Gamida Cell Reports Third Quarter 2022 Financial Results and Provides Company Update

November 14, 2022

– Commercial launch preparations underway ahead of January 30, 2023 PDUFA target action date –

– New data presented across multiple medical meetings to support the potential of omidubicel as an advanced cell therapy, including long term follow-up data from the Phase 3 study, a real-world analysis of donor sources, and health-related quality of life scores and the potential for omidubicel to increase access to transplant for patients –

– Appointed Abigail Jenkins as President and CEO as part of planned succession –

– Strengthened financial position with sale of ordinary shares for gross proceeds of $20 million and signed a commitment letter for $25 million senior secured convertible term loan, both in September 2022 –

– Company to host conference call at 8:00 a.m. ET today –

BOSTON--(BUSINESS WIRE)--Nov. 14, 2022-- Gamida Cell Ltd. (Nasdaq: GMDA**), the leader in the development of NAM-enabled cell therapies for patients with hematologic and solid cancers and other serious diseases**, today provided a business update and reported financial results for the quarter ended September 30, 2022. Net loss for the third quarter of 2022 was $17.8 million, compared to a net loss of $23.2 million in the third quarter of 2021. As of September 30, 2022, Gamida Cell had total cash, cash equivalents and investments of $61.3 million.

Recently, Gamida Cell:

- Advanced commercial readiness activities to support the potential launch of omidubicel in preparation for the target action date of January 30, 2023 under Prescription Drug User Fee Act (PDUFA).
- Presented new data supporting the potential of omidubicel for the treatment of patients with blood cancers in need of allogeneic hematopoietic stem cell transplant at the Tenth Annual Meeting of the Society of Hematologic Oncology (SOHO) and the 2022 Cord Blood Connect Meeting (CBC). Data presented included new three-year follow-up data from the Phase 3 study that demonstrated that patients treated with omidubicel had an overall and disease-free survival rate of 63% and 56% at three years, respectively. Additional data presentations demonstrated that treatment with omidubicel led to higher health-related quality of life scores, and that, if approved, omidubicel is projected to meaningfully improve patient outcomes among racial and ethnic minorities by extending access and reducing time to transplant for patients who may not be able to currently find a donor source.
- Appointed Abigail “Abbey” Jenkins as President and CEO as part of a planned succession.
- Executed an underwritten public offering in September 2022 that raised $20 million before deducting underwriting discounts, commissions and offering expenses. The company also announced a commitment letter for a $25 million senior secured convertible loan in September 2022 with Highbridge Capital Management, LLC.
- Continued pre-clinical development of the company’s proprietary NAM-enabled NK cell pipeline, including genetically modified product candidates GDA-301, GDA-401, GDA-501 and GDA-601, which aim to treat solid-tumor and hematological cancers. These cell therapy candidates utilize CAR, membrane bound- and CRISPR-mediated technologies to increase the NK cell targeting, potency and persistence against hematologic malignancies and solid tumors. At the Society for Immunotherapy of Cancer’s 37 th Annual Meeting (SITC), Gamida Cell announced encouraging preclinical data on GDA-501, supporting its continued pre-clinical development. “Gamida Cell is entering a pivotal time of growth as we prepare to transition from being a clinical stage to commercial stage company upon the potential approval of omidubicel. The January 30, 2023 PDUFA date for omidubicel is rapidly approaching and, if approved, omidubicel will offer a transformative new option to patients in need of an allogeneic stem cell transplant,” said Abbey Jenkins, president and CEO of Gamida Cell. “The Gamida Cell team has utilized robust market insights to understand the important role that omidubicel can play for transplanters, if approved, in terms of both improving patients outcomes and increasing access for patients who cannot currently find a donor source. We have now accelerated launch preparations across our commercial, operations and medical affairs teams to ensure we can begin making omidubicel available upon potential approval in January. Beyond omidubicel, we are enrolling patients in our company-sponsored Phase 1/2 study of GDA-201 and are continuing to develop our genetically modified NK cell immunotherapy programs that leverage CAR- and CRISPR-mediated technologies. We are excited about the progress across our pipeline as we advance on our mission to deliver potentially curative therapies to patients with cancer and other serious diseases.”

