mesoblast
the regenerative medicine company

Chronic Low Back Pain: MPC-06-ID

Strategic Development & Commercialization Partnership with Grünenthal for Europe & Latin America

10 September 2019

Nasdaq: MESO ASX: MSB

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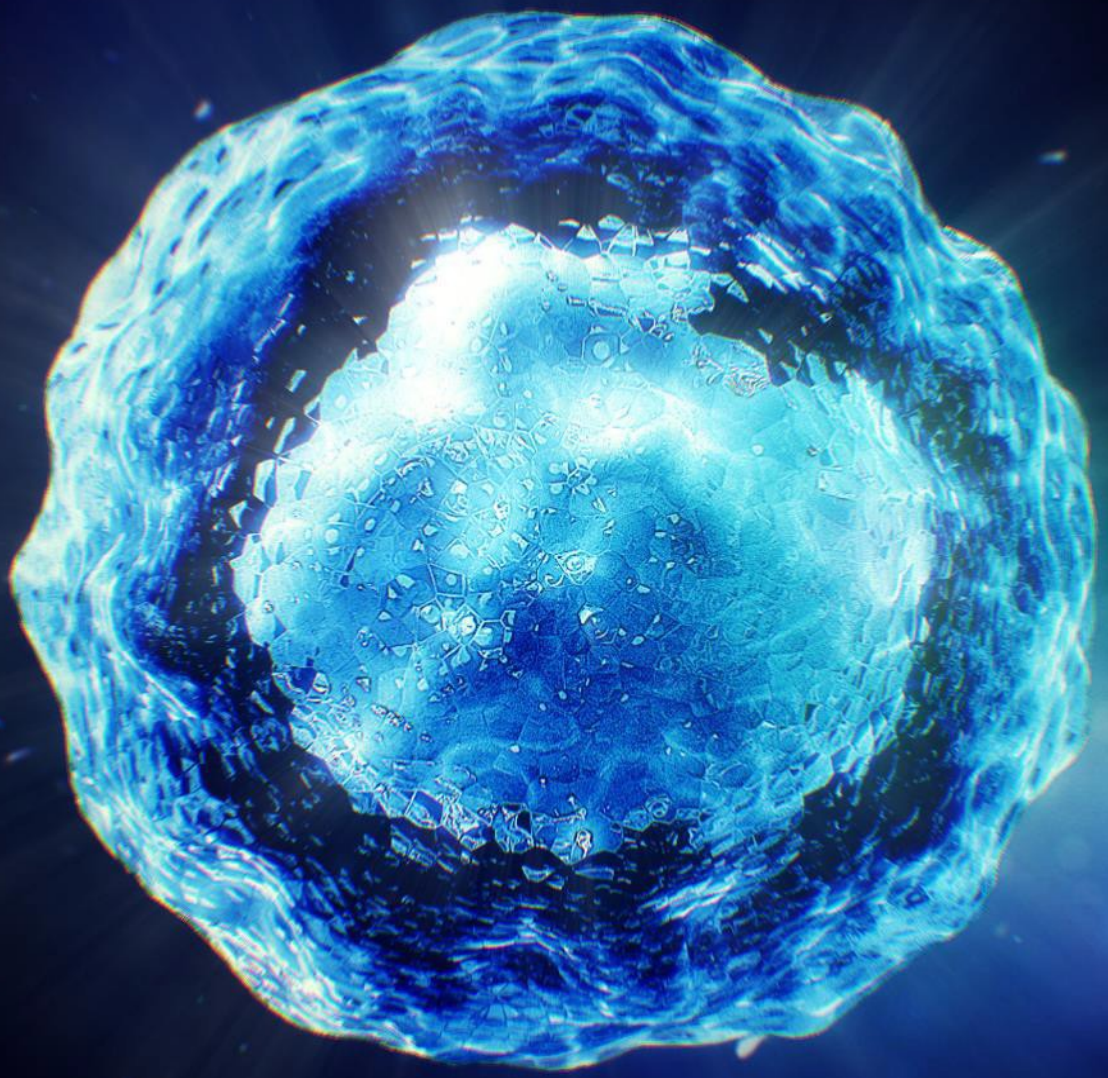
Our Mission

Mesoblast is committed to bringing to market innovative cellular medicines to treat serious and life-threatening illnesses



Corporate History

Over a decade of scientific, manufacturing, clinical development and corporate development experience targeted at bringing to market allogeneic, off-the-shelf cellular medicines for inflammatory diseases

2004:
Mesoblast founded in Melbourne, Australia and listed on the ASX

2010:
Entered into strategic alliance with Cephalon to develop and commercialize MPC therapeutics

2011:
Entered into manufacturing partnership with Lonza Group in Singapore for MPC medicines

2013:
Acquired MSC business from Osiris Therapeutics with trailing earn-out and milestone payments

2014:
Granted manufacturing pioneer status by Economic Development Board of Singapore

2015:
Dual listed on the Nasdaq

2016:
TEMCELL® HS Inj (MSC medicine) launched in Japan by Mesoblast licensee JCR

2017:
Entered licensing agreement with Takeda for the treatment of certain fistulae; in 2018 Alofisel® received approval in EU

2018:
Entered into partnership agreement with Tasly for cardiovascular assets in China

2019:
Smith & Nephew acquired Osiris Therapeutics, became Mesoblast's licensor for the MSC business

2019:
Initiated first BLA submission to US FDA: remestemcel-L (MSC) for steroid refractory acute graft versus host disease (aGVHD)

2019:
Strategic Partnership in Chronic Low Back Pain in Europe & Latin America with Grünenthal

Premier Global Cellular Medicines Company

Innovative Technology Platform[1]	Late Stage Pipeline	Commercialization
▪ Innovative technology targets some of the most severe disease states refractory to conventional therapies ▪ Well characterized multimodal mechanisms of action ▪ Underpinned by extensive, global IP estate	▪ Initiated rolling filing with US FDA for approval for steroid-refractory aGVHD ▪ Two Phase 3 product candidates – heart failure and back pain – with near term US trial readouts ▪ Heart failure Phase 3 product candidate partnered in China	▪ Building US sales force for aGVHD launch, if approved ▪ Industrial-scale manufacturing to meet commercial demand ▪ First approved products commercialized by licensees in Japan[2] and Europe[3] ▪ Continued growth in royalty revenues from strategic partnerships

1. Mesenchymal precursor cells (MPCs) and their culture-expanded progeny mesenchymal stem cells (MSCs).
2. Licensee JCR Pharmaceuticals Co., Ltd. received the first full PMDA approval for an allogeneic cellular medicine in Japan and markets this product under its trademark, TEMCELL® Hs Inj.
3. Licensee Takeda received first central marketing authorization approval from the European Commission for an allogeneic stem cell therapy and markets this product under its trademark Alofisel®.

