

August 2017

Company Overview

Curative Treatments for Cancer and Orphan Genetic Diseases





Curative Treatments for Orphan Indications

- NiCord[®] a bone marrow transplantation treatment for patients with high risk leukemia and lymphoma
 - Breakthrough Therapy designation by FDA
 - Phase 3 registration study is enrolling patients
 - Positioned to become the graft of choice for patients with no suitable donor
 - Estimated one billion USD peak sales
- Platform NAM technology and a clinical stage product pipeline
- GMP validated in house manufacturing capacity; to be expanded towards NiCord[®] commercialization
- Broad worldwide patent portfolio with 55 granted;
 Worldwide rights to all products
- US plans for 2017: hire senior leadership; office in the US East coast



Clinical Stage Therapies Addressing Orphan Indications

Platform Technology with Multiple Pipeline Products





NiCord[®]

Breakthrough Therapy Designation (First in BMT)

Orphan Drug Designation

Phase 3 is enrolling patients



BMT is a Potential Cure for High Risk Blood Cancers, But Limited by Availability and Quality of Donor Cells

- Re-shaped treatment and prognosis of cancer patients
- A curative therapy also for rare genetic diseases such as sickle cell disease and thalassemia
- Requires full tissue matching between the patient and the donor and a sufficient cell dose
- Search algorithm shows that only 30% of patients have a high probability to find a match. 70% face an intermediate or low probability search^a

(a) J.-M. Tiercy, Bone Marrow Research, Volume 2012, Article ID 695018



Half of Indicated Patients Never Get to Transplant

70% of Patients Have a Low or Intermediate Probability of Finding a Match



Cord Blood Stem Cells Offer a Potential Solution

No Need for Full Tissue Matching, Can Practically be Available to all Patients in Need

Advantages

- Cord Blood (CB) is readily and rapidly available from public CB banks worldwide
- Full tissue matching is not required, therefore a CB unit can rapidly be available to all patients in need
- Low incidence of GvHD, yet graft vs. leukemia effect is not mitigated (advantage over haplo transplant)



Gamida Cell's Solution:

Ex vivo (in culture) expansion of CD34+ stem/progenitor cells





NAM Technology Expands Cord Blood Stem Cell Population While Preserving Functionality

- Epigenetic regulation by the small molecule, nicotinamide (NAM), a multifunctional derivative of vitamin B3
- Addresses the two limitations of ex vivo expansion
 - Inhibits rapid cell differentiation resulting in high number of stem and progenitor cells (CD34+ /CD133+ cells)
 - Enhances cell functionality: migration, homing and engraftment in the bone marrow



NAM Technology Improves Graft Functionality Platform to Pipeline Products

Active molecule is NAM

- Precursor of NAD, inhibits enzymes that use NAD, including Sir2 (SIRT1-7), class-III NAD-dependent histone-deacetylase
- Modulates cell energy and metabolism
- Biological modifier of cell cycle

Increased Efficiency of Homing to the Bone Marrow

Preserved Gene Expression

NiCord[®] Manufacturing Process is Validated and Cost Effective

Product is Shipped to the Hospital Ready for Infusion

NiCord is transfused at the transplant center

Cryopreserved formulation, ready for infusion

NiCord[®] Smoothly Integrates into Current Transplant Practice and Procedures

 Patient often receives conditioning regimen (8-11 days) during NiCord[®] manufacturing period NiCord[®] is manufactured in a central manufacturing site, for global distribution

to hospital ready for infusion

NiCord[®] Pilot Study Demonstrated Prompt and Durable Engraftment

- 11 adult, high-risk hematological malignancy patients, with myeloablative conditioning, at Duke and Loyola universities (U.S.)
- All patients transplanted with NiCord[®] together with unmanipulated CB unit
- Prompt, robust and durable long term engraftment with NiCord[®]
 - 8/11 patients engrafted with NiCord[®]; 2/11 patients engrafted with the unmanipulated CB unit

Time to neutrophil engraftment (median)	11 days
Time to Platelet engraftment (median)	33 days
Engraftment failure	1 patient
Primary hospitalization (median)	19 days
Alive and <u>out</u> of hospital first 100 days (median)	80.5 days
aGVHD grade III-IV at 100 days	0%
cGvHD moderate-severe at 3 years	13.3%
Non-relapse mortality at 3 years	10%
Overall Survival at 3 years	66.7%
Disease free survival at 3 years	66.7%
Relapse at 3 years	23.3%

