

mgc pharma



Developing innovative medical treatments for unmet medical needs

Dec 2023 – Non-Deal Roadshow

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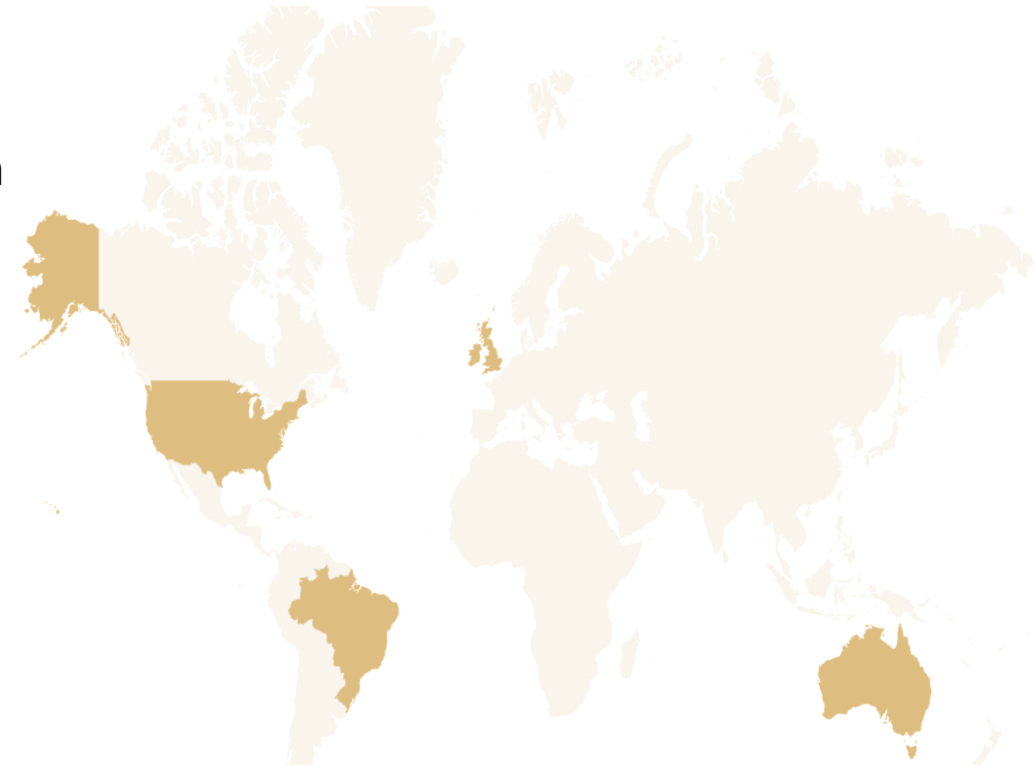
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MGC Pharma – a Biopharmaceutical company, committed to research and development of innovative medical treatments for unmet medical needs

- ❖ **Innovative drug delivery systems** combined in **pharmaceutical formulations** (IP held Products)
- ❖ **Early Revenues generating products** through early access scheme in selected territories (UK, Ireland, Australia, USA, and Brazil)
- ❖ **First product** now **available in the UK and Ireland** - addressable market of 150,000 patients with drug resistant epilepsy
 - ❖ A 5% market share in the UK alone would generate circa £40m gross sales
- ❖ Strong **R&D pipeline** with **4 further treatments** in progress
- ❖ Fully integrated business with **GMP standard manufacturing facilities** in Malta and Slovenia
- ❖ **Integrated research** hub in Slovenia



CannEpi[®]

Refractory Epilepsy

- ❖ **CannEpi[®] - REVENUE GENERATING** Neurology
- ❖ Approximately **30% of generalised seizure epilepsy patients** have **Refractory Epilepsy** aka “Drug-Resistant Epilepsy” (DRE)¹
- ❖ **Results of Preclinical and Clinical programme to date :**
 - ❖ Shows positive safety assessments
 - ❖ Safety study completed - **CannEpi[®]** was found to be safe for post-treatment driving activities³
 - ❖ Head-to-head clinical study on 100 patients comparing **CannEpi[®]** to a CBD only formulation⁵
- ❖ **Available to patients in the UK, Ireland and Australia by Named Patient Request**
- ❖ The first UK patient has access to **CannEpi[®]** through the **NHS RESCAS** pathway and “**I AM Billy Foundation**”
- ❖ **Accepted by the Irish Health Product Regulatory Authority (HPRA)** and fully covered under Ireland's Primary Care Reimbursement Service²
- ❖ **1st Inaugural Multidisciplinary Neurology Advisory Board meeting** was held in London during July 2023

