# mgc pharma

**Developing innovative medicines for under-treated medical conditions** 

February 2023

### MGC Pharma is developing innovative medicines for under-treated medical conditions

"Our vision is to have a global impact on under-treated medical conditions and diseases.

Wielding the power of plant-inspired medicines in novel combinations by using innovative medical technologies to harness knowledge and science towards achieving our "Nature to Medicine" strategy and creating the next-generation of medications."

Roby Zomer Co-Founder, Director & CEO

#### Established pharma platform

- Plant-inspired ingredients and pharmaceutical formulations
- Advanced clinical programs with innovative formulations
- Core drug development in progress with a strong R&D pipeline
- Integrated global research hub
- Experienced corporate and pharmaceutical team
- Malta GMP standard manufacturing facility
- ESG focussed corporate culture

## Invested in a highly qualified team focused on moving products through clinical trials



**Roby Zomer** Managing Director & CEO





Chairman

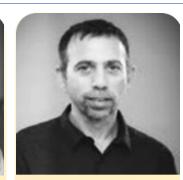






Dr. Nadya Lisodover **Chief Medical Officer** 





Amir Polak **Chief Pharmaceutical Development Officer** 



GSK Jaf **Deloitte** 



**V**Sciensus

and Supply Chain Officer





## MGC Pharma is a pharmaceutical company, accelerating medicine for clinical trial

- Robust development pipeline targeting widespread medical conditions, focusing on CimetrA<sup>®</sup> and CannEpil<sup>®</sup> (in the short term)
- Develop and supply high-quality, plant-inspired medicines for the medical markets globally
- Growing patient base in Australia, the UK, Brazil and Ireland and a global distribution footprint via an extensive network of commercial partners
- Partnerships established with renowned institutions and academia to optimise the development of targeted plant-inspired medicines
- EU-GMP certified manufacturing facilities

## 2022 achievements

During the past 24 months the Company refocussed into a pharmaceutical business

#### Drug development

- 2 core drugs in clinical development
  - ☆ CimetrA<sup>TM</sup>
  - CannEpil<sup>®</sup>
- 5 further drugs in development pipeline
- ☆ Completion of two successful Phase II studies on CogniCann<sup>®</sup> and CimetrA<sup>™</sup>

#### Strategic development

- CannEpil<sup>®</sup> approved by the Irish Medical Cannabis Products Reimbursement Scheme (MCPRS) and obtaining full health insurance converge
- Establishment of long term 'early access' supply agreement with our partner 'Sciensus Rare' (EU, UK and MENA) for CannEpil<sup>®</sup>
- Construction completed of two pharma-grade production sites (Malta and Slovenia)
- Cost rationalisation program completed and implemented

## **Research and manufacturing**

#### Integrated research hub

- Currently manages and runs all clinical trials in-house\*
- Israeli CRO ('MediCaNL') delivers significant cost savings to the Company compared to third party services
- Opportunity for third party revenue generation

#### Fully built GMP pharma standard manufacturing facility

- Two, high-quality, European production facilities to manufacture and distribute MGC's proprietary IMP products CimetrA<sup>TM</sup>, CannEpil<sup>®</sup>, and CogniCann<sup>®</sup>
- Slovenia production facility EU-GMP since 2018
- Malta production facility EU-GMP certification in early 2023





