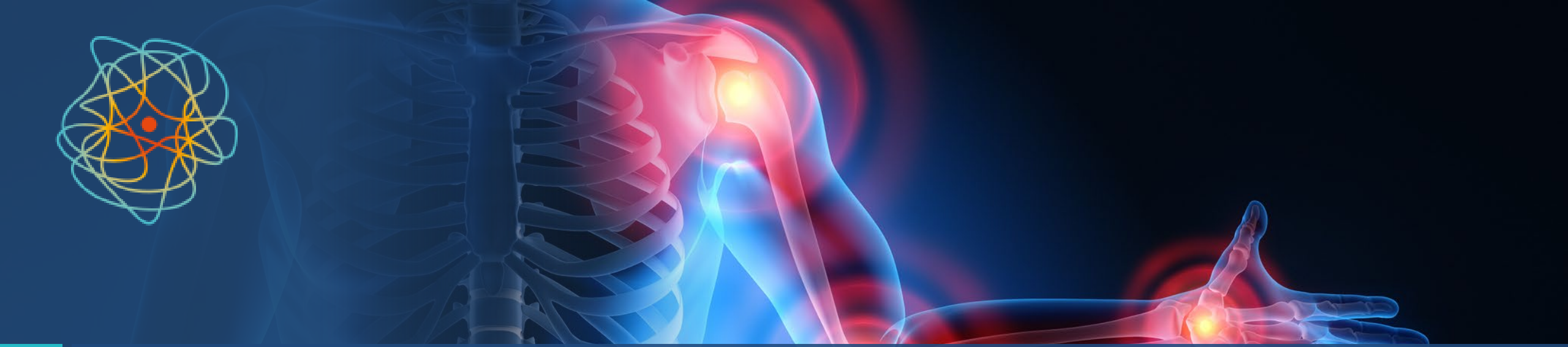
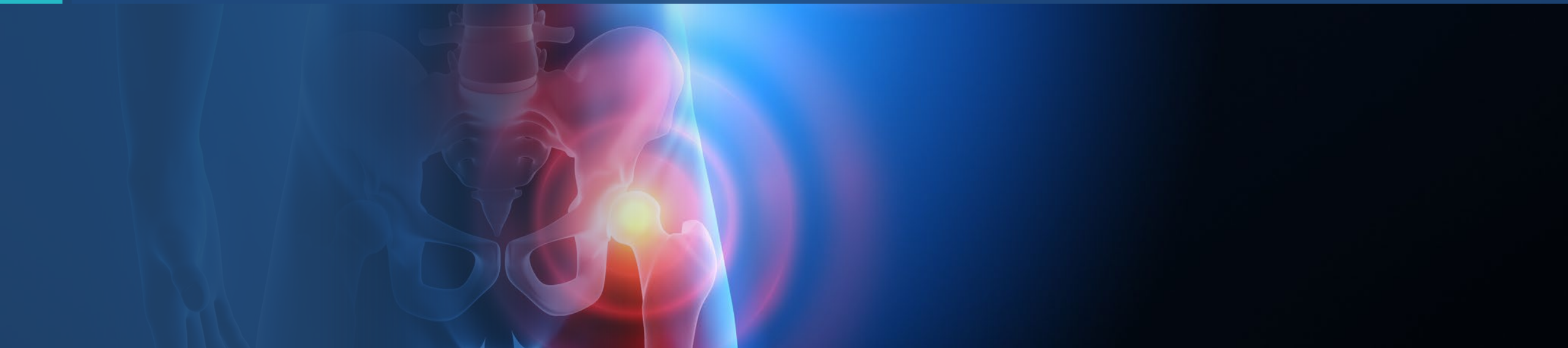


Paradigm Biopharmaceuticals LTD (ASX:PAR)

Corporate Update

paradigm
BIOPHARMA



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BLOCKBUSTER MARKET OPPORTUNITY

SIGNIFICANT MARKET SIZE WITH UNMET NEED

~72M+
Total prevalence of OA in these markets.