1. Fattorusso A, et al. (2021) The Pharmacoresistant Epilepsy: An Overview on Existant and New Emerging Therapies. Front. Neurol. 12:674483.
2. <https://www2.hse.ie/services/schemes-allowances/medical-cannabis-products-reimbursement-scheme/>
3. ASX Announcement 15/8/22
4. <https://www.biospace.com/article/epilepsy-therapeutics-market-worth-15-1-bn-by-2030-at-a-cagr-of-4-5-percent/>
5. <http://www.investi.com.au/api/announcements/mxc/2f988bb4-0b6.pdf>

Phase IIb



**Total Addressable Global
Market £15bn⁴**

Looking ahead (2024-2025) Key strategic milestones

- ❖ **CannEpi[®]** IND submission to the US FDA
- ❖ Ramp up of **CannEpi[®]** ‘early access’ programme in EU
- ❖ Landmark Neurology conference in the UK, Ireland and Malta on **CannEpi[®]**
 - ❖ Ireland Medicinal Cannabis Meeting January 2024 with Irish Neurology specialist
 - ❖ London Advisory Board meeting – Q1 2024 & Q4 2024 with UK Neurology Specialist
 - ❖ Malta & London Advisory Board meeting – April 2024 with Neurology specialist

CannEpil®

Market Potential

CannEpil® already sold in the UK, Ireland and Australia

There are 50m¹ million epilepsy sufferers of which 6.2m¹ in Europe and the UK

Approximately **30% of generalised seizures epilepsy patients** have **Refractory Epilepsy** aka "Drug-Resistant Epilepsy" (DRE)²



Worldwide Potential Patients with DRE

- **15m Patients**



UK Potential Patients with DRE

- **150k Patients**
- **c.4% penetration rate**

Treatment Estimate per patient



- Treatment cost estimated **£7000³**

5% market share in UK alone³ values at c. £40m gross sales per annum
(estimated Maximum potential peak gross sales in UK & Europe £1.2bn³)

Key points

- ❖ MGC Cannepil's commercial strategy is a combination of **3rd party distribution supported by in house Medical Scientific Liaison**
- ❖ Key wholesaler partner in the UK and Europe **PCCA and Medisonal**
- ❖ Initiate CannEpil® **IND submission to the US FDA**
- ❖ Continuing the work with the **I am Billy Foundation** and the pathway to **NHS RESCAS** for paediatric Refractory Epilepsy
- ❖ Dedicated Neurology and Paediatrician collaboration with '**European Paediatric Neurology Society**'⁴ in-house



1. <https://www.who.int/news-room/fact-sheets/detail/epilepsy>
2. Fattorusso A, et al. (2021) The Pharmacoresistant Epilepsy: An Overview on Existant and New Emerging Therapies. Front. Neurol. 12:674483.
3. Alacrita Report 2019
4. <http://dpnsee.org/2019/01/22/treatment-with-medicines-derived-from-cannabis/>

CimetrA®

Immunomodulation treatment of COVID-19 symptoms & ARDS

- ❖ **CimetrA® (ArtemiC™)** - **REVENUE GENERATING** Immunology
- ❖ IMP based on two active ingredients-Dry extracts of Curcuma longa and Boswellia serrata
- ❖ **ArtemiC™ (CimetrA® OTC)** delivered 50,000 units to the USA market
 - ❖ **ArtemiC™** has now been listed as an over-the-counter (**OTC**), non-prescription unlicensed drug in the **USA**, following the listing on the FDA National Drug Code Database (NDC)
- ❖ **Results of Preclinical and Clinical programme to date:**
 - ❖ Demonstrated **suppression of cytokine storm** in COVID-19 patients¹
 - ❖ Pre-clinical study indicates **wide-ranging application as an immunomodulation and anti-inflammatory treatment**¹
 - ❖ Effective blocking of the IL-32mRNA expression¹, the pro-inflammatory cytokine related to **Autoimmune diseases, rheumatoid arthritis, inflammatory bowel disease, asthma, psoriasis, and chronic obstructive pulmonary disease**

* Developed from our food supplement ArtemiC™.

