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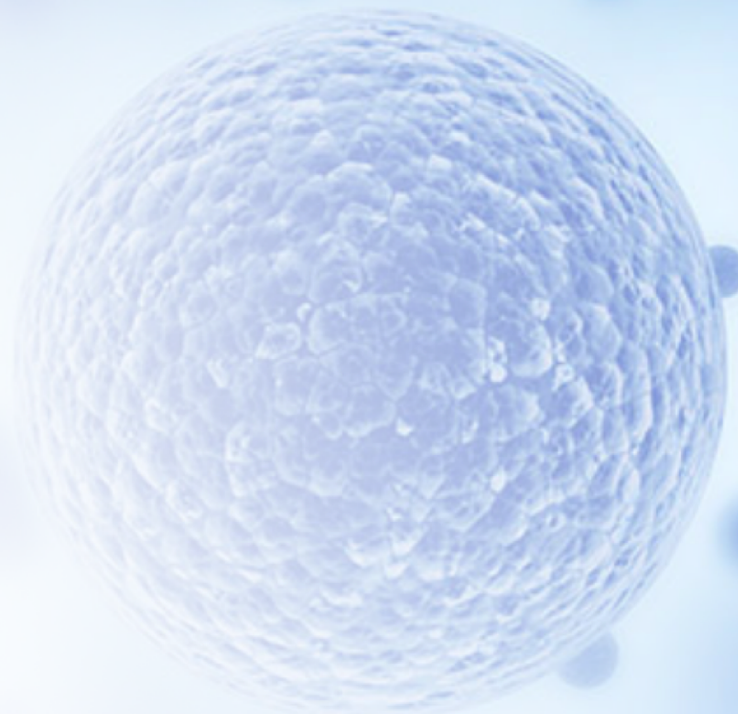

biorestorative therapies

BRTX-100 Investor Overview

Summer 2018

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BioRestorative Therapies, Inc. (“BRT”) develops therapeutic treatments from adult stem cells

- Full-service research lab, based in Melville, NY
- Publicly-listed (OTC: BRTX)
- 10 employees, most with technical/science backgrounds
- Leadership and scientific advisors are pioneers in stem cell therapeutics space

We have developed BRTX-100®, a stem-cell based treatment for chronic lumbar disc disease (“cLDD”):

- Autologous stem cell-based biologic
- Hypoxic cultured, bone marrow-derived
- Single intradiscal injection

BRTX-100 is our lead clinical candidate:

- Prior human data provides insight into the potential efficacy of BRTX-100
- FDA authorized commencement of Phase 2 clinical trial
- Large indication with few comparable therapies

BRT is seeking a partner to finance a private Newco, which would be spun off from BRT – proceeds from the financing would be devoted solely to the development of BRTX-100

LOW BACK PAIN IS A LEADING CAUSE OF DISABILITY AND HAS ENORMOUS SOCIAL AND ECONOMIC IMPACT

Chronic Lumbar Disc Disease is degenerative:

- Compromised disc is associated with lower back pain
- Over time, functionality is also limited
- Disc degeneration is presently irreversible

80% of adults experience lower back pain:

- More than 30% of people aged 30-50 have some degree of disc degeneration
- While not always symptomatic, in people over 60, disc degeneration is a typical finding on MRI scans

Standard of care focuses on pain management with mixed outcomes and significant adverse effects:

- Failed conservative intervention leads to surgery
- Conservative interventions include physical therapy, NSAIDs, steroids, and narcotics, spinal injections
- U.S. opioid epidemic, low back pain common gateway, loss of life catastrophic, long term NSAID therapy also not benign
- Surgical interventions include spinal fusions and discectomies

- Katz JN. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. J Bone Joint Surg Am. 2006;88 (Suppl 2):21–24.
- Lumbar Degenerative Disc Disease (DDD) (Peter F. Ullrich, Jr., MD, 2013)

CURRENT TREATMENT OPTIONS INCLUDE CONSERVATIVE INTERVENTIONS THAT OFTEN LEAD TO INVASIVE SURGICAL PROCEDURES

Conservative Treatment Options

Oral Medication Treatment

- OTC pain medications (NSAIDs, analgesics)
- Narcotics (codeine, oxycodone-acetaminophen combination)
- Nerve pain medications (gabapentin, pregabalin, duloxetine, tramadol)