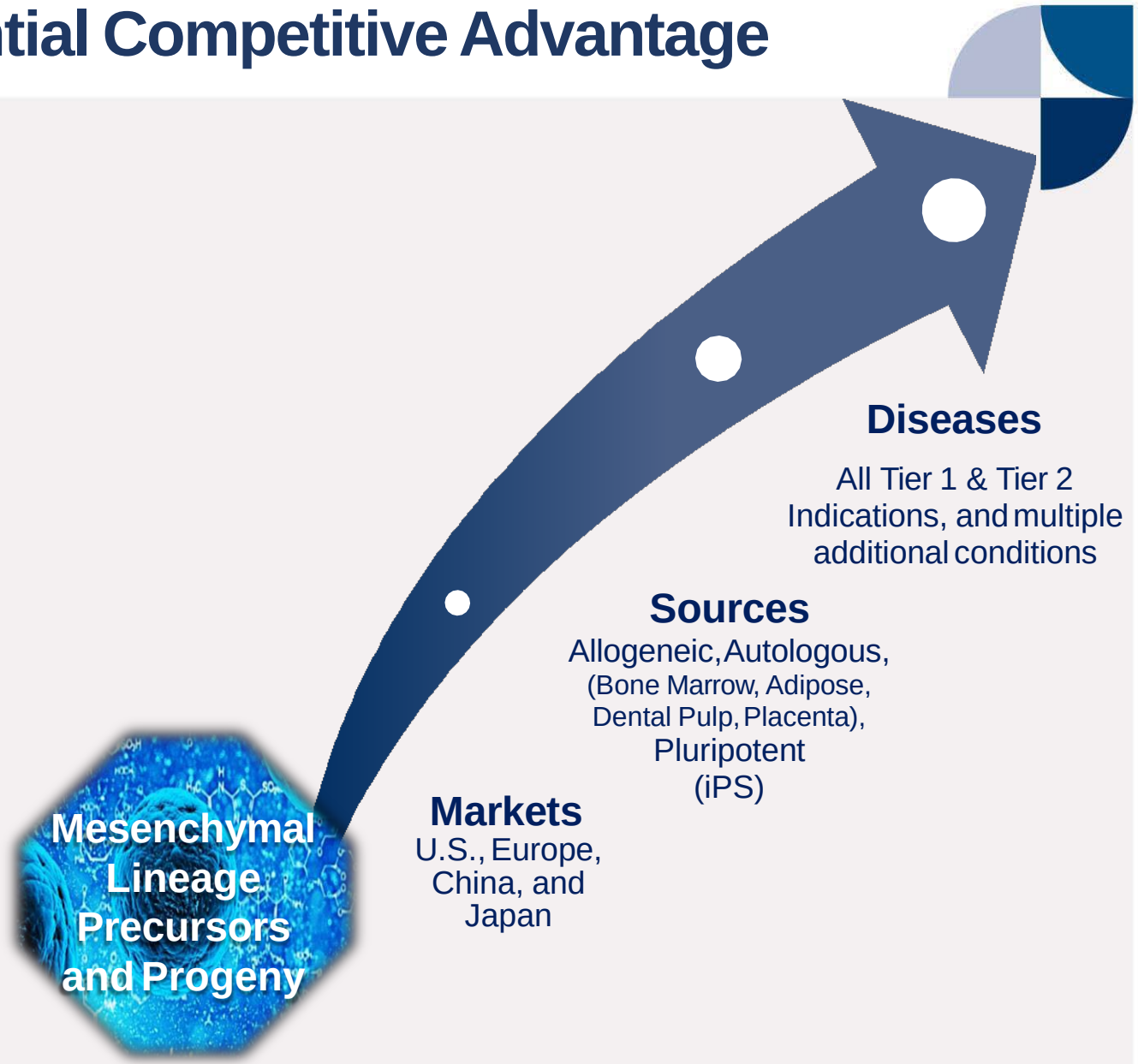
Commercial Scale Manufacturing Capability

- Scalable allogeneic “off-the-shelf” cellular medicine platform
- Manufacturing meets stringent criteria set by international regulatory agencies including FDA and EMA
- Robust quality assurance processes ensure final product with batch-to-batch consistency and reproducibility
- Culture expansion scalable for near term commercial needs
- Proprietary xeno-free technologies being developed to enable sufficient yields for long term global commercial supply
- Next generation processes using 3D bioreactors to reduce labor and drive down cost of goods

Lonza contract manufacturing facility in Singapore

Global IP Estate Provides Substantial Competitive Advantage

- ~995 patents and patent applications (68 patent families) across all major jurisdictions
- Covers composition of matter, manufacturing, and therapeutic applications of mesenchymal lineage cells
- Enables licensing to third parties for different indications, when in alignment with our corporate strategy e.g.TiGenix (subsequently acquired by Takeda)
- Provides strong global protection against competitors seeking to develop products in areas of core commercial focus



Commercial and Late-Stage Product Pipeline

MARKETED

PLATFORM	PRODUCT	THERAPEUTIC AREA		APPROVAL	COMMERCIAL RIGHTS
MSC (Bone Marrow)	TEMCELL® HS Inj[1]	Acute Graft Versus Host Disease	1st allogeneic regen med approved in Japan	✓	JCR Japan
MSC (Adipose)	Alofisel®[2]	Perianal Fistula	1st allogeneic regen med approved in Europe	✓	Takeda Global

IN DEVELOPMENT

PLATFORM	PRODUCT CANDIDATE	THERAPEUTIC AREA	PRE-CLINICAL / PHASE 2 / PHASE 3		COMMERCIAL RIGHTS
MSC suite	Remestemcel-L	Acute Graft Versus Host Disease Crohn's Disease Knee Osteoarthritis		BLA submission to FDA underway	mesoblast the regenerative medicine company
MPC suite	Revascor	**Advanced HF** (Class II/III) **End-Stage HF** (Class III/IV)			TASLY China mesoblast ROW
	MPC-06-ID	Chronic Low Back Pain			GRÜNENTHAL Europe Lat Am mesoblast ROW
	MPC-300-IV	Rheumatoid Arthritis Diabetic Nephropathy			mesoblast the regenerative medicine company

This chart is figurative and does not purport to show individual trial progress within a clinical program