1. ASX Announcement 27/6/2022

2. <https://www.researchandmarkets.com/reports/5733923/coronavirus-covid-19-current-therapy-global>

Phase IIb and Phase III



Total Addressable Global Market
£13.6bn⁴

Looking ahead (2024- 2025) Key strategic milestones

- ❖ **CimetrA®** IND submission to the US FDA
- ❖ Initiate an early patient access scheme

Potentially, CimetrA[®] can be used to treat inflammatory conditions

Influenza symptoms

3-5m

3 to 5 million cases of **severe illness** of influenza worldwide per annum

[https://www.who.int/news-room/fact-sheets/detail/influenza-\(seasonal\)](https://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal))

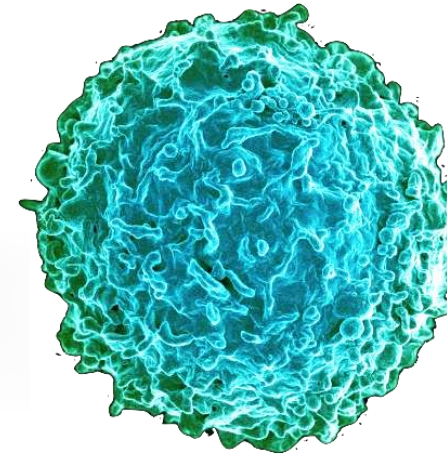
290-650k

290 000 to 650 000 respiratory **deaths** per annum

Anti Inflammatory market

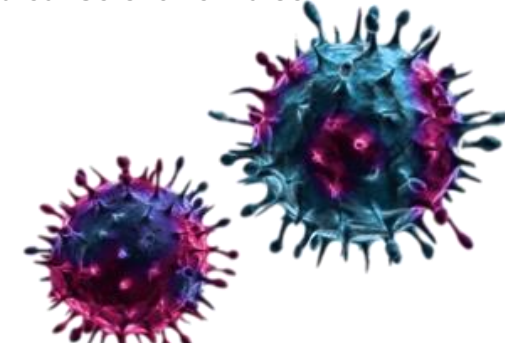
£100b Total Addressable Market

<https://www.precedenceresearch.com/anti-inflammatory-therapeutics-market>



Key points

- ❖ MGC's sales strategy is to licence and distributes through **3rd party distribution supported by in house Medical Scientific Liaison**
- ❖ Key wholesaler partners in the USA and MENA– **AMC**
- ❖ Initiate CimetrA[®] **IND submission to the US FDA**



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Appendix

Key members of MGC's Management Team

Highly qualified team with relevant industry experience



Roby Zomer
Managing Director & CEO



10 years of experience in the BioTech and AgroTech sectors alongside running large scale projects, bringing his extensive business contacts, scientific and engineering.



Yifat Steuer
Chief Operational Officer & Deputy CEO



A well-versed c level executive with **over 20 years' of experience** ranging from **J&J and GSK** to hands-on implementation in SMEs/start-ups. A chartered accountant with **Deloitte**.



Amir Polak
Chief Pharmaceutical Development Officer



Over 20 years' of experience in the **pharma / Chemical industry, managing R&D workstreams** from concept to production. Amir holds an **MSC in organic chemistry**.



Itay Nissim
Chief Manufacturing & Supply Chain Officer



With a wealth of experience in multiple industries, from large scale agricultural rollouts to customer facing retail-oriented product development,



Yair Tal
Chief Information Security Officer



Yair's experience in security management, data protection and physical cyber security, from the company's facilities to it's online operations and most significantly, patient data.



Sabina Suljaković
Vice President of Global Quality



An EU registered Qualified Person, Responsible Person and a Pharmacist, who brings **over 10 years of experience in the pharmaceutical quality, manufacturing and regulatory fields**.