Injection Treatment

- Epidural steroid injections
- Epidural anesthetic injections

Physical Measures

- Physical therapy
- Chiropractic/osteopathic manipulation
- Exercise or activity modifications

Surgical Treatment Options

Spinal Fusion Surgery

- Posterior lumbar fusion (PLF)
- Posterior lumbar interbody fusion (PLIF) & Transforaminal lumbar interbody fusion (TLIF)
- Anterior lumbar interbody fusion (ALIF)
- Extreme lateral interbody fusion (XLIF)

Discectomy

- Microdiscectomy
- Open discectomy

Disc Replacement Surgery

- Artificial disc replacement (ADR)

- **Minimal long term efficacy; mostly pain management**
- **Frequent and continuous need for treatment**
- **Very costly over sustained periods of treatment**
- **Significant adverse effects from oral and injectable medications**

- **Highly invasive, with surgical risk**
- **Variable efficacy (35%) with risk of long term disability**
- **Very expensive**

BRTX-100 SHOWS GREAT PROMISE TO TREAT COMPROMISED DISCS WITHOUT SURGERY

Description

- Targeted for patients whose pain and disabilities have not been alleviated by conservative treatments and face the prospect of surgery
- Product formulated from autologous hypoxic cultured mesenchymal stem cells (or MSCs) collected from the patient's bone marrow and co-administered with an autologous biomaterial carrier (human platelet lysate)
- **Production/Treatment Process (5 weeks):**
  - Physician extracts bone marrow and blood from patient's hip; unprocessed samples are shipped to BRT
  - BRT initiates culturing of stem cells, selecting and expanding cells that are able to survive in hypoxic (low oxygen) environments
  - BRT formulates and cryopreserves BRTX-100 with autologous platelet lysate. BRTX-100 is shipped back to the physician
  - Physician administers BRTX-100 in 30-min outpatient procedure

Key Attributes

- **One-time, intradiscal injection performed as a 30-minute outpatient procedure**
- **Autologous product minimizing safety concerns**
- **Potent hypoxic-cultured MSCs designed to survive in disc microenvironment**
- **Co-administered with biomaterial carrier (Platelet Lysate) to increase potency, viability and survivability**
- **Robust, scalable, highly-reproducible, proprietary formulation process**
- **Early evidence of improved efficacy and safety over alternatives**
- **Low cost and minimally invasive**

HUMAN DATA FROM STUDIES OF THERAPIES SIMILAR TO BRTX-100 SHOW REDUCED PAIN, INCREASED FUNCTION, AND AN ABSENCE OF SIGNIFICANT SAFETY ISSUES WITH A DURABLE RESPONSE


Centeno et al. J Transl Med (2017) 15:197 DOI 10.1186/s12967-017-1300-y

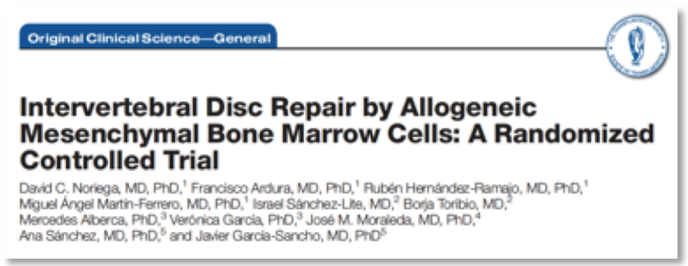
Journal of Translational Medicine

RESEARCH Open Access

Treatment of lumbar degenerative disc disease-associated radicular pain with culture-expanded autologous mesenchymal stem cells: a pilot study on safety and efficacy

Christopher Centeno[1,2], Jason Markle[1], Ehren Dodson[2*], Ian Stemper[2], Christopher J. Williams[1], Matthew Hyzy[1], Thomas Ichim[3] and Michael Freeman[4]