Source: J Clin Invest. 2014 Jul;124(7):3121-8. Horwitz ME et al

NiCord[®] Phase 1/2 Study Provides Basis for Phase 3

- 24 Adult, high risk hematological malignancy patients with myeloablative conditioning, treated in 6 sites in the US and Europe
- NiCord[®] transplanted as a standalone product, cryo preserved formulation
- Meaningful improvement in time to engraftment, reduced incidence of bacterial and non-viral infections, shorter length of hospitalization

NiCord Phase 1/2 Study Results	
Time to neutrophil engraftment (median, n=23)	11 days (range 6-26)
Time to platelet engraftment (median, n=19)	33 days (range 26-96)
aGvHD grade III-IV at 100 days	19% (all grade III)
cGvHD Moderate-Severe at 1 year	13.4% (all moderate)
Primary hospitalization (median, n=24)	19 days
Alive and out of the hospital, first 100 days (median, n=20)	74 days
Transplant Related Mortality at 1 year	14.5%

Median follow-up of survivors: 334 days (28-829)

NiCord[®] Neutrophil Engraftment is Significantly More Rapid Than Cord Blood

Time to Neutrophil Engraftment is The Primary Endpoint in the Phase 3 Study

<u>Controls</u>: CIBMTR registry data of 125 matched (age, disease, conditioning, CBU dose) patients who received unmanipulated myeloablative cord blood transplantation between years 2010-2013

NiCord[®] Non-Relapse Mortality is Lower than Matched Controls

<u>Controls</u>: CIBMTR; 125 matched (age, disease, conditioning, CBU dose) patients who received unmanipulated myeloablative cord blood transplantation between years 2010-2013

NiCord[®] Positive Impact on Morbidity and Mortality Predicts Potential for Widespread Adoption

Improved Pharmacoeconomics; Validating Breakthrough Therapy designation

- Transplantation of NiCord[®] is associated with a significant improvement in:
 - Recovery of neutrophils and platelets (Horwitz et al. 2016 ASCO Annual Meeting)
 - Recovery of innate and adaptive immune system (Horwitz et al. 2016 ASCO Annual Meeting)
 - Reduced bacterial and fungal infections a major cause of death in the first 100 days post transplantation (Anand et al. BBMT 2017)
 - Shorter hospitalization (Anand et al. BBMT 2017)
 - Reduced non-relapse mortality (Horwitz et al. International Cord Blood Symposium 2016)
- Breakthrough Therapy designation
 - FDA acknowledgement of preliminary clinical evidence of efficacy
 - Validation of Phase 3 primary endpoint to represent clinical benefit
 - Reduced regulatory risk for approval
- Orphan Drug designation by FDA and EMA

NiCord[®] is Positioned to Shift BMT Paradigm

A Potential Graft of Choice for Patients with no Matched Related Donor

Clinical Factors of Interest	Peripheral Blood – MUD ¹	NiCord [®] 41 patients treated ²
Availability of graft to transplant	30% of patients (3-4 months)	Most patients (1 month)
Time to neutrophil engraftment	14 days	11 days
Time to platelet engraftment	19 days	33 days
T cell recovery (median)	Day 100-180	Day 100-180
Alive and out of the hospital, in the first 100 days (median)	75 days	74 days
Acute GvHD grade III-IV, 100 days	6-19%	12.6% ³
Chronic GvHD, 2 years	21-55%	28.9%
Non-relapse mortality, 2 years	20-33%	19%
Relapse, 2 years	22-28%	25%
Overall survival, 2 years	45-63% ⁴	56.8%

(1) EBMT and CIBMTR analyses of adults with AML & ALL following myeloablative MUD transplant 2006-2011; Eapen M et al, Lancet, 2010

(2) Based on patients from Pilot and Phase 1/2 studies; Median follow-up of survivors: 398.5 days (27-2149)

(3) 2 patients developed moderate cGvHD; No case of severe cGvHD

(4) Does not include patients that died because they could not find a matched donor