1. TEMCELL® Hs. Inj. is a registered Trademark of JCR Pharmaceuticals Co Ltd
2. Alofisel® is a registered Trademark of Takeda Pharmaceuticals

Key Terms of the Strategic Partnership with Grünenthal GmbH

Grünenthal takes exclusive license to develop and commercialise MPC-06-ID

- **Indication:** for discogenic chronic back pain, disc degeneration and/or functional disability
- **Territory:** Europe and Latin America/Caribbean

In consideration, Mesoblast will receive

- **Up to US$150 million** in upfront and milestone payments prior to product launch, as well as further commercialisation milestone payments.
- Payments include commitments up to **US$45 million within the first year** comprising US$15 million on signing, US$20 million on receiving regulatory approval to begin a confirmatory Phase III trial in Europe, and US$10 million on certain clinical and manufacturing outcomes
- **Cumulative milestone payments could exceed US$1 billion** depending on the final outcome of Phase III studies and patient adoption.
- Mesoblast will also receive **tiered double digit royalties** on product sales.
- Mesoblast retains the rights for the rest of world, including the US and Japan markets

Transaction Benefits to Mesoblast

- ✓ **Strong commercial partner**
  - Delivers commercialization, distribution, sales & marketing
  - Field force comprises around 1,600 people across Europe, Latin America & US – overall focus is on pain – visited nearly 300,000 stakeholders in 2018 (physicians, pharmacists & health administrators)
  - Provides knowledge and knowhow in manufacturing, regulatory affairs (Europe in particular)
- ✓ **Advances approval pathway**
  - Provides funding for Phase 3 trial in Europe reducing Mesoblast cash outflow
  - Mesoblast and Grünenthal will collaborate on the study design for a confirmatory Phase 3 trial in Europe
  - Confirmatory European and US (currently ongoing) Phase 3 trials are expected to support regulatory approval in both Europe and US
- ✓ **Transaction focuses on Europe**
  - Mesoblast maintains rights to all other geographic markets, including US, Japan and China for additional partnering opportunities to maximize shareholder return
- ✓ **Third party endorsement provides validation of technology platform**

Grünenthal – Global Leader in Pain Management

#2 Europe[1]

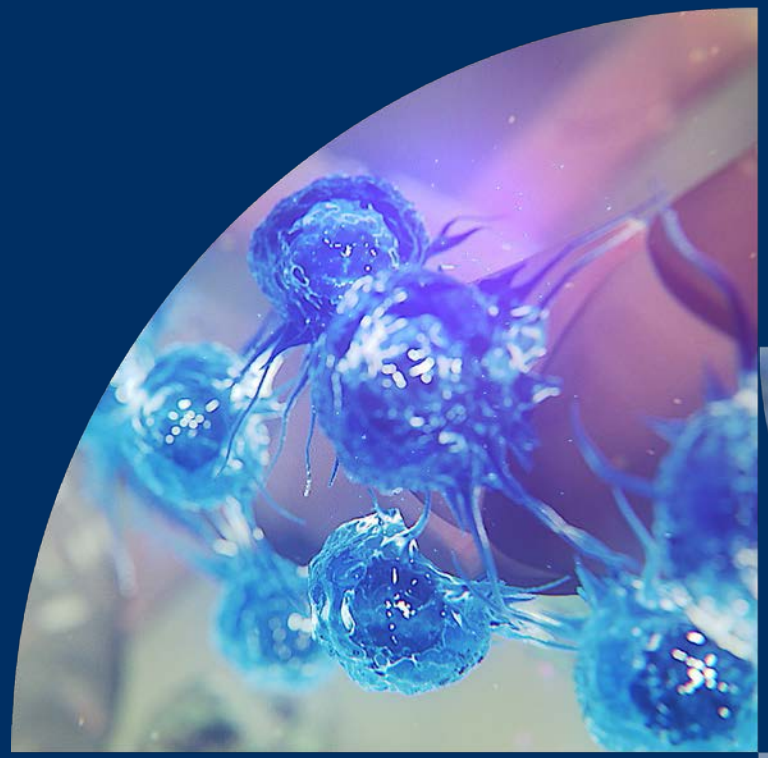
#1 Latin America[1]

Overview

- Grünenthal is a global leader in pain management and related diseases, with 50 years in pain research
- A long track record of bringing innovative treatments and state-of-the-art technologies to patients worldwide
- Strong and capable team with c. 4,900 employees worldwide
- Solid revenue base with € 1.3 billion in 2018 (c. US$1.5 billion)
- Commercial presence in 30 countries across Europe, Latin America and the US
- Products are sold in more than 100 countries

Source: Grünenthal

1. The ranking based on corporation sales (fixed EUR acc. IQVIA – Status 2018-Q4) in the area of major centrally acting analgesics.



MPC-06-ID for Chronic Low Back Pain due to Degenerative Disc Disease – Commercial Opportunity

MPC-06-ID: A New Paradigm for Treatment of Chronic Low Back Pain Due to Degenerative Disc Disease

Burden of Illness

- Back pain causes more disability than any other condition[1]
- Inflicts substantial direct and indirect costs on the healthcare system[1], including excessive use of opioids in this patient population

Minimal Treatment Options

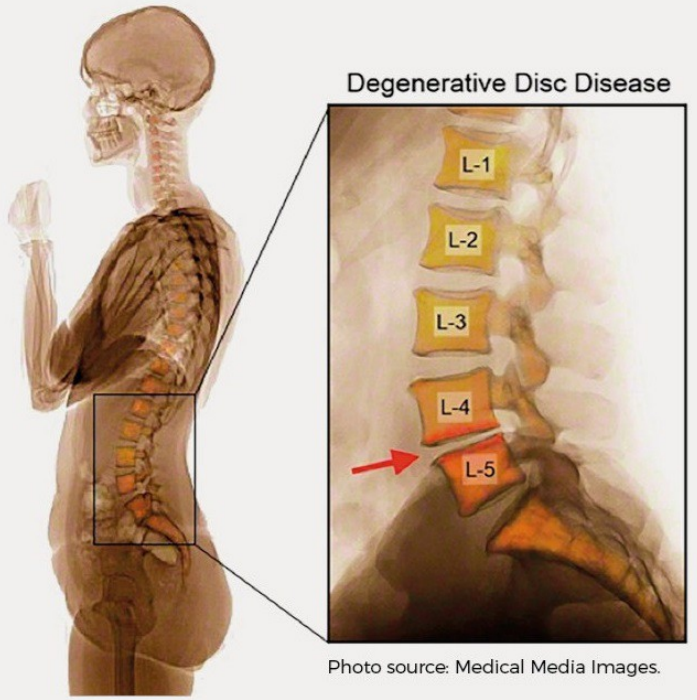
- Minimal treatment options for patients with chronic low back pain (CLBP) who fail conservative therapy include opioids and surgery
- 50% of opioid prescriptions are for CLBP

