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GmbH

Business Presentation

MiHKAL GmbH

The first and only psychedelic start-up in Europe

Patent assets

- *Novel Safrylamine derivates having prodrug properties* (MDMA-Lys = MDMA prodrugs) - WO2022053696 *
- *Novel nootropic prodrugs of phenethylamine* (= MDMA derivatives) - WO2024056678
- *Novel N,N,-Dimethyltryptamine (DMT) derivatives and uses thereof* (= DMT prodrugs) - EP22211625.3
- *Improved method for the production of LSD and novel derivatives thereof* (= LSD-derivatives) - WO2022008627 *
- *New patent application about LSD derivatives* (= LSD prodrugs) EP24167939.8

*Reassigned from Compass Pathways

Patent continued by Compass pathways:

- *Novel Psilocin derivates having prodrug properties* - WO2022038299
  - Patent developed by MiHKAL
  - 3 years collaboration MiHKAL / Compass
  - Patent nationalized in 16 countries
- Reassignment of MDMA and LSD Patent to MiHKAL

Raising demand in Psilocybin and MDMA

3rd February 2023	Change to classification of psilocybin and MDMA to enable prescribing by authorised Australian psychiatrists
1st July 2023	Official Legalisation of psilocybin and MDMA for medical treatment in Australia
Australian approval of MDMA and psilocybin	Australian approval of MDMA and psilocybin
Australian Government Department of Health Therapeutic Goods Administration	A 'baby step in the right direction', medical experts say

Global acceptance for therapy

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February 2024: FDA granted priority review for market approval

MAPS
MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC STUDIES

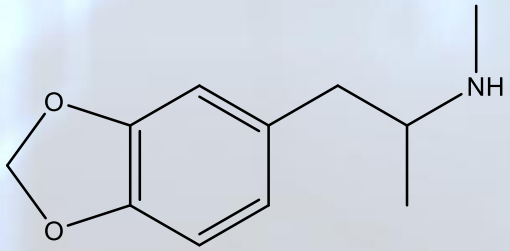
FDA approves Lykos Therapeutics' new drug application for MDMA therapy

August 11th 2024

FEBRUARY 12, 2024 / CANNABIS NEWS

The U.S. Food and Drug Administration has accepted a new drug application from Lykos Therapeutics, previously known as MAPS Public Benefit Corporation, for the use of MDMA-assisted therapy in treating post-traumatic stress disorder.

The acceptance finally kicks off an anticipated review process, with the FDA granting the application priority status and setting a target action date of August 11, 2024. If approved, the therapy would be the first of its kind to receive federal approval, potentially offering a new treatment option for individuals with severe mental afflictions.



MDMA
(Methylenedioxymethamphetamine)

NEWS | 14 September 2023 | Correction 15 September 2023

Psychedelic drug MDMA moves closer to US approval following success in PTSD trial

Long-awaited trial data show drug is effective at treating post-traumatic stress disorder in a diversity of people.

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Ongoing clinical trials with MDMA for PTSD treatment

(Post-traumatic stress disorder)

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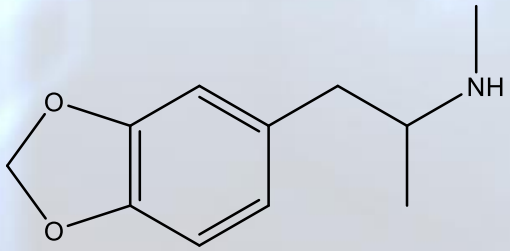

MDMA
(Methylenedioxymethamphetamine)

- **2017** FDA granted Breakthrough Therapy designation to MDMA for the treatment of PTSD
- **1st Phase 3 by MAPS** successful: **88%** of the participants treated with MDMA assisted therapy had a clinically significant improvement in their PTSD symptoms and 67% no longer qualified for a PTSD diagnosis
- **2nd Phase 3 by MAPS** : 104 patients → **86%** of the participants treated with MDMA assisted therapy had a clinically significant improvement in their PTSD symptoms and **71%** no longer qualified for a PTSD diagnosis
- Treatment consists of three guided 8 hour sessions including 120 – 180 mg MDMA consisting of 2-split doses
- → **11.000 $ cost saving per patient***

* Marseille E, Mitchell JM, Kahn JG (2022): Findings from a phase 3 trial.

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2-split-doses MDMA for 8 hour therapy (in human) – Systolic blood pressure as Biomarker