NiCord[®] Phase 3 Registration Study is Enrolling

Breakthrough Therapy Designation Granted by FDA

Randomized controlled Phase 3 Registration Study 120 patients

Adult patients with high risk hematological malignancies including AML, ALL, MDS and CML

- Registration pivotal Phase 3 study in 10-15 clinical sites in the U.S. and EU
- Clinical protocol has been approved by FDA and EMA
- Primary endpoint: time to neutrophil engraftment
- Key secondary endpoints include clinical and pharmacoeconomic parameters
- Additional analysis will compare NiCord to patients transplanted with MUD
- Top line data will be available in H1/2019

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NiCord[®] Business Opportunity

NiCord[®] Provides Significant Benefits to Patients, Hospitals and Payers

Patients

- Better clinical outcomes
- Rapid hematopoietic recovery
- Reduced morbidity
- Reduced transplant related mortality

Hospital

- Shorter hospital stay by ~20 days
- Improved efficiency in beds utilization (census)
- Decrease in resource utilization
- Enables more patients to get a transplant

Payer

- Reimbursement is by case rate at \$200 400K, but billing may be significantly higher (source: Boston Healthcare independent research for Gamida Cell, 2016)
- Reduced treatment charges
- A standalone graft, eliminates need for a second cord blood unit, saving \$45K (US standard practice is use of 2 CB units. NiCord requires only 1 CB unit)

NiCord[®] Can Become the Graft of Choice for Patients With No Suitable Donor

Target Population in the US, Europe and Japan Alone: 35,800 Patients in Peak Year Based on Penetration Assumptions, Peak Sales ~9,000 Patients Annually

44,800 Indicated Patients (US, Europe and Japan only) ^(a)

(a) Data are based on reports from WMDA, EBMT, NMDP, CIBMTR, and scientific literature (b) Patients already referred by the Hem/Onc to a transplant center, a formal search for a match through the public registries was initiated

NiCord[®] Revenues Potential (USA, Europe and Japan) Over \$ 1 billion in potential annual sales (peak year 2025)

Graft Source ^(a)	U.S.A.	Europe	Japan	Total ^(b)	% Penetration (peak)	Number of patients treated (peak)
Matched Related Donor	2,700	5,070	1,240	9,010	0%	0
Matched Unrelated Donor	6,110	11,075	2,035	19,220	20%	3,844
Haplo	1,090	2,120	0	3,210	40%	1,284
Umbilical Cord Blood	680	400	1,200	2,280	75%	1,710
Not Transplanted	8,060	3,025	0	11,085	20%	2,217
Total	18,640	21,690	4,475	44,805		9 <i>,</i> 055

(a) Data are based on reports from WMDA, EBMT, NMDP, CIBMTR, and scientific literature, estimated for peak year 2025.

(b) Additional 20,000-40,000 patients are estimated in the rest of the world. We assume potential for additional >3,000 patients treated

Low COGS Ensures Margins of Profitability

In House Manufacturing Capability; Logistical Infrastructure is Efficient

- In-house GMP manufacturing capacity in Israel, approved by the Israeli Ministry of Health
- A central manufacturing site to accommodate commercial needs will be established prior to FDA approval
- Low COGS. A standalone graft in a cryo-preserved formulation was optimized
- Robust manufacturing process with <5% failure rate
- Successful technology transfer processes to CMOs
- Logistics infrastructure carefully established
 - Shipping procedure is validated
 - Timely delivery was demonstrated to be robust with over 140 batches shipped to clinical sites all over U.S. and EU
- Full transition from R&D to robust GMP manufacturing scale, including testing and release, was developed based on internal expertise

NiCord[®] Market Exclusivity Supported by Three Strategic Barriers

REGULATORY EXCLUSIVITY

NiCord[®] has an orphan drug designation in the US and EU

SCIENTIFIC BARRIERS

NiCord[®] manufacturing process, SOPs and cryopreservation method are trade secrets

INTELLECTUAL PROPERTY

55 Granted patents worldwide, of which 25 granted and 2 pending applications related to NiCord[®] . Until 2028-2029

GRANTED CLAIMS

Composition of matter: Population(s) of HSC expanded using nicotinamide Method of manufacturing: Culturing and expanding undifferentiated and mature cells with nicotinamide Method of use: Therapeutic applications of the expanded cell populations NiCord[®] product: a new application related directly to the product has been submitted in 2017