Unmet Need

- Disease modifying therapy for durable improvement in pain and function has potential to prevent progression to opioid use or surgical intervention

Market Opportunity

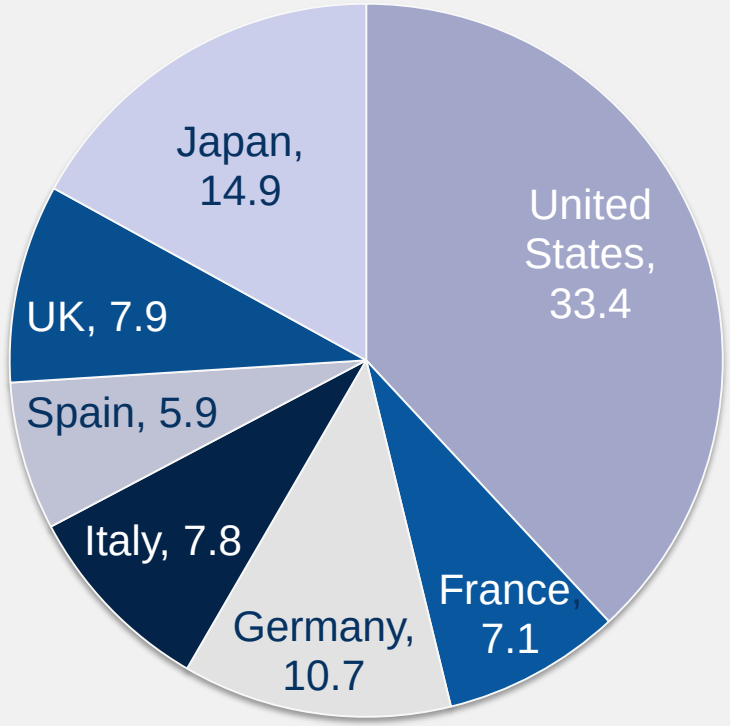
- Over 7m patients are estimated to suffer from CLBP due to degenerative disc disease (DDD) in each of the U.S. and E.U.5 [3,4,5]
- MPC-06-ID development program targets over 3.2m patients in U.S. and 4m in E.U.5 with moderate to severe disease



1. Williams, J., NG, Nawi, Pelzter, K. (2015) Risk factors and disability associated with low back pain in older adults in low-and middle-income countries. Results from the WHO Study on global ageing and adult health (SAGE). PloS One. 2015; 10(6): e0127880., 2. Simon, J., McAuliffe, M., Shamim, F. (2015) Discogenic Low Back Pain. Phys Med Rehabil Clin N Am 25 (2014)305–317., 3.Decision Resources: Chronic Pain December 2015., 4. LEK & NCI opinion leader interviews, and secondary analysis., 5. Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014., 6. HealthCare Utilization and Cost of Discogenic Lower Back Pain in the US – Anthem/HealthCore.

Approx. 10 – 15% of Adult Population Suffers from Chronic Lower Back Pain Across the 7 Major Pharmaceutical Markets

Prevalence of Chronic Lower Back Pain (millions)[1]

