Completed public follow-on offering of approximately $40 million in gross proceeds:** In July, Gamida Cell announced that the company closed an underwritten public offering of 7,000,000 ordinary shares and that the underwriters exercised in full their option to purchase an additional 1,050,000 ordinary shares at the public offering price of $5.00 per share. The aggregate gross proceeds to Gamida Cell from the offering, including the shares sold pursuant to the underwriters' option, before deducting underwriting discounts and commission and offering expenses, were $40.3 million.

- **Bolstered management team with appointment of Tracey Lodie, Ph.D., as chief scientific officer:** In June, the company announced the appointment of Tracey Lodie, Ph.D., as chief scientific officer. Prior to joining Gamida Cell, Dr. Lodie served as senior vice president, translational immunology at BlueRock Therapeutics, where she helped to advance their universal pluripotent stem cell platform into central nervous system, cardiovascular, and autoimmune therapeutic areas. She also served as vice president of immunology at Syros Pharmaceuticals, where she developed new autoimmunity and immuno-oncology research programs. Prior to Syros Pharmaceuticals, Dr. Lodie spent over 14 years at Sanofi-Genzyme, where she held roles of increasing responsibility. She obtained a PhD. in immunology and pathology at Boston University School of Medicine before completing a post-doctoral fellowship at Beth Israel Deaconess Medical Center in the Department of Hematology/Oncology.

- **Shawn Cline Tomasello and Stephen Wills elected to Board of Directors, reflecting company's progress toward commercialization:** In June,Shawn Cline Tomasello and Stephen T. Wills were elected to Gamida Cell's board of directors. Ms. Tomasello has extensive experience in commercializing first-in-class medicines for the treatment of cancer, including Yescarta® (at Kite Pharma, now part of Gilead Sciences) and Imbruvica® (at Pharmacyclics, now part of AbbVie). Mr. Wills has extensive operational, financial and transactional experience over nearly three decades in the life sciences and accounting industries. He has served as chief financial officer of Palatin Technologies, a publicly-traded biotechnology company developing peptide therapeutics, since 1997 and also serves as Palatin's chief operating officer and executive vice president.

Anticipated 2019-2020 Milestones

Gamida Cell's anticipated program milestones in 2019-2020 are as follows:

Omidubicel

- Complete enrollment in Phase 3 study of omidubicel in patients with hematologic malignancies by the end of 2019
- Report topline data from the Phase 3 study of omidubicel in patients with hematologic malignancies in the first half of 2020
- Complete BLA submission for omidubicel in hematologic malignancies in the second half of 2020, should Phase 3 data be positive

GDA-201

- Complete patient enrollment in the ongoing Phase 1 study in the second half of 2019
- Present additional data at a medical meeting in the second half of 2019
- Initiate multi-center, Phase 1/2 clinical study in patients with NHL in 2020

Second Quarter 2019 Financial Results

- Research and development (R&D) expenses in the second quarter of 2019 were $7.0 million and were also $7.0 million in the same period in 2018. R&D expenses were higher in the second quarter of 2019 compared to the same period in 2018 due to the advancement of omidubicel and GDA-201 but were offset by a $2.0 million increase in grants related to the Israeli Innovation Authority (IIA).

- General and administrative expenses were $3.8 million for the second quarter of 2019, compared to $2.9 million in the same period in 2018. The difference was attributable mainly to a $0.4 million increase in cash and non-cash expenses related to hiring and establishing the U.S. headquarters as well as a $0.5 million increase in professional services, including an increase in expenses associated with being a publicly-traded company.

- Finance income, net, was $16.8 million for the second quarter of 2019, compared to finance expenses, net, of $3.2 million in the same period in 2018. The net increase was primarily due to non-cash income resulting from the re-valuation of warrants, offset by non-cash expenses from the re-valuation of the IIA royalty-bearing grant liability.

- Net income for the second quarter of 2019 was $6.0 million, compared to a net loss of $13.1 million in the same period in 2018.

As of June 30, 2019, Gamida Cell had total cash, cash equivalents and available-for-sale securities of $41.7 million, compared to $60.7 million as of December 31, 2018. The June 30, 2019, cash position excludes the aggregate gross proceeds from the company's recent public follow-on offering, which were $40.3 million.

2019 Financial Guidance
Gamida Cell continues to expect cash used for ongoing operating activities in 2019 to range from $35 million to $40 million, reflecting anticipated expenditures to advance the company's clinical programs.

Gamida Cell expects that its 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 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, August 6, 2019, 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 409-216-0605 (international) and refer to conference ID number 2127937. A replay of the webcast will be available for approximately 30 days.

About Omidubicel
Omidubicel (formerly known as NiCord®), 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., 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 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 (formerly known as NAM-NK), 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 a clinical-stage biopharmaceutical company committed to developing advanced cell therapies with the potential to cure blood cancers and rare, serious hematologic diseases. We are leveraging our proprietary nicotinamide-based, or NAM-based, cell expansion technology to develop product candidates designed to address the limitations of cell therapies. For additional information, please visit 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 enrollment in and timing of initiation and progress of and data reported from the clinical trials of Gamida Cell's product candidates, 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 of Gamida Cell's public filing on Form 20-F, filed with the SEC on February 25, 2019, 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.

[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.

INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

U.S. dollars in thousands

	June 30,		December 31,
	2019	2018	2018

	Unaudited		Audited
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	$ 37,078	$ 19,004	$ 40,272
Available-for-sale financial assets	4,618	9,632	20,417
Prepaid expenses and other current assets	886	1,525	1,502
Total current assets	42,582	30,161	62,191
NON-CURRENT ASSETS:			
Property and equipment, net	3,437	1,546	2,311
Right-of-use assets	6,157	-	-
Other assets	1,355	1,141	662
Total non-current assets	10,949	2,687	2,973
Total assets	$ 53,531	$ 32,848	$ 65,164
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Trade payables	$ 2,121	$ 1,158	$ 1,985
Employees and payroll accruals	2,753	-	2,888
Current maturities of lease liabilities	1,945	-	-
Accrued expenses and other payables	2,699	4,057	1,832
Total current liabilities	9,518	5,215	6,705

NON-CURRENT LIABILITIES:			
Liabilities presented at fair value	7,654	13,700	24,049
Employee benefit liabilities, net	274	217	183
Lease liability	4,627	-	-
Liability to Israel Innovation Authority (IIA)	10,906	9,753	9,540
Total non-current liabilities	23,461	23,670	33,772
SHAREHOLDERS' EQUITY:			
Total shareholders' equity	20,552	3,963	24,687
Total liabilities and shareholders' equity	$ 53,531	$ 32,848	$ 65,164

INTERIMCONSOLIDATED 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,**
	2019	**2018**	**2019**	**2018**	**2018**
	Unaudited				**Audited**
Operating expenses:					
Research and development, net	$ 14,319	$ 12,037	$ 7,036	$ 6,977	$ 22,045
General and administrative	7,574	4,570	3,761	2,917	11,599
Operating loss	21,893	16,607	10,797	9,894	33,644

Finance expenses	1,604	4,204	1,336	3,230	20,259
Finance income	(14,052)	(330)	(18,169)	(34)	(1,042)
Loss (income) before taxes on income	9,445	20,481	(6,036)	13,090	52,861
Taxes on income	100	-	74	-	70
Net loss (income)	9,545	20,481	(5,962)	13,090	52,931
Net loss (income) per share:					
Basic net loss (income) per share	$ 0.38	$ 29.69	$ (0.23)	$ 18.97	$ 10.53
Diluted net loss (income) per share	$ 0.87	$ 29.69	$ 0.44	$ 18.97	$ 10.53

INTERIMCONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Six months ended June 30,		**Three months ended June 30,**		**Year ended December 31,**
	2019	**2018**	**2019**	**2018**	**2018**
	Unaudited				**Audited**
Cash flows from operating activities:					
Net (loss) income	$ (9,545)	$ (20,481)	$ 5,962	$ (13,090)	$ (52,931)
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	1,245	97	703	48	269
Financial income, net	(569)	(375)	(378)	(362)	(858)
Cost of share-based compensation	2,410	1,623	1,319	779	3,575
Change in employee benefit liabilities, net	8	17	(3)	33	(15)
Amortization of premium on available-for-sale financial assets	101	(9)	51	(90)	272
Revaluation of financial derivatives	(13,471)	3,400	(17,378)	3,000	17,600
Revaluation of liability to IIA	1,199	2,600	631	2,188	2,037
	(9,077)	7,353	(15,055)	5,596	22,880
Changes in asset and liability items:					
Decrease (Increase) in prepaid expenses and other current assets and other assets	117	(1,156)	(292)	(1,256)	942
Increase (decrease) in trade payables	244	(1,232)	1,088	306	(405)
Increase in accrued expenses and other payables and employee and payroll accrual	162	1,871	141	1,611	2,296
	523	(517)	937	661	2,833
Cash received during the period for:					
Interest received	830	391	309	378	792
Interest paid	(51)	-	(23)	-	-
	779	391	286	378	792
Net cash used in operating activities	(17,320)	(13,254)	(7,870)	(6,455)	(26,426)
Cash flows from investing activities:					

Purchase of property and equipment	(878)	(703)	(528)	(472)	(1,645)
Purchase of available-for-sale financial assets	-	-	-	-	(10,905)
Proceed from sale of available-for-sale financial assets	-	4,984	-	-	4,949
Proceed from maturity of available-for-sale financial assets	15,740	-	1,847	-	-
Proceeds from bank deposits	-	5,000	-	-	5,000
Investment in restricted bank deposits	-	-	-	-	(150)
Net cash provided by (used in) investing activities	14,862	9,281	1,319	(472)	(2,751)

INTERIMCONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Six months ended June 30,		**Three months ended June 30,**		**Year ended December 31,**
	2019	**2018**	**2019**	**2018**	**2018**
	Unaudited				**Audited**
Cash flows from financing activities:					
Receipt of grants from the IIA	167	1,653	167	-	612
Proceeds from issuance of shares, net	(346)	-	(108)	-	47,479
Payment of lease liabilities	(764)	-	(324)	-	-
Exercise of options	117	-	117	-	2
Net cash provided by (used in) financing activities	(826)	1,653	(148)	-	48,093
Exchange differences on balances of cash and cash equivalents	90	-	28	-	31
Increase (decrease) in cash and cash equivalents	(3,194)	(2,321)	(6,671)	(6,927)	18,947

Cash and cash equivalents at beginning of period	40,272	21,325	43,749	25,931	21,325
Cash and cash equivalents at end of period	$ 37,078	$ 19,004	$ 37,078	$ 19,004	$ 40,272

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