CordIn[™] A Potential Cure for Sickle Cell Disease

CordIn[™] - a Cure of Rare Genetic Diseases Where Bone Marrow Transplantation is the Only Established Cure

- BMT is the only cure of Sickle Cell Disease (SCD) and thalassemia which has been clinically established
 - Gene therapy does not provide a long term cure to many of the patients
- SCD and thalassemia are initial indications of CordIn[™]
 - SCD: 100,000 patients in U.S.; thalassemia: 200,000 patients worldwide (a)
 - Cost of treating SCD patient over lifetime is \$8 9M ^(b)
- Additional market opportunities include
 - Bone marrow failure syndromes
 - Genetic metabolic diseases
 - Refractory autoimmune diseases

- (a) Source: <u>https://www.ncbi.nlm.nih.gov/pubmed/20331952</u>
- (b) Trinity Partners 2013, Independent research for Gamida Cell

Clinical Proof of Concept in Curing Sickle Cell Disease Data Presented at ASH 2016

- First evidence of successful engraftment in patients with Sickle Cell Disease (SCD)
 - Eleven patients treated
 - Very rapid engraftment of donor cells (median 7 days)
 - 2 patients died (one of secondary graft failure and one of GvHD)
 - No symptoms of SCD in surviving patients:
 - Transfusions free
 - Normal hemoglobin profile
 - All GvHD was resolved by the time of last follow up
 - Improved quality of life in surviving patients
 - Compares favourably with the outcomes of transplanting matched related donors
- Interim data of first 9 treated patients presented at ASH 2016
- Results suggest great potential for CordIn[™] to increase access to BMT for patients with SCD

CordIn[™] in Bone Marrow Failure Syndromes: Aplastic Anemia (AA) and Myelodysplastic Syndrome (MDS)

- Investigator initiated study in collaboration with Prof. Richard Childs at the U.S. National Heart, Lung and Blood Institute (NHLBI)
- Approximately 30 patients age 4-55
- First part of the study: up to 6 patients will be transplanted with CordIn and a backup haplo graft
- Second part of the study: patients will be transplanted with CordIn as a standalone graft
- Primary endpoint is early and durable engraftment of CordIn
- First patient has been transplanted

Natural Killer (NK) Cell Product Immune Therapy of Cancer

NAM-NK Cells for Immunotherapy of Blood and Solid Cancers

- NK cells play an important role in the immune system fight of cancer
- Unlike T cells, NK cells do not need prior sensitization and do not increase the risk of GvHD
- NK cells in cancer patients are exhausted
- Functionality is compromised following cell expansion: impaired homing, retention and *in vivo* proliferation
- NAM-NK product is comprised of highly functional cells

Robust and Cost Effective Manufacturing of NAM-NK Cells

Potential Off-the-shelf Cell Product Based on Common Haplotypes

Leukapheresis

CD3 depletion using CliniMACS

Efficient *ex-vivo* expansion process

- Only one cell selection step
- No need for feeder cells
- Only one feeding between seeding and harvest
- Clinical dose
- Process under GMP

Seeding

- NK cells ~ 5-30%
- B cells
- Granulocytes,
- Monocytes
- Residual T and NKT

After 14 days in culture

NK cells > 98% T cells < 0.5%

NAM Technology Improves Efficacy of NK Cells

Enhanced Direct and Adaptive Immune Killing

Excellent Homing and Retention of NK Cells in Animal Models

Comparative studies were conducted at NHLBI ^{1,2}

(1) Blood 2013 122:897

(2) Hematology Am Soc Hematol Educ Program. 2013;2013:234-46. doi: 10.1182/ash education-2013.1.234

Enhanced Direct and Adaptive Immune Tumor Killing

- Direct: increased degranulation and FAS-L expression: key to direct killing by NK cells
- Indirect: priming of T cells through increased secretion of cytokines: IFN-y and TNF-alpha

NAM Reduces Expression of PD-1 in NK Cells

May be Associated With Reduced Tumor Escape

Ligation of CD200 / CD200R or PD-L1 / PD1 suppresses NK cell function and inhibits patient anti-tumor response

Source: Gamida preclinical studies

Immunosuppression

Improved In Vivo Proliferation of NK Cells Cultured with NAM

NK Cells Proliferation in the BM is an Important Measure of Their Activity

Percent of *in vivo* proliferating cells

BrdU assay for detection of proliferating cells by FACS

Only proliferating cells incorporate BrdU into their DNA and can later be detected using FITC anti BrdU

NAM-NK Cells Phase 1 Study to Begin H1/2017

- Patients with B-cell lymphoma and multiple myeloma
- Donor derived NK cells are expected to be more effective, in particular for patients resistant to treatment
- in combination with Rituximab (for B-cell lymphoma) or with Elotuzumab (for multiple myeloma)
- Primary endpoint: safety and preliminary estimate of efficacy. Total follow up is 1 year
- Principal Investigator: Dr Jeffrey Miller, Director Experimental Therapeutics, University of Minnesota

High affinity antibodies to specific targets on tumor and NK cells, bring the NK and cancer cells in proximity, trigger the killing cascade and increased the specificity and efficacy of NK cells

Financials and Business Overview

Financials and Shareholders

- Cash, June 30, 2017: \$10 M
- \$40 M financing closed in July 2017
- Approved 2017 support by Israeli government: \$3.5M
- Use of proceeds:
 - Complete Phase 3 study of NiCord[®] and prepare for product commercialization
 - Continue pipeline development
 - Hire additional senior management in the US; Open headquarters office in the US East coast
 - Expand in-house manufacturing capacity
- Shareholders include Novartis, Clal Biotechnology Industries, Elbit Imaging, Israel Healthcare Ventures, Shavit Capital Fund, VMS Investment Group, Denali Ventures, Auriga Ventures and Israel Biotech Fund

Value Creation During 2016-2018

R&D	Indication	2016	2017	2018	Value
NiCord®	Hematological malignancies	Phase 1/2 data readout Begin Phase 3	Phase 1/2 Clinical Day 180 final analysis	Phase 3 complete enrollment;	First in class cure for hematological malignancies; standalone graft
	SCD & thalassemia; double cord configuration	Top line data readout of first 9 patients		Data readout	No gene manipulation; Address the engraftment and donor availability barrier in non-malignant patients
CordIn™	SCD & thalassemia; single cord configuration	Begin Phase 1/2, up to 10 patients		Phase 2 data readout	Cure of a chronic disease with a standalone graft
	Aplastic anemia		Begin Phase 1/2	Preliminary data readout of up to 5 patients	Expansion of indications
NK cells	Hematological malignancies		Begin Phase 1/2	Preliminary data readout of up to 5 patients	Diversification of immune therapy products

Corporate	Domain	
Manufacturing	Manufacturing facility to	be operational towards NiCord [®] launch
Management	Hire key senior manager	nent and open headquarters office in the US East coast

Management Team in Israel and in the US

- Dr. Yael Margolin President & CEO since 2005. Previously VP of Denali Ventures LLC, and manager of new R&D initiatives at Teva Pharmaceuticals. Ph.D. in Biology from the Weizmann Institute of Science and was a post-doctoral associate at the Yale University School of Medicine.
- Dr. Tony Peled Chief Scientific Officer and Vice President of Research & Development. Cofounder of the company and the scientist credited with the discoveries that have led to Gamida Cell's key patents
- Dr. Ronit Simantov Chief Medical Officer. >20 years of experience in research, development, registration, and launch of hematology and oncology drugs. Previously VP and Head of Global Medical Affairs at Pfizer Oncology. B.A. from Johns Hopkins University and MD from New York University School of Medicine.
- Dr. David Snyder Vice President, Clinical Development and Regulatory Affairs. Experience in senior management teams of international pharmaceutical and biotechnology companies, since 1994. Ph.D. in medical biochemistry from the Hebrew University in Jerusalem and postdoctoral work in neurobiology at Duke University.
- **Dorit Harati Vice President, Quality Assurance.** 25 years of experience in the pharmaceutical and biotechnology industries, 16 years experience in cell therapy.
- Naftali Brikashvili Chief Financial Officer. More than 20 years of experience in all aspects of accounting and finance. B.A. in accounting & economics from the Hebrew University, Jerusalem and an LLM degree from Bar Ilan University.