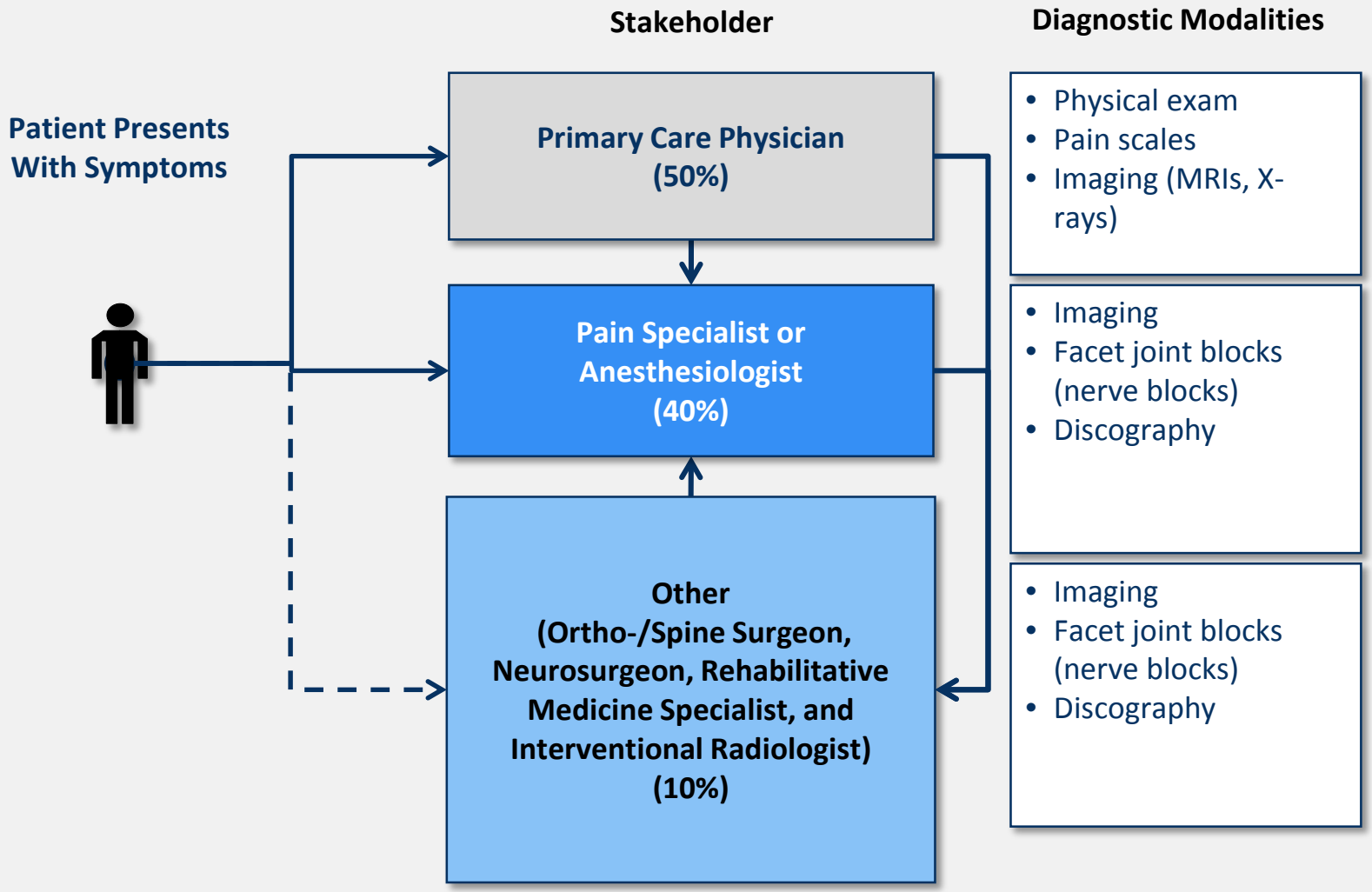


- US prevalence 33.4 million, EU5 39.4 million, Japan 14.9 million
- Growth in the prevalence of CLBP in the U.S. going forward will likely mirror the growth rate of the overall population[2]
- CLBP is most common within the 45-64 age group
- CLBP is nearly twice as common in women as in men in the same age group
- Higher percentage of CLBP patients seeking medical care in the EU3 (~70-80%) compared to the U.S. (~55 – 60%) mainly driven by the broader healthcare coverage in the EU3
  - "… Most of the patients with CLBP will see a doctor, because medical care is free in Germany …"

    Orthopedist, Private practice,

[1] Decision Resources: Chronic Pain Report 2015
[2] LEK Primary / Secondary Research 2013

US/EU Patient Journey – 50% of Patients With Moderate-to-Severe CLBP Progress To Specialists For Diagnosis And Treatment Of Discogenic Cause



Navigant: Commercial Assessment for a Proprietary Cell-Based Therapy for DDD in the U.S. and the EU3 – August 2014.

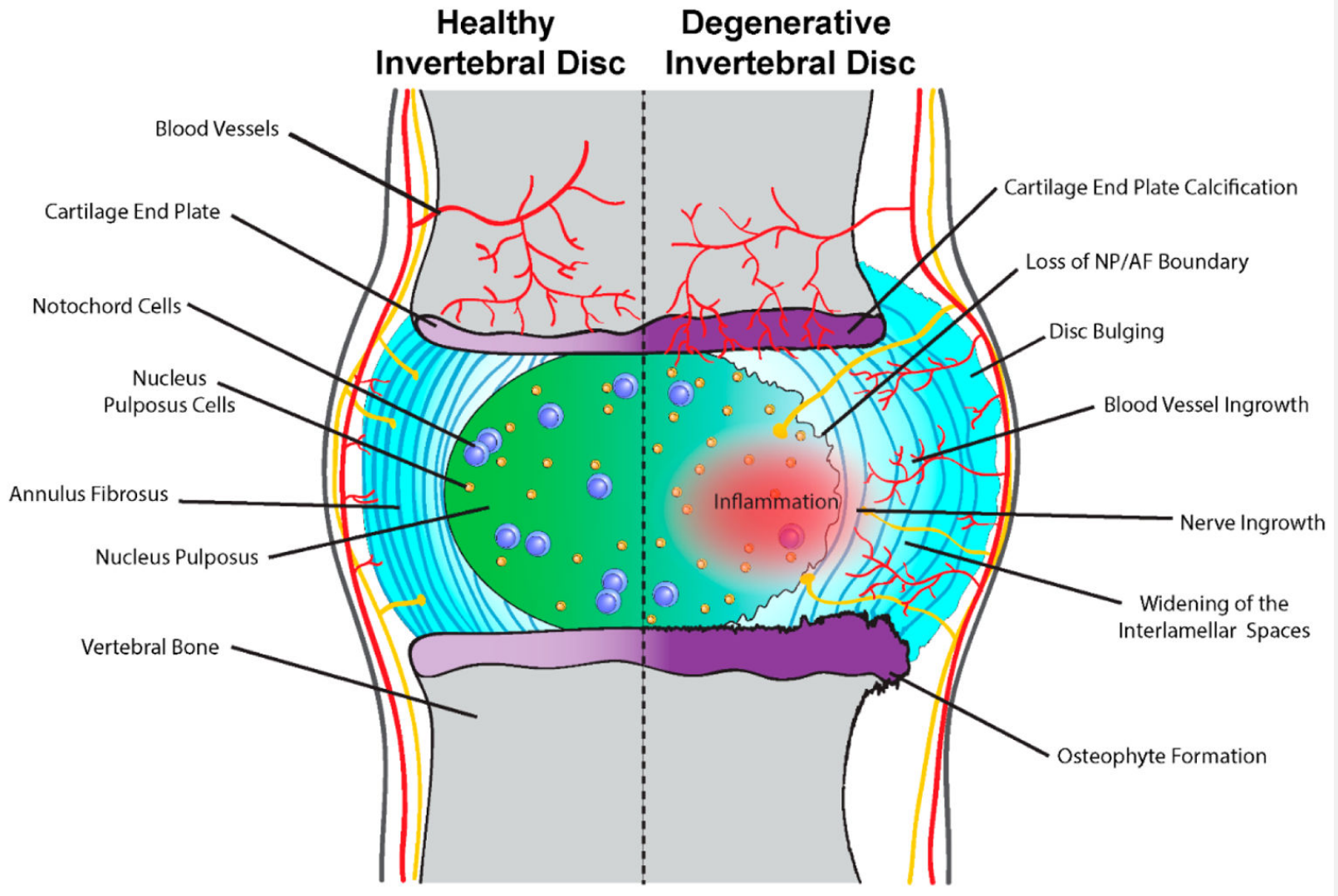
Current Patient Treatment Journey (US/EU) for Discogenic CLBP (DCLBP): MPC-06-ID Potential First-Line for DCLBP Refractory to Conservative Treatments

MPC-06-ID: targeting moderate-to-severe DCLBP

	Conservative treatments	Opioid analgesics	Interventional therapies	Surgeries
Products	▪ NSAIDs ▪ Physical therapy ▪ Chiropractic treatments ▪ Acupuncture ▪ Anticonvulsants (e.g., gabapentin)	▪ Weak opioid analgesics (e.g., tramadol) ▪ Strong opioid analgesics (e.g., oxycodone)	▪ Epidural steroid injections (off-label) ▪ Radio frequency ablation ▪ Spinal cord stimulation ▪ Intrathecal pumps	▪ Spinal fusion ▪ Disc replacement