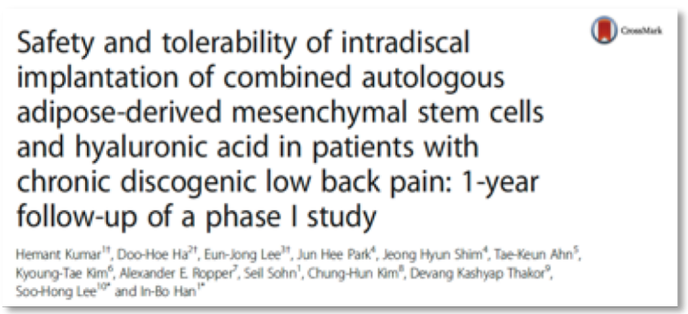
- **Description**: 33 patients diagnosed with degenerative disc disease received an intradiscal injection of autologous, hypoxic cultured, bone marrow-derived MSCs (15.1 to 51.6 million cells) as part of a US based investigator initiated study. Prospective registry data was obtained at multiple time intervals up to 6 years post-treatment.
- **Results:** Study results on the use of hypoxic cultured autologous MSCs demonstrated no safety issues, substantially reduced pain, increased function, and reduced disc bulge size. Pain change score relative to baseline were significant at 3, 36, 48, 60 and 72 months post-treatment. Single assessment numeric evaluation ratings showed improvement of 60% at 3 years post-treatment. Functional rating index post-treatment change scores exceeded the minimally clinically important difference. 85% of the patients (n=20) who underwent post-treatment MRIs had a 25 % reduction in disc bulge size.


Original Clinical Science—General

Intervertebral Disc Repair by Allogeneic Mesenchymal Bone Marrow Cells: A Randomized Controlled Trial

David C. Noriega, MD, PhD,[1] Francisco Ardura, MD, PhD,[1] Rubén Hernández-Ramajo, MD, PhD,[1] Miguel Ángel Martín-Ferrero, MD, PhD,[1] Israel Sánchez-Lite, MD,[2] Borja Toribio, MD,[3] Mercedes Alberca, PhD,[3] Verónica García, PhD,[3] José M. Moraleda, MD, PhD,[4] Ana Sánchez, MD, PhD,[5] and Javier García-Sancho, MD, PhD[5]

- **Description**: 24 patients with chronic back pain were randomized into either treatment group or control group. Treatment group received 25x10^6 bone marrow-derived MSCs. Clinical outcomes were followed up for 1 year and included evaluation of pain, disability and quality of life.
- **Results:** Feasibility and safety of a 25x10^6 cell dose was confirmed and clinical efficacy was identified. MSC-treated patients displayed a quick and significant improvement in algo-functional indices versus controls. VAS and ODI were significantly reduced at 3 months after MSC transplantation and the improvement maintained at 6 and 12 months. Degeneration, quantified by Pfirrmann grading, improved in the MSC-treated patients and worsened in the control group


Safety and tolerability of intradiscal implantation of combined autologous adipose-derived mesenchymal stem cells and hyaluronic acid in patients with chronic discogenic low back pain: 1-year follow-up of a phase I study

Hemant Kumar[1†], Doo-Hoe Ha[2†], Eun-Jong Lee[3†], Jun Hee Park[4], Jeong Hyun Shim[4], Tae-Keun Ahn[5], Kyoung-Tae Kim[6], Alexander E. Ropper[7], Seil Sohn[1], Chung-Hun Kim[8], Devang Kashyap Thakor[9], Soo-Hong Lee[10*] and In-Bo Han[1*]

- **Description**: 10 patients with chronic back pain received a single injection of 20x10^6 and 40x10^6 of autologous adipose-derived MSCs. Safety and clinical outcomes were evaluated by assessing VAS, ODI, Short Form-36 (SF-36), and imaging at regular intervals over 1 year.
- **Results:** No serious or adverse events were reported during the 1-year follow up period. VAS, ODI, and SF-36 scores significantly improved in both dosing cohorts compared to base line. In addition three patients of the ten included in the study were determined to have increased water content based on an increased diffusion coefficient on diffusion MRI.

INDEPENDENT CONSULTING FIRM HAS VALIDATED BRTX-100 APPROACH

DefinedHealth
a CELLO HEALTH business

In May 2018, Defined Health conducted a study with relevant key opinion leaders (KOLs) to provide an informed, independent review of BRTX-100, its supporting data, and its potential to treat cLDD. Key findings include:

- **Stem-cell therapies have "great potential" to treat cLDD (and related therapeutic areas)**
- **Autologous products (as opposed to allogeneic) are the "future of cell-based therapies"**
    - Autologous approaches contain reduced risk of host rejection and infection and are more durable
- **KOLs had positive reactions to preclinical/clinical data and were "optimistic that the clinical data presented to date is likely to be mirrored in future [trials]"**
- **KOLs anticipate that if approved, BRTX-100 would be "integrated into the standard of care for eligible cLDD patients"**