Scientific and Clinical Advisors are Internationally Preeminent

Joanne Kurtzberg, MD

Director, Carolinas Cord Blood Bank Chief Scientific Officer, Robertson Clinical and Translational Cell Therapy Program Director, Pediatric Blood and Marrow Transplant Program Duke University Medical Center, Durham, NC

Mitchell Horwitz, MD

Associate Professor of Medicine, Director of Clinical Research, Adult Blood and Marrow Transplant Program Duke University Medical Center, Durham, NC

• Nelson Chao, MD

Donald D. and Elizabeth G. Cooke Professor of Medicine and Immunology, Chief Division of Hematologic Malignancies Chief, Division of Cellular Therapy/BMT Duke University Medical Center, Durham, NC

Jeffrey Miller, MD

MD Associate Director Experimental Therapeutics University of Minnesota Cancer Center, Minneapolis

Guillermo Sanz, MD Professor and Head of Clinical H

Professor and Head of Clinical Hematology Department Hospital Universitario La Fe, Valencia, Spain

Mary Laughlin, MD Cell and Gene Therapy Unit

Novartis Pharmaceuticals Corp., East Hanover, NJ

Jaap Jan Boelens, MD, PhD Pediatrician – Oncologist, Immunologist Pediatric Blood and Marrow Transplantation Program University Medical Center, Utrecht, The Netherlands

• Amnon Peled, PhD Professor, Genetic Therapy Institute Hadassah Medical Center, Jerusalem, Israel

• Richard Maziarz, MD

Professor of Medicine, Medical Director Adult Blood and Marrow Stem Cell Transplant Program Oregon Health and Science University, Portland, OR

Board of Directors

• Dr. Julian Adams - Chairman of the Board

More than 30 years of experience in drug discovery and development with a strong focus on cancer research. Senior vice president of drug discovery and development at Millennium Pharmaceuticals, heading the successful Velcade[®] program. President of research and development at Infinity Pharmaceuticals until 2017

• Prof. Roger Kornberg

Professor of Structural Biology at Stanford Medical School since 1978. Won the Nobel Prize for Chemistry in 2006 for his studies of the molecular basis of transcription, the process whereby information in DNA is read out for the direction of all activities of all organisms, including humans. Recipient of the 2006 Dickson Prize from University of Pittsburgh and the 2006 Louisa Gross Horwitz Prize from Columbia University. In 2009, he was elected a Foreign Member of the Royal Society.

• Dr. Kenneth I. Moch

President & CEO of CogRx. Previously served as President & CEO of Chimerix, Inc., BioMedical Enterprises, Alteon, Inc., and Biocyte Corporation, where he pioneered the storage and therapeutic use of cord blood stem cells and launched the first cord blood stem cell storage bank.

• Dr. Mike Perry

Director and Operating Partner at Bioscience Managers Pty Ltd. Recently retired from Novartis as SVP and CSO Global BD&L, CSO Cell & Gene Therapy Unit. Formerly Novartis' observer on the Gamida Cell Board of Directors. Serves on the Boards of Avita Medical Ltd (AVH:ASX), Arrowhead Pharmaceuticals (ARWR:NASDAQ) and AmpliPhi Biosciences (APBH:NYSE). Adjunct Professor at the University of Colorado, School of Medicine, Gates Center for Regenerative Medicine and Stem Cell Biology and serves as Chair of the Translational Medicine Advisory Board of the Houston Methodist Research Institute

• Mr. Ofer Gonen

CEO of Clal Biotechnology Industries (TASE: CBI). Board Member of MediWound (NASDAQ: MDWD), CureTech, D-Pharm (TASE: DPRM), Biocancell (TASE: BICL), Avraham, Campus Bio, Polyheal, CLS)

• Dr. Hadar Ron

Managing director of Israel Healthcare Ventures, Ltd. (IHCV). Extensive medical, legal and management experience gained while serving in senior positions at a range of insurance companies, law firms, medical and educational institutions

• Mr. Boaz Lifschitz

General Partner and Co-founder of Peregrine Ventures. Board member of Elbit Imaging Ltd. (EMITF), Insightec Ltd., Cartiheal Ltd. and WhiteSource

• Dr. Yael Margolin - President & CEO

More than 30 years of experience in pharmaceutical and biotech industry and in venture capital. President & CEO of Gamida Cell since 2005

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