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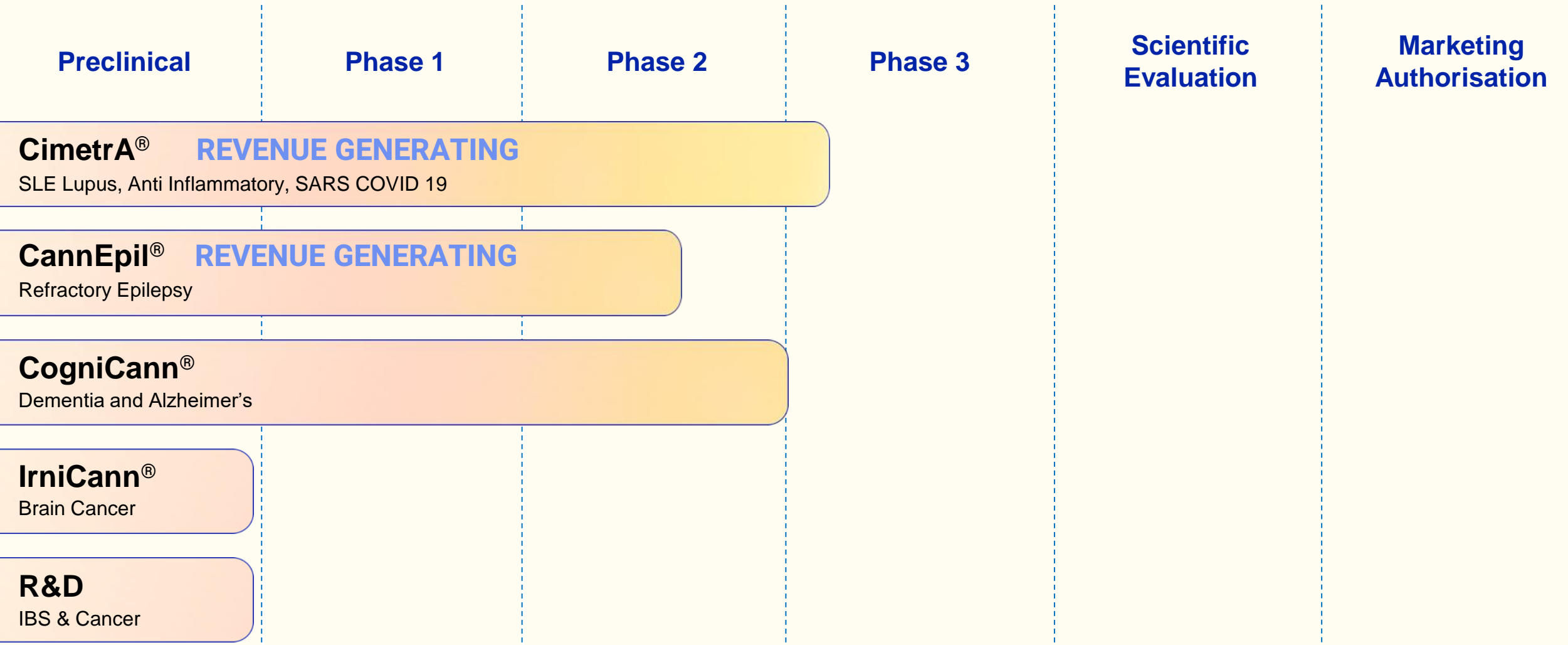


Products Portfolio

Developing innovative medicines for unmet medical needs

Research and Development – Product Pipeline

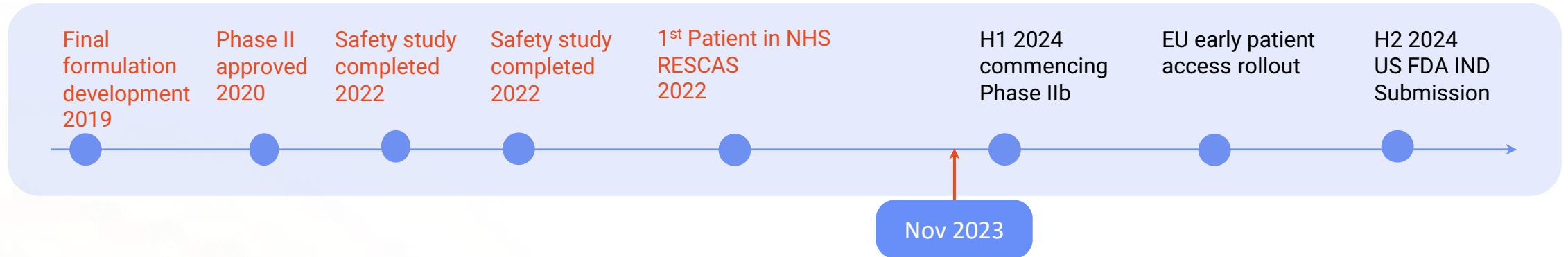
FDA (US) & EMA registration



MGC Pharma drug development programme

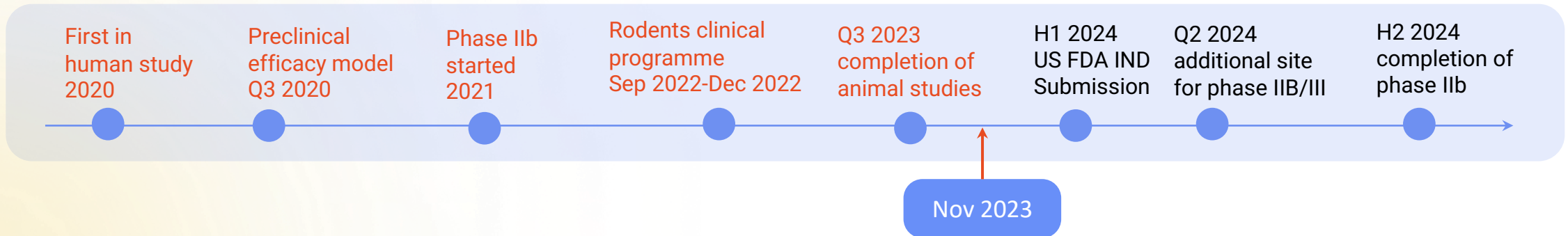
CannEpi[®]