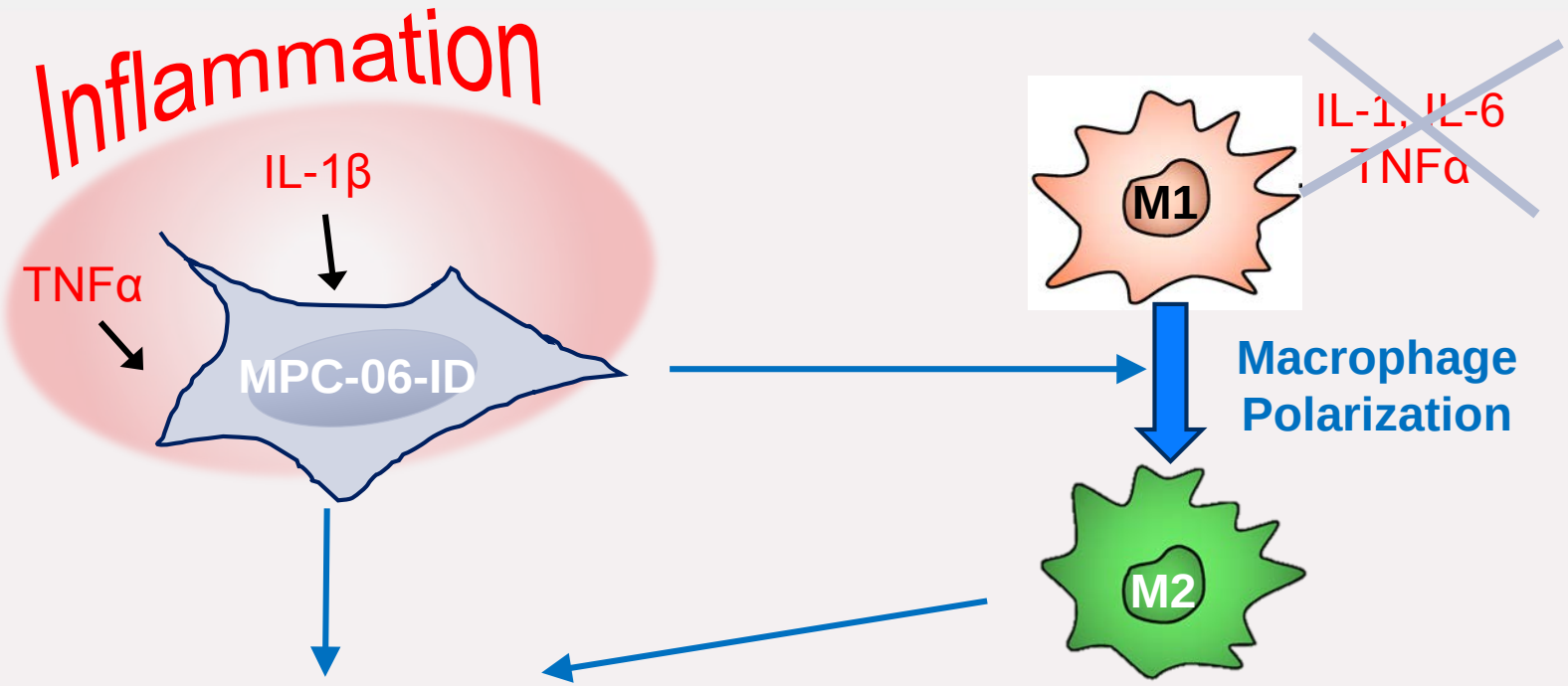
Chronic Low Back Pain

Inflammation is at the Core of Degenerative Disc Disease

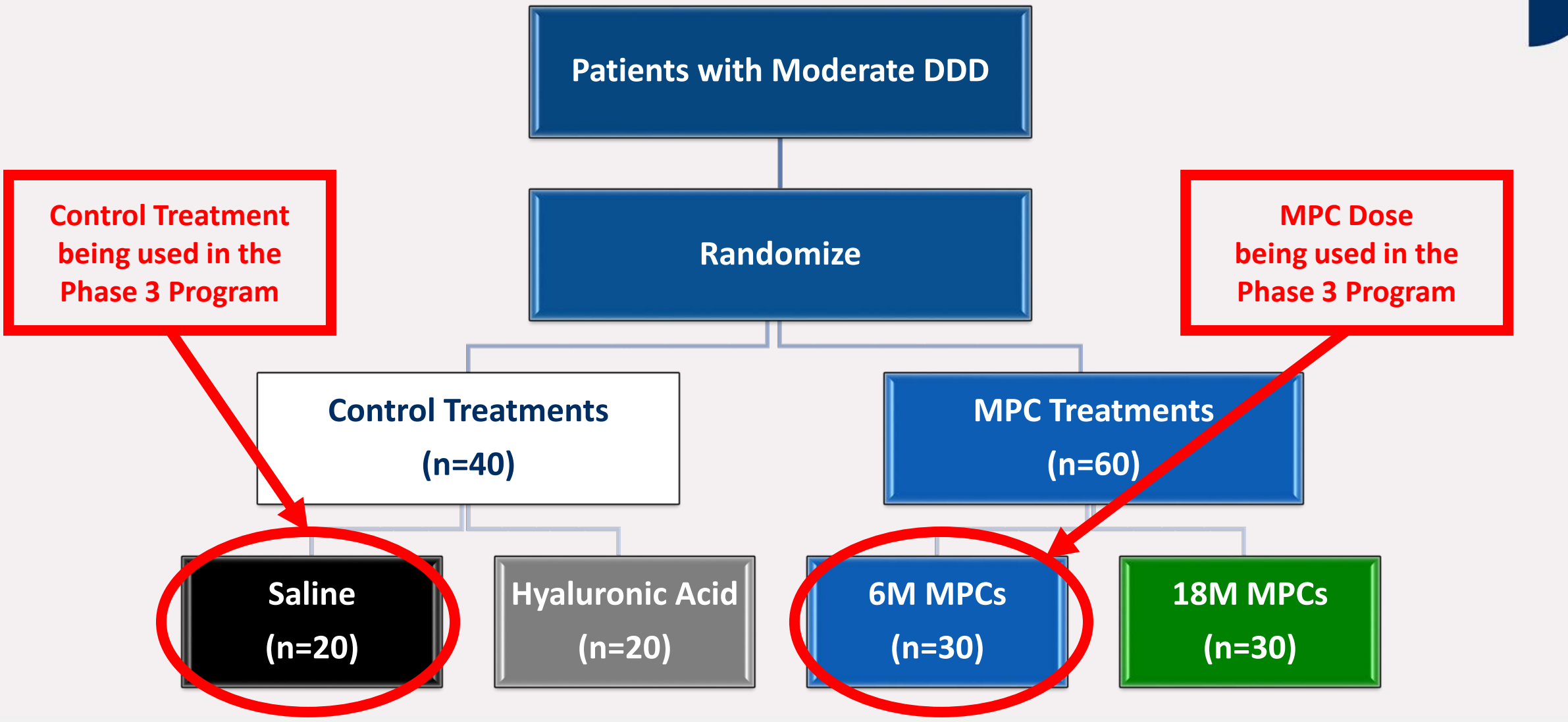


McCann MR and Seguin CA. Notochord Cells in Intervertebral Disc Development and Degeneration. J. Dev. Biol. **2016**, *4*(1), 3; doi:10.3390/jdb4010003