Third Quarter and Recent Developments

Omidubicel: Advanced Cell Therapy Candidate

- **Data presentations at the 64th American Society of Hematology (ASH) Annual Meeting:** In November, Gamida Cell announced it will present new real-world analysis data comparing the safety and efficacy of omidubicel to alloHCT donor sources used in clinical practice from the Center for International Blood and Marrow Transplant Research (CIBMTR) database at the December ASH annual meeting. The analysis demonstrated that omidubicel was associated with more rapid neutrophil recovery (median: 10 days) than all other donor sources (median 15-20 days; p-value <0.001) and evaluated other outcomes comparing omidubicel Phase 3 results and those from the CIBMTR database. Overall survival (OS) was comparable across donor sources.
- **Presented new long-term data from Phase 3 trial at SOHO:** In September, at SOHO, Gamida Cell presented new long term follow-up data and health-related quality of life scores of patients treated with omidubicel. In an analysis of 105 patients transplanted with omidubicel between 2006 and 2020 (median follow-up of 22 months), the data demonstrated an overall and disease-free survival rate of 63% (95% CI, 53%-73%) and 56% (95% CI, 47%-67%) at three years, respectively. A second presentation featured an analysis of 108 patients that completed validated health-related quality of life (HRQL) surveys on screening and days 42, 100, 180, and 365 post-transplant. Measures of physical and functional well-being and other HRQL scores were more favorable with omidubicel and suggest clinically meaningful and sustained improvements in physical, functional and overall well-being compared to umbilical cord blood (UCB) transplantation.
- **Presented data demonstrating the impact of transplantation with omidubicel for patients with hematologic malignancies at CBC:** In September, at CBC, Gamida Cell presented data supporting the potential of omidubicel for the treatment of patients with blood cancers in need of an allogeneic hematopoietic stem cell transplant. The data suggest during the first-year post-transplant, patients receiving omidubicel had meaningfully greater preservation or improvement of important HRQL domains compared to UCB recipients. A second poster featured an analysis of the projected impact of allogeneic hematopoietic cell transplant on clinical outcomes and potential access for patients who currently cannot find a donor source, with the greatest improvements among the racial and ethnic groups underserved by the current standard of care. In a third poster, results of a translational sub-study from the Phase 3 trial showed that patients transplanted with omidubicel had more rapid and robust immune reconstitution than controls, including higher numbers of Recent Thymic Emigrants in peripheral blood at one year post transplant compared to transplantation with UCB, which suggest faster thymopoiesis and provide a mechanistic rational for the lower infection rates in these patients.
- **Continued launch preparations in preparation for January 30, 2023 PDUFA date:** The company's Biologics License Application (BLA) for omidubicel is under review with the U.S. Food and Drug Administration (FDA) with a target action PDUFA date of January 30, 2023. Gamida Cell continues to advance readiness activities throughout the organization to support the potential launch of omidubicel.

GDA-201: NAM-Enabled NK Cell Therapy

- **Continued advancement of Phase 1/2 study of cryopreserved formulation of GDA-201:** Gamida Cell continues to advance its company-sponsored Phase 1/2 study evaluating a cryopreserved formulation of GDA-201 for the treatment of follicular and diffuse B-cell lymphomas.

NAM-Enabled NK Cell Pipeline Development

- **Presented preclinical data on GDA-501:** At the SITC Annual Meeting, Gamida Cell announced new preclinical data on GDA-501, a genetically modified HER2-CAR NAM-NK cell therapy candidate, that provide support for its continued preclinical development. GDA-501 displayed significantly enhanced *in vitro* cytotoxicity when cultured with HER2+ targeted cancer cells, as well as increased potency based on elevated levels of proinflammatory cytokines and biomarkers compared with control cells. Importantly, increased cytotoxicity and potency were persistent. These preclinical data demonstrate potent antitumor activity.
- **Continued the development of NAM-enabled genetically modified NK pipeline:** Gamida Cell continues to progress its NAM-enabled genetically modified NK pipeline, which utilizes CAR, membrane bound- and CRISPR-mediated technologies to increase targeting, potency and persistence against hematologic malignancies and solid tumors. In order to both prioritize resources to the commercialization of omidubicel and advancement of GDA-201, as well as enable development activities to progress further, the company will hold on selecting an IND candidate and will continue to conduct *in vitro* and *in vivo* preclinical proof-of-concept studies for these genetically modified NK therapeutic targets.