## Looking ahead (2023- 2024)

**Key strategic milestones** 

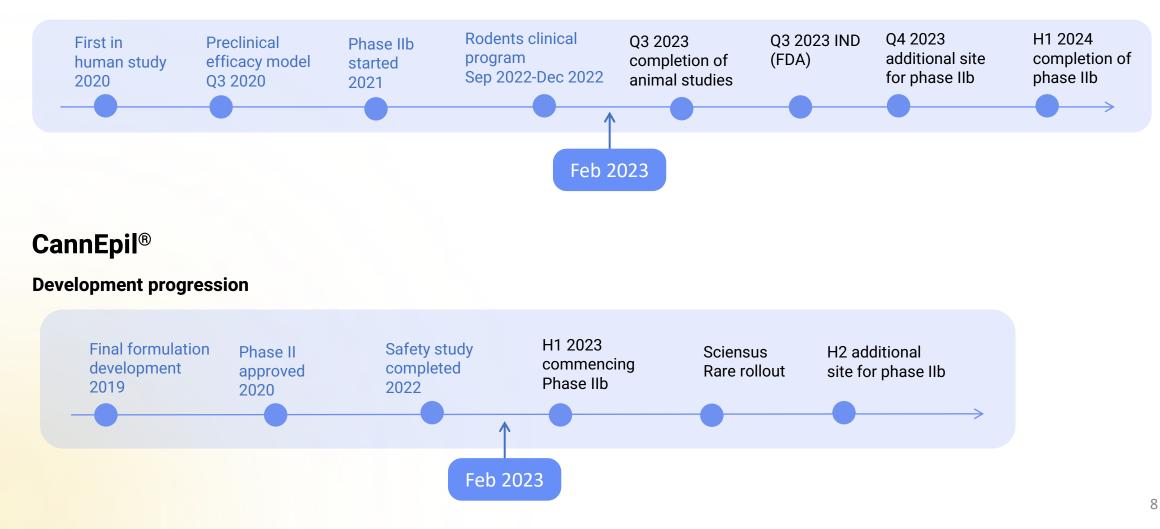
- ♦ Completion of large animal study for CimetrA<sup>TM</sup>
- ☆ CimetrA<sup>TM</sup> IND submission to the US FDA
- Ramp up of CannEpil<sup>®</sup> 'early access' program with Sciensus Rare
- Progress on CannEpil® Phase IIb
- ☆ Commissioning and GMP approval of Maltese CimetrA<sup>™</sup> and CannEpil<sup>®</sup> facility



## MGC Pharma drug development programme

#### CimetrA™

#### **Development progression**



## Flagship Product – COVID-19 and anti-inflammatory

#### **CimetrA<sup>™</sup>**

- IMP based on two active ingredients:
  - Dry extracts of Curcuma longa and Boswellia serrata
- Delivered via nanoparticle suspension
- Results:
  - Demonstrated suppression of cytokine storm in COVID-19 patients<sup>1</sup>
  - None of the treatment group patients in the on-going study have required additional oxygen, mechanical ventilation, or admission to intensive care<sup>2</sup>
  - Pre-clinical in-vitro study indicates wide-ranging application as an antiinflammatory treatment through the modulation of the production of pro-inflammatory cytokines<sup>1</sup>
  - Effective blocking of the IL-32mRNA expression<sup>1</sup>, the pro-inflammatory cytokine related to rheumatoid arthritis, inflammatory bowel disease, asthma, psoriasis, and chronic obstructive pulmonary disease

#### IP protected (IP Number – SIPO 26055)

- \* Developed from our food supplement ArtemiC®.
- 1. ASX Announcement 27/6/2022
- 2. ASX Announcement 15/12/2020
- 3. https://www.researchandmarkets.com/reports/5733923/coronavirus-covid-19-current-therapy-global

#### Phase IIb and Phase III



#### Total Addressable Market £13.6bn<sup>4</sup>

## Flagship Product – Refractory Epilepsy

#### **CannEpil**<sup>®</sup>

- IMP based on two active ingredients:
  - Cannabidiol and Delta-9-Tetrahydrocannabinol
- Approximately 25% of patients have Refectory Epilepsy aka "Drug-Resistant Epilepsy" (DRE)<sup>1</sup>
- Delivered by oral mucosal solution
- Fully covered under Ireland's Primary Care Reimbursement Service via special access program<sup>2</sup>
  - Real-world data and early regulatory approval (150 patients under early access)
- Results:
  - Shows positive safety assessments
  - Safety study completed CannEpil<sup>®</sup> was found to be safe for post-treatment driving activities<sup>3</sup>
- IP protected (IP Number SIPO 26056)

#### Phase IIb



#### Total Addressable Market £12.5bn<sup>4</sup>

<sup>1.</sup> Fattorusso A, et al. (2021) The Pharmacoresistant Epilepsy: An Overview on Existant and New Emerging Therapies. Front. Neurol. 12:674483.

<sup>2.</sup> https://www2.hse.ie/services/schemes-allowances/medical-cannabis-products-reimbursement-scheme/

<sup>3.</sup> ASX Announcement 15/8/22

<sup>4.</sup> https://www.biospace.com/article/epilepsy-therapeutics-market-worth-15-1-bn-by-2030-at-a-cagr-of-4-5-percent-/

## **CannEpil<sup>®</sup> market potential**

There are 65 million epilepsy sufferers worldwide, of which 3.4m in the US and 6.2m in Europe including UK

Refractory Epilepsy accounts for c.16m sufferers worldwide (approx. 25% of total epilepsy patients)



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