BRTX-100 IS SAFER AND MORE POTENT THAN ITS CLOSEST COMPARABLE

	biorestorative therapies	mesoblast		BRTX-100's Advantages
Drug name and description	**BRTX-100**: adult stem cell biologic, administered via 30-minute outpatient intradiscal injection	**MPC-06-ID**: adult stem cell biologic, administered via 30-minute outpatient intradiscal injection		
Key attributes				
	Autologous – uses patients own stem cells	**Allogeneic** – uses cadaver-derived human stem cells (not from patient)	✓	Autologous cells means low to no risk of rejection, greater safety profile (introduction of viral/genetic), streamlined regulatory path
	Hypoxic cultured – in low oxygen environment (5%)	**Normoxic cultured** – with normal oxygen environment (~20%)	✓	Hypoxic culturing creates increased cell proliferation, greater plasticity, increased paracrine effect and increased cell survival after application
	Autologous Platelet Lysate Carrier	**Hyaluronic Acid** Carrier	✓	Autologous platelet lysate provides growth factors that interact with the cells, allowing for better cell survival
	100% Animal-Free Manufacturing Process	**Animal Products** Used in Manufacturing Process	✓	Low to no risk of safety concerns related to immunological and zoonotic transmission
Stage of Development	**Phase 2** clinical trial approved under active IND 17275	**Phase 3** clinical trial currently enrolling participants	✓	Autologous approach leader

CHRONIC BACK PAIN IS A $100B MARKET IN U.S. ALONE, WITH SPINAL FUSION COSTS APPROACHING $40B ANNUALLY

“Back pain is a $100-billion-per-year industry in the US.”[1]

“Spinal fusion surgery is the form of elective surgery that people spend the most on in the US, costing a total of $40 billion per year. The problem is, it rarely works.”[2]

250 million

American adult population

25 million

American adults with chronic lower back pain prevalence

12 million

American adults with diagnosed and treated disc degeneration

5.6 million

With significant radiographic, not always symptomatic, abnormalities

500,000

Spinal fusion surgeries per year

1 Katz JN. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. J Bone Joint Surg Am. 2006;88 (Suppl 2):21–24.
2 The $100 billion per year back pain industry is mostly a hoax, (Quartz, June 26, 2017) *available at* https://qz.com/1010259/the-100-billion-per-year-back-pain-industry-is-mostly-a-hoax/

OUR ANALYSIS INFERS PRICING CAN EXCEED $25K PER TREATMENT, ACHIEVING HIGHER QUALITY OUTCOMES AT LOWER COST THAN CURRENT STANDARDS OF CARE

Conservative Treatments (OFTEN RECURRENT)

Oral Medication Treatment

$1,000-$2,000 annually

+

Injection Treatment

$8,000 annually

($2,000 per injection, 2 injections per treatment, semi-annual treatment)

+

Physical Measures

$20,000 annually

(~$200 per session x 2 sessions per week)

Surgical Treatments (WITH RE-OP RATES OFTEN 10-20%)

Spinal Fusion Surgery

$80,000-$150,000

Discectomy

$20,000-$50,000

Disc Replacement Surgery

$80,000-$150,000

$25,000 for a single treatment using BRTX-100 is easily justifiable based on the cost of alternatives

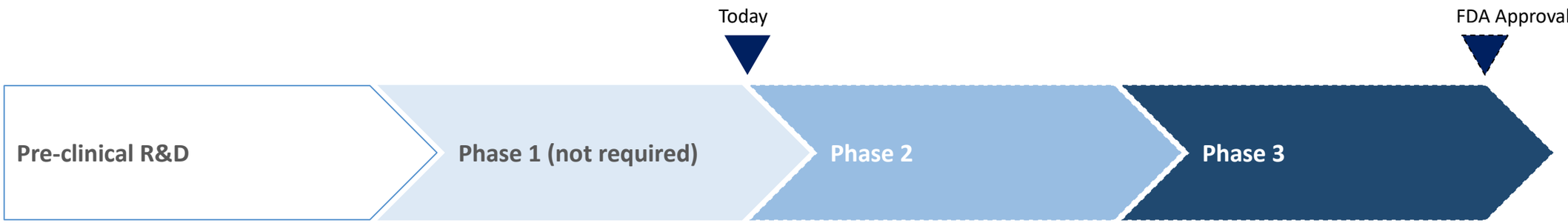
Compares favorably to conservative treatment costs, which persist for years