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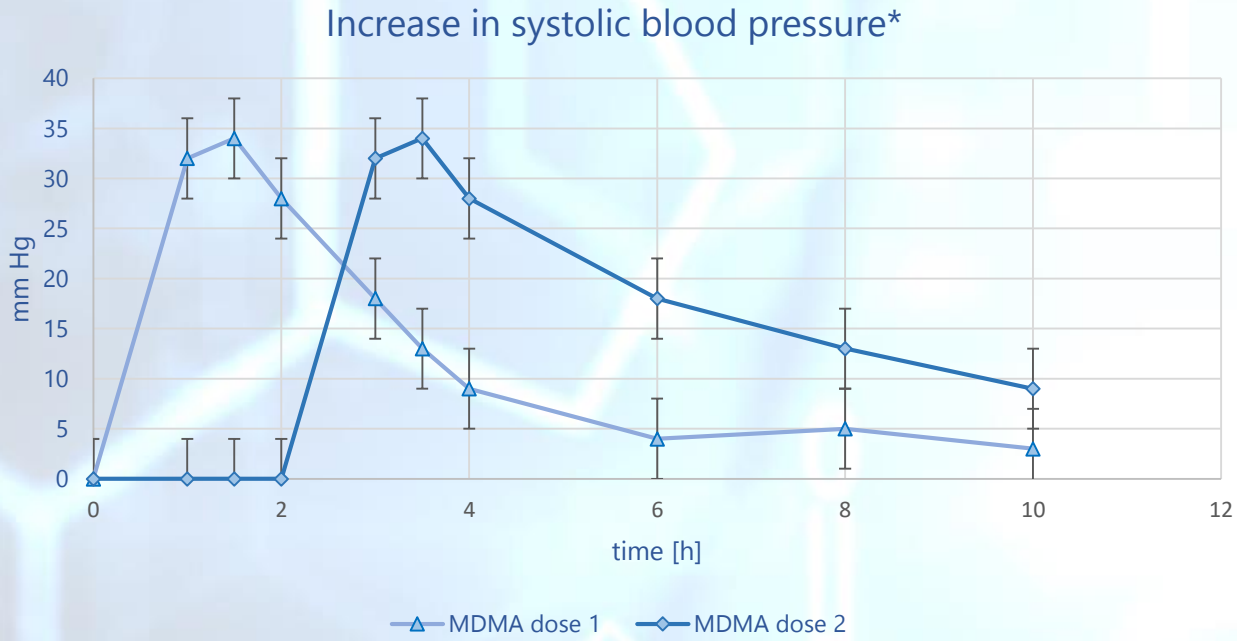
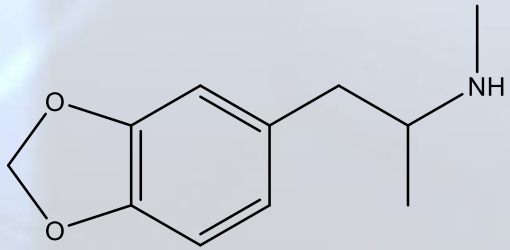


End of effects of dose 1 at 5 hours*

* *Neuropsychopharmacology volume 45, pages 462–471 (2020)*
125 mg MDMA p.o.
Overall effects 4.4 +/- 1.7 hours



MDMA
(Methylenedioxymethamphetamine)

* Blood pressure as biomarker for the systemic effects in human as Pharmacokinetics does NOT necessarily equal continuing effect in human!

n = 8

According to Journal of Pharmacology and Exp. Therapeutics, July 1999, 290 (1) pages 136-145.

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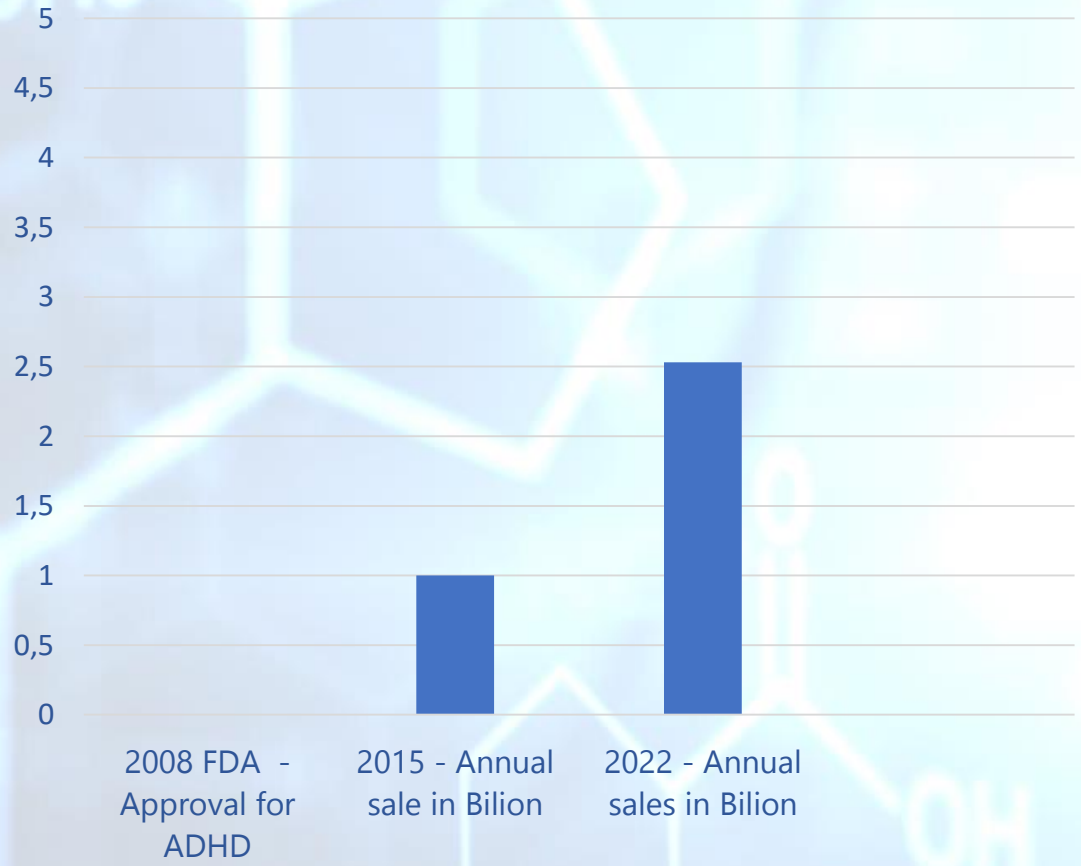
The Vyvanse story – model for our MDMA-prodrug project = prodrug of amphetamine

Competitor to Ritalin and Amphetamine



Takeda

Shire

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