Corporate Updates

- **Appointed Abigail Jenkins as President and CEO:** As part of a CEO succession plan, Julian Adams retired as CEO and Abigail "Abbey" Jenkins was appointed as President and CEO. Ms. Jenkins has also been appointed to Gamida Cell's Board of Directors. Ms. Jenkins brings over 25 years of leadership experience in the biopharmaceutical industry developing life-enhancing therapies from research to commercialization. Julian Adams will remain on the company's Board of Directors.
- **Strengthened financial position:** In September 2022, Gamida Cell executed an underwritten public offering raising approximately $20 million, before deducting underwriting discounts, commissions and offering expenses. Also, in

September 2022, the company announced it entered into a commitment letter with Highbridge Capital Management, LLC for a $25 million senior secured, convertible term loan. These capital commitments will be used to fund the commercial readiness activities to support the potential launch of omidubicel, if approved, and to further the clinical development of its NK product candidates, including GDA-201.

Third Quarter 2022 Financial Results

- Research and development expenses were $9.9 million in the third quarter of 2022, compared to $11.7 million in the same quarter in 2021. The decrease was attributable mainly to a $1.6 million decrease in clinical activities relating to the conclusion of the Phase 3 clinical trial and a decrease of $0.2 million in GDA-201 clinical program.
- Commercial expenses were $2.8 million in the third quarter of 2022, compared to $5.8 million in the third quarter of 2021. The decrease was attributable mainly to an $2.5 million decrease in launch readiness activities, and $0.6 million decrease in headcount related expenses.
- General and administrative expenses were $4.4 million in the third quarter of 2022, compared to $5.0 million in the same period in 2021. The decrease was mainly due to a $0.3 million decrease in professional services expenses and $0.3 million decrease in headcount related expenses.
- Finance expenses, net, were $0.7 million in the third quarters of 2022 and 2021, with no material changes.
- Net loss was $17.8 million in the third quarter of 2022, compared to a net loss of $23.2 million in the third quarter of 2021.

2022 Financial Guidance

Gamida Cell expects that its current total cash position, together with recent financing, will support the company's ongoing operating activities into mid-2023, excluding the cost of commercializing omidubicel beyond the initial launch. This cash runaway guidance is based on the company's current operational plans and excludes any additional funding and any business development activities that may be undertaken. Gamida Cell continues to assess all financing options that support its corporate strategy.

Expected Milestones in 2023

Omidubicel

- PDUFA target action date of January 30, 2023.

Conference Call Information

Gamida Cell will host a conference call today, November 14, 2022, at 8:00 a.m. ET to discuss these financial results and company updates. To access the conference call, please register here and be advised to do so at least 10 minutes prior to joining the call. 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. A replay of the webcast will be available approximately two hours after the event, for approximately 30 days.

About NAM Technology
Our NAM-enabling technology is designed to enhance the number and functionality of targeted cells, enabling us to pursue a curative approach that moves beyond what is possible with existing therapies. Leveraging the unique properties of NAM (nicotinamide), we can expand and metabolically modulate multiple cell types — including stem cells and natural killer cells — with appropriate growth factors to maintain the cells' active phenotype and enhance potency. Additionally, our NAM technology improves the metabolic fitness of cells, allowing for continued activity throughout the expansion process.