AND

Significantly less expensive than the most common surgical procedures

- Low Back Treatment Trends Affecting Health Insurance Payers (ChiroCare, 2014)
- Degenerative Disc Treatment Cost, available at http://health.costhelper.com/degenerative-disc.html
- https://www.mdsave.com/procedures/epidural-steroid-injection/d583f9c4

BRTX-100 HAS AN ACTIVE IND AND AUTHORIZATION FROM THE FDA TO BEGIN A PHASE 2 TRIAL



- BRT secures relevant license from Regenerative Sciences in 2012
- Develops commercial and scalable BRTX-100 product
- Proceeds with clinical strategy to leverage prior human experience using MSCs to treat cLDD

- BRT submits IND
- FDA authorizes commencement of Phase 2 trial

- BRT ready to begin double-blind, placebo-controlled, randomized Phase 2 study
- Primary endpoints are measured at 6 months, with follow ups at 12 and 24 months

- In the event of a successful Phase 2 trial, expected value of BRTX-100 should increase significantly

BRTX-100'S PHASE 2 TRIAL IS A DOUBLE-BLINDED, PLACEBO CONTROLLED, RANDOMIZED STUDY

- **Study includes 72 subjects (2:1 product to placebo)**
- **Included subjects will have only one diseased disc**
- **Endpoints are based on a 30% reduction in pain and a 30% increase in function**
  - Considered by FDA and key opinion leaders as minimal clinically important differences
  - Functional improvement based on the Oswestry questionnaires (ODI)
  - Pain reduction measured using the Visual Analogue Scale (VAS)
- **Co-primary endpoints are measured at 6 months, with follow ups at 12 and 24 months**
  - MRI evaluations—at screening and semi-annually thereafter—will also be used
  - Phase 2 expected completion in 2022
- **Comparative control group consists of saline injection; platelet lysate arm can be added to Phase 2, or conducted in Phase 3**

PATENTS PENDING AND DATA EXCLUSIVITY REPRESENT BARRIERS TO COMPETITION AND ENHANCE MARKET OPPORTUNITY

IP and legislative protections include:

- **Licensed patent application covering methods of culturing cells under hypoxic conditions and their use in avascular areas, currently being reviewed by the US Patent and Trademark Office (PTO)**
  - Pending claims include method of treatment and method of manufacture
  - BRT has responded to the PTO's latest action, and is awaiting its response
- **As a reference product, BRTX-100 will be afforded 12 years of data exclusivity via the Biologics Price Competition and Innovation Act**

K&L Gates, a highly reputable law firm in biotechnology intellectual property, is representing BRT in its patent prosecutions, with John Desmarais, a BRT board member and well-known patent counsel supervising the work

PHASE 2 CLINICAL TRIAL TO COST $18M

(thousands)	Year 1	Year 2	Year 3	Total
Clinical Development				
Patient Costs		$3,089		**$3,089**
Salaries/Consultants	$313	$313	$250	**$875**
CRO	$598	$2,763	$2,357	**$5,717**
Manufacturing/Quality	$1,593	$3,286	$738	**$5,617**
G&A	$510	$720	$720	**$1,950**
R&D	$200	$300		**$500**
Total	**$3,213**	**$10,470**	**$4,065**	**$17,748**

SUMMARY AND KEY TAKEAWAYS

FDA granted authorization to commence a Phase 2 clinical trial using BRTX-100 under active IND 17275

Independent review was optimistic that existing clinical results are likely to be mirrored in Phase 2 trial

BRTX-100 is targeting a large indication that has few comparable treatment options

- 25M Americans suffer from chronic lower back pain, with 5.6M experiencing major disc issues (i.e. protrusion, bulging) and 500K undergoing spinal fusion surgery each year
- Less expensive and likely more efficacious than current treatments

Pending patent applications, as well as 12 years of exclusivity post launch provide significant barriers to competition

BRT is offering a partner the opportunity to acquire an interest in the development of BRTX-100

The opportunity represents market share preservation and potentially meaningful growth

biorestorative therapies

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