MPC-06-ID: Potential Mechanisms of Action in Treating Inflammatory Disc Disease



Phase 2 Clinical Trial – Randomized Patient Allocation



Phase 2 Clinical Trial

Clinical Study Patient Population

A prospective, multicenter, double blinded, controlled clinical study comparing two doses of immunoselected, culture-expanded, nucleated, allogeneic MPCs when combined with hyaluronic acid to two control intradiscal injections in subjects with chronic low back pain (> 6 months) due to moderate DDD at one lumbar level from L1 to S1 and unresponsive to conservative therapy for at least 3 months (including physical therapy)

Inclusion Criteria

- DDD with back pain >6 months
- Failed 3 Months Non-Operative Care
- Patients with a modified Pfirrmann score of 3, 4, 5 or 6
- With or without contained disc herniation up to a 3mm protrusion with no radiographic evidence of neurological compression
- Disc height loss of <30% compared to a normal adjacent disc based upon radiographic evaluation
- VAS Back pain >40
- ODI Score >30

Exclusion Criteria

- Modified Pfirrmann score of 1 & 2 or 7 & 8
- Clinically significant nerve or sacroiliac joint pain
- Clinically significant facet pain as determined by a diagnostic medial branch block or facet joint injection
- Symptomatic involvement of more than one lumbar disc level
- Discs with full thickness tears with free-flowing contrast through the annulus fibrosis
- Lumbar intervertebral foraminal stenosis at the affected level(s) resulting in clinically significant spinal nerve root compression

Phase 3 Responder Criteria Used in Post-Hoc Assessment of Phase 2 Clinical Trial Results

FDA Guidance on Minimally Important Change (MIC) for Pain and Function[1] using a composite endpoint consistent with the CDRH IDE guidance for spinal systems (i.e. spine fusion & artificial disc replacement

Questionnaire	Scoring Range	MIC (Absolute Cutoff)	MIC (% Improvement from Baseline)	MSB Phase 3 Cutoff
Visual Analog Scale (VAS)	0-100	15 points	30%	50%
Oswestry Disability Index (ODI)	0-100	10 points	30%	15 points

Mesoblast Phase 3 VAS and ODI Cutoffs

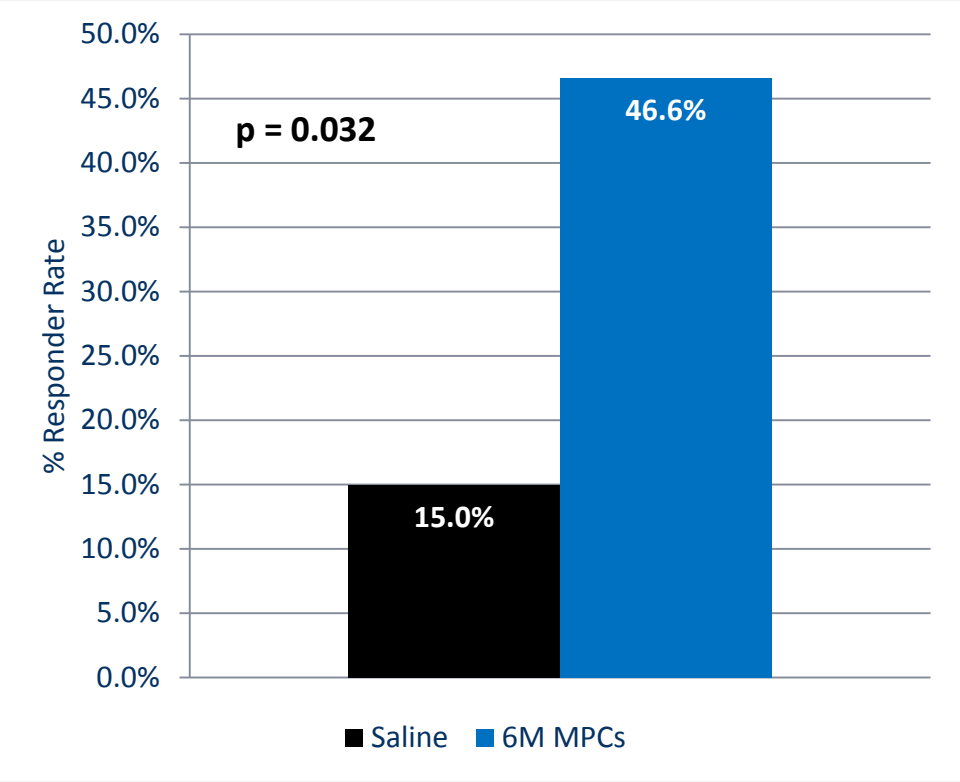
- 50% VAS reduction based upon KOL, regulatory, and payer input
- 15 point ODI reduction based upon previous FDA approvals of spine products, such as artificial disc replacements and spine fusion devices

1. Ostelo et al. (Spine Vol 33,no1.pp90-94) established MICs for the most frequently used questionnaires to evaluate pain and function in patients with chronic low back pain

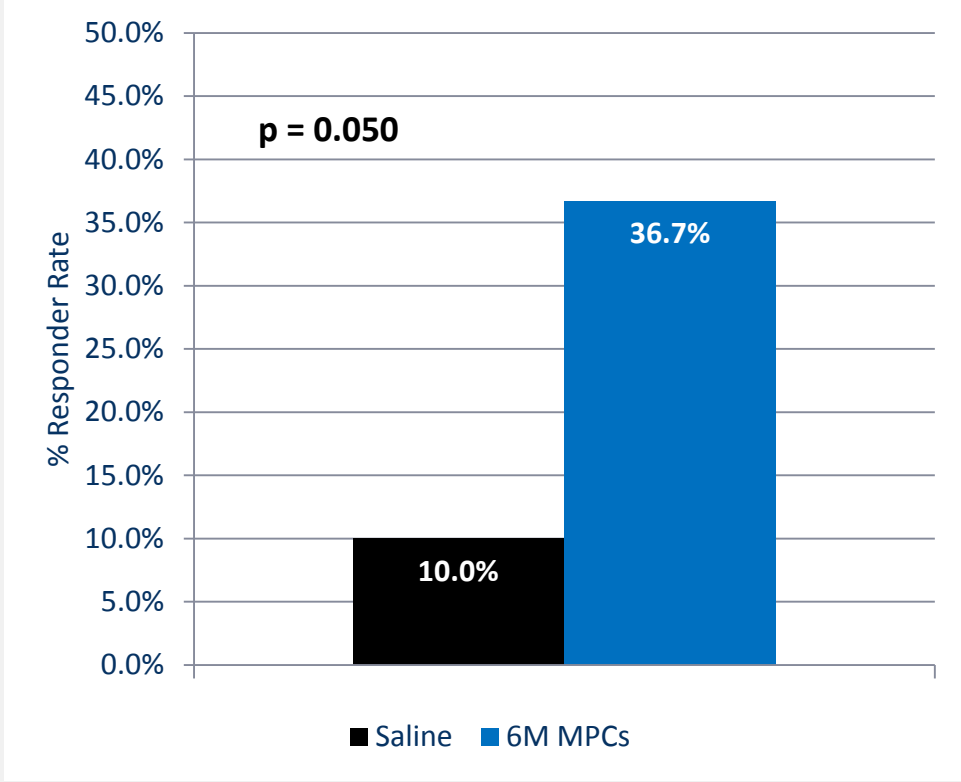
Chronic Low Back Pain

MPC-06-ID – Post-Hoc Phase 2 results provide target endpoints for Phase 3 trial

A: Phase 2: Treatment Success Responders[1,2] at 12 Months



B: Phase 2: Treatment Success Responders[1,2] at both 12 & 24 Months



1. Subjects with missing data are classified as non-responders.
2. Treatment Success Responders have a 50% reduction in LBP as measured by VAS AND a 15 point improvement in function as measured by ODI at a) 12 months, and b) both 12 and 24 months and no intervention through 24 months.

Phase 2 Clinical Trial – 36 Month Results

MPC therapy provides durable results through 36 months

- **Over 36 months:**
  - 82% of the 6 million MPC group who achieved the Phase 3 primary endpoint composite over 24 months maintained treatment success[1]
  - 86% of the 6 million MPC group who successfully met the Phase 3 pain responder criteria (50% pain reduction with no additional intervention at both 12 and 24 months) remained pain responders[2]
  - 92% of the 6 million MPC group who met the Phase 3 functional responder criteria (15-point reduction in ODI and no additional intervention at both 12 and 24 months) remained functional responders[3]

- **There were no significant differences in safety events cell-treated patients and controls over 36 months**

1. Composite Responder must have an optimal pain (50% reduction in VAS) AND function (15 point reduction in ODI) response AND no additional intervention.
2. Pain Responder must have an optimal pain response (50% reduction in VAS) AND no additional intervention.
3. Functional Responder must have an optimal functional improvement (15 point reduction in ODI) AND no additional intervention.

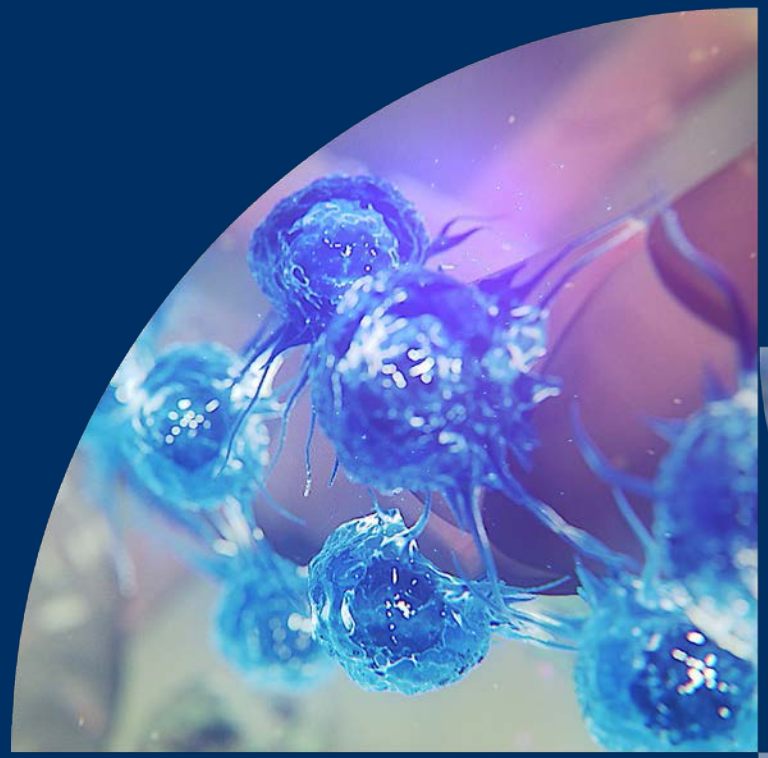
MPC-06-ID – Ongoing US Phase 3 Clinical Trial

- Three-arm study comparing 6-million MPC with or without hyaluronic acid (HA) against saline control
- Primary efficacy endpoint agreed to with FDA:
  - Overall Treatment Success Composite at both 12 and 24 months as measured by:
    - At least 50% reduction from baseline in Visual Analogue Scale (VAS) pain score at both 12 and 24 months post-treatment; and
    - At least a 15 point decrease from baseline in Oswestry Disability Index (ODI) function score at both 12 and 24 months post-treatment; and
    - No interventions affecting the treated disc through 24 months
- Study powered to show efficacy for both 6-million MPC arms (with and without HA)

404 patient 2:1 randomized Phase 3 trial completed enrollment March 2018; all patients have completed 12 month safety and efficacy follow-up

MPC-06-ID – Development Strategy for US & Europe

- Phase 3 trial in chronic low back pain completed enrollment in March 2018 with 404 patients randomized to receive MPC-06-ID or placebo. All patients have now completed at least 12 months of safety and efficacy follow-up.
- Follow-up continuing to a 24-month assessment of safety and efficacy by the first quarter of CY 2020, with readouts planned mid-CY2020
- Initiate confirmatory Phase 3 trial in Europe in partnership with Grünenthal
- Complete commercial manufacturing in partnership with Grünenthal
- Results of confirmatory Phase 3 clinical trials in US and Europe, together with commercial manufacturing, expected to support regulatory approval and commercial launches in both Europe and US for MPC-06-ID in chronic discogenic low back pain



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