Development progression



CimetrA[®]

Development progression



CogniCann®

Dementia and Alzheimer's

- ❖ IMP based on two active ingredients: Delta-9-Tetrahydrocannabinol and Cannabidiol.
- ❖ Designed as a treatment for the symptoms associated with Dementia and Alzheimer's.
- ❖ The safety and efficacy were assessed in a Phase II study in Australia;
- ❖ Patients in the Placebo group experienced a deterioration in their condition, compared with the stable neuropsychiatric profile of those patients in the treatment group with CogniCann®;
- ❖ Patients' aggressive behaviour improved by 13%, compared with the Placebo Group, which improved by 4%;
- ❖ This important finding indicates not only improvement in the health status of the patients but also the improved quality of life of the families and caregivers taking care of dementia patients;

Phase II



Dementia

Alzheimer's



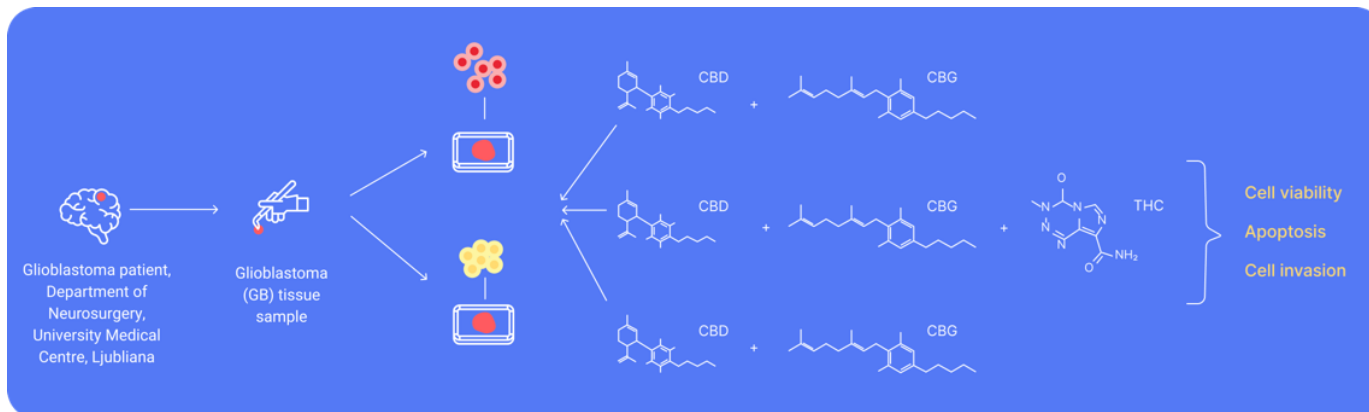
Oromucosal spray

Pharmaceutical
dosage form

IrniCann®

R&D Pipeline - Glioblastoma

- ❖ IMP based on two active ingredients: Cannabidiol and Cannabigerol.
- ❖ The Glioblastoma pre-clinical research , conducted between 2019-2022, initially used a formulation that included THC (delta-9-tetrahydrocannabinol), which was later replaced with Cannabigerol (CBG), which has no known psychotropic effects.
- ❖ The study demonstrated that IrniCann® was cytotoxic to Glioblastoma tumour and stem cells, reducing the cells' viability and inducing caspase-dependent cell apoptosis (or cell death).
- ❖ MGC Pharma is planning to undertake additional research to further demonstrate the formulation's efficacy as a treatment for Glioblastoma.



Pre-clinical



Glioblastoma



Capsules

Pharmaceutical dosage form

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Research and Manufacturing sites

Developing innovative medicines for unmet medical needs

Research and manufacturing

Integrated research hub

- ❖ Currently manages and runs clinical trials both in-house* and with third party CROs
- ❖ 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 **CannEpil®**, **CimetrA®**, and **CogniCann®**
- ❖ Slovenia production facility EU-GMP since 2018, Malta production facility EU-GMP since 2023
- ❖ 80% government funded Malta production facility was EU-GMP certification in April 2023



MGC Pharma produces innovative medical treatments for unmet medical needs

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