AUS
US
Canada
EU5

81%
Number of OA patients dissatisfied with current treatments[1]

Target uptake: 10% dissatisfied market[1]

Zilosul® Indicative Price: US$2500 per year[2]

A PARADIGM SHIFT IN THE TREATMENT MARKET FOR OA

US$15B+[3]
Conservative Estimate Addressable Market for OA

1. National Institute of Health; Emerging drugs for osteoarthritis; Hunter DJ and Matthews G 16(3): 479–491; 2011 September.
2. Pricing elasticity research commenced.
3. This is a company estimate based on Zilosul® receiving registration and several commercial assumptions

GOAL: HARMONISED GLOBAL REGISTRATION

USA

Pre IND meeting February 2020
- Bene pharmaChem product
- Two adequately sized P3 trials

Type C meeting
- Submitted briefing package to FDA
- Awaiting written response

IND
- Harmonisation of clinical trial design for multiple regions
- Type C feedback will ensure Paradigm's trial will have all the necessary components for registration should the Phase 3 trials be successful.

EUROPE

EMA meeting September 2020
- Agree with Clinical Trial design and endpoints
- Confirmation no-comparator arm
- Ability to recruit Eu patients
- Clear path to product registration

AUSTRALIA

Provisional Approval TGA.
- Awaiting feedback from FDA Type-C meeting

Finalising pay-for-use SAS program.

CONFIDENCE: PHASE 3 STUDY DESIGN

CONSISTENT RESULTS ACROSS MULTIPLE PROGRAMS IN PAIN REDUCTION FOR KNEE OA

Phase 2B OA/BML Clinical Trial

- Double-Blinded Placebo Controlled study (n=112)
- Met Primary & Secondary Endpoints
- Confirmed safety profile, target population and informed Phase 3 design

Special Access Scheme (SAS)

- KOOS : >50% mean pain reduction across 205 patients
- WOMAC: 47.3% mean pain reduction across 76 patients

Expanded Access Program (EAP)

- First IND opened with US FDA
- Treatment of 10 Ex-NFL players reported on average a 65% reduction in WOMAC pain from baseline

COMPETITOR FIELD UPDATE

COMPANIES	DRUG	MECHANISM OF ACTION	TARGET	STATUS
Galápagos / GILEAD Creating Possible / SERVIER	GLPG1972, S201086	ADAMTS-5 Inhibitor	• Cartilage Degradation	• Discontinued.
Pfizer / Lilly	Tanezamub	Anti-NGF	• Pain Reduction	• Multiple clinical holds due to Adverse Events • Submitted for Registration
Roche	Tocilizumab	IL- 6 Blocker	• Reduction of Inflammatory cytokine	• Recent failure to meet Primary Endpoint in Hand OA
CENTREXION THERAPEUTICS	CNTX-4975	IA Trans-capsaicin	• Pain Reduction	• Ph 2/3
paradigm BIOPHARMA	Zilosul®	ADAMTS-5 Inhibitor Downregulation of NGF Reduction of Joint Inflammation Reduces BML's	• Cartilage Degradation • Pain reduction • Reduction of pro-inflammatory cytokines • Improving vascular blood flow in subchondral bone	• Proven Safety and Efficacy in Ph 2b, SAS and EAP • Harmonised global Phase 3 clinical trial design

Multi-modal activity

Source:
https://www.fiercebiotech.com/biotech/galapagos-osteoarthritis-drug-flunks-phase-2-dashing-hopes-250m-gilead-deal?
https://www.medpagetoday.com/rheumatology/arthritis/85781
https://ard.bmj.com/content/early/2020/10/19/annrheumdis-2020-218547
https://www.medpagetoday.com/meetingcoverage/asipp/88481

UPCOMING PRESENTATION FOR INVESTORS

R&D DAY, 21ST / 22ND DEC 2020 (DATE TBC)
PRESENTATIONS FROM, DR DONNA SKERRETT (CMO) AND DR RAVI KRISHNAN (CSO)

- Share feedback from Type-C Meeting written response
- Detail on OA and MPS trial designs and timelines
- Update on scientific research pipeline

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