About Omidubicel
Omidubicel is an advanced cell therapy candidate developed as a potential life-saving allogeneic hematopoietic stem cell (bone marrow) transplant for patients with blood cancers. Omidubicel demonstrated a statistically significant reduction in time to neutrophil engraftment in comparison to standard umbilical cord blood in an international, multi-center, randomized Phase 3 study (NCT0273029) in patients with hematologic malignancies undergoing allogeneic bone marrow transplant. The Phase 3 study also showed reduced time to platelet engraftment, reduced infections and fewer days of hospitalization. One-year post-transplant data showed sustained clinical benefits with omidubicel as demonstrated by significant reduction in infectious complications as well as reduced non-relapse mortality and no significant increase in relapse rates nor increases in graft-versus-host-disease (GvHD) rates. Omidubicel is the first stem cell transplant donor source to receive Breakthrough Therapy Designation from the FDA and has also received Orphan Drug Designation in the US and EU.

The BLA for omidubicel has been assigned a Prescription Drug User Fee Act (PDUFA) target action date of January 30, 2023. If approved, omidubicel will be the first allogeneic advanced stem cell therapy donor source for patients with blood cancers in need of a stem cell transplant.

Omidubicel is an investigational stem cell therapy candidate, and its safety and efficacy have not been established by the FDA or any other health authority. For more information about omidubicel, please visit https://www.gamida-cell.com.

About GDA-201
Gamida Cell applied the capabilities of its nicotinamide (NAM)-enabled cell expansion technology to develop GDA-201, an innate NK cell immunotherapy candidate for the potential treatment of hematologic and solid tumors in combination with standard of care antibody therapies. GDA-201, the lead candidate in the NAM-enabled NK cell pipeline, has demonstrated promising initial clinical study data. Preclinical studies have shown that GDA-201 may address key limitations of NK cells by increasing the cytotoxicity and *in vivo* retention and proliferation in the bone marrow and lymphoid organs. Furthermore, these data suggest GDA-201 may improve antibody-dependent cellular cytotoxicity (ADCC) and tumor targeting of NK cells. There are approximately 40,000 patients with relapsed/refractory lymphoma in the US and EU, which is the patient population that will be studied in the currently ongoing GDA-201 Phase 1/2 clinical trial.

For more information about GDA-201, please visit https://www.gamida-cell.com. For more information on the Phase 1/2 clinical trial of GDA-201, please visit www.clinicaltrials.gov.

GDA-201 is an investigational cell therapy candidate, and its safety and efficacy have not been established by the FDA or any other health authority.

About Gamida Cell

Gamida Cell is pioneering a diverse immunotherapy pipeline of potentially curative cell therapy candidates for patients with solid tumor and blood cancers and other serious blood diseases. We apply a proprietary expansion platform leveraging the properties of NAM to allogeneic cell sources including umbilical cord blood-derived cells and NK cells to create therapy candidates with potential to redefine standards of care. These include omidubicel, an investigational product with potential as a life-saving alternative for patients in need of bone marrow transplant, and a line of modified and unmodified NAM-enabled NK cells targeted at solid tumor and hematological malignancies. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on LinkedIn, Twitter, Facebook or Instagram at @GamidaCellTx.

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 (including omidubicel and GDA-201), regulatory filings submitted to the FDA (including the potential timing of the FDA's review of the BLA for omidubicel), commercialization planning efforts and launch activities, the potentially life-saving or curative therapeutic and commercial potential of Gamida Cell's product candidates (including omidubicel and GDA-201), progress on the preclinical NAM-enabled NK cell pipeline, and Gamida Cell's expectations regarding its projected cash to be used for operating activities and cash runway. Any statement describing Gamida Cell's goals, expectations, financial or other projections, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to a number of risks, uncertainties and assumptions, including those related to the impact that the COVID-19 pandemic could have on our business, and including the scope, progress and expansion of Gamida Cell's clinical trials and ramifications for the cost thereof; clinical, scientific, regulatory and technical developments; and those inherent in the process of developing and commercializing product candidates that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such product candidates. 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 Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission (SEC) on August 15, 2022, as amended, 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. Although Gamida Cell's forward-looking statements reflect the good faith judgment of its management, these statements are based only on facts and factors currently known by Gamida Cell. As a result, you are cautioned not to rely on these forward-looking statements.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 55,071	$ 55,892
Marketable securities	6,224	40,034
Prepaid expenses and other current assets	1,408	2,688
Total current assets	62,703	98,614
NON-CURRENT ASSETS:		
Restricted deposits	3,556	3,961
Property, plant and equipment, net	39,940	35,180
Operating lease right-of-use assets	5,459	7,236
Severance pay fund	1,595	2,148
Other long-term assets	1,059	1,647
Total non-current assets	51,609	50,172
Total assets	$ 114,312	$ 148,786

	September 30, 2022	December 31, 2021
LIABILITIES AND SHARHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 1,916	$ 8,272

Employees and payroll accruals	5,689	4,957
Operating lease liabilities	1,880	2,699
Accrued interest of convertible senior notes	551	*1,640*
Accrued expenses and other current liabilities	12,677	7,865
Total current liabilities	22,713	25,433
NON-CURRENT LIABILITIES:		
Convertible senior notes, net	71,999	71,417
Accrued severance pay	1,865	2,396
Long-term operating lease liabilities	4,174	*5,603*
Total non-current liabilities	78,038	79,416
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' EQUITY:		
Share capital	210	169
Additional paid-in capital	407,387	*381,225*
Accumulated deficit	(394,036)	*(337,457)*
Total shareholders' equity	13,561	43,937
Total liabilities and shareholders' equity	$ 114,312	$ 148,786

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
	(unaudited)		(unaudited)	
Research and development expenses, net	$ 9,864	$ 11,725	$ 31,732	$ 36,435
Commercial expenses	2,760	5,755	9,832	14,974
General and administrative expenses	4,437	5,001	12,866	12,388
Total operating loss	17,061	22,481	54,430	63,797
Financial expenses, net	741	692	2,149	2,119
Loss	$ 17,802	$ 23,173	$ 56,579	$ 65,916
Net loss per share attributable to ordinary shareholders, basic and diluted	0.29	0.39	0.95	1.11
Weighted average number of shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	60,440,765	59,281,243	59,821,655	59,219,757

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

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

	Nine months ended September 30,	
	2022	2021
Cash flows from operating activities:		
Loss	$ (56,579)	$ (65,916)
Adjustments to reconcile loss to net cash used in operating activities:		

Depreciation of property, plant and equipment	391	317
Financing expense (income), net	(2,461)	89
Share-based compensation	3,829	3,122
Amortization of debt discount and issuance costs	582	453
Operating lease right-of-use assets	1,922	1,542
Operating lease liabilities	(2,395)	(1,764)
Accrued severance pay, net	23	-
Decrease in prepaid expenses and other assets	1,719	558
Increase (decrease) in trade payables	(6,355)	1,533
Increase (decrease) in accrued expenses and current liabilities	5,079	(1,361)
Net cash used in operating activities	(54,245)	(61,427)
Cash flows from investing activities:		
Purchase of property, plant and equipment	(2,865)	(9,577)
Purchase of marketable securities	(4,557)	(97,808)
Proceeds from maturity of marketable securities	37,972	56,717
Proceeds (investments) from restricted deposits	500	(5,803)
Net cash provided by (used in) investing activities	$ 31,050	$ (56,471)
Cash flows from financing activities:		
Proceeds from exercise of options	$ 76	$ 566
Proceeds from share issuance, net	22,298	-
Proceeds from issuance of convertible senior notes, net	-	70,777
Net cash provided by financing activities	22,374	71,343
Decrease in cash and cash equivalents	(821)	(46,555)
Cash and cash equivalents at beginning of period	55,892	127,170
Cash and cash equivalents at end of period	$55,071	$ 80,615
Significant non-cash transactions:		
Purchase of property, plant and equipment on credit	281	1,561
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ (4,406)	$ (2,191)

View source version on businesswire.com: https://www.businesswire.com/news/home/20221114005403/en/

For investors:
Courtney Turiano
Stern Investor Relations, Inc.
Courtney.Turiano@sternir.com
1-212-362-1200

For media:
Heather DiVecchia
Director, Investor Relations and Corporate Communications
Heather@gamida-cell.com
1-617-892-9083

Source: Gamida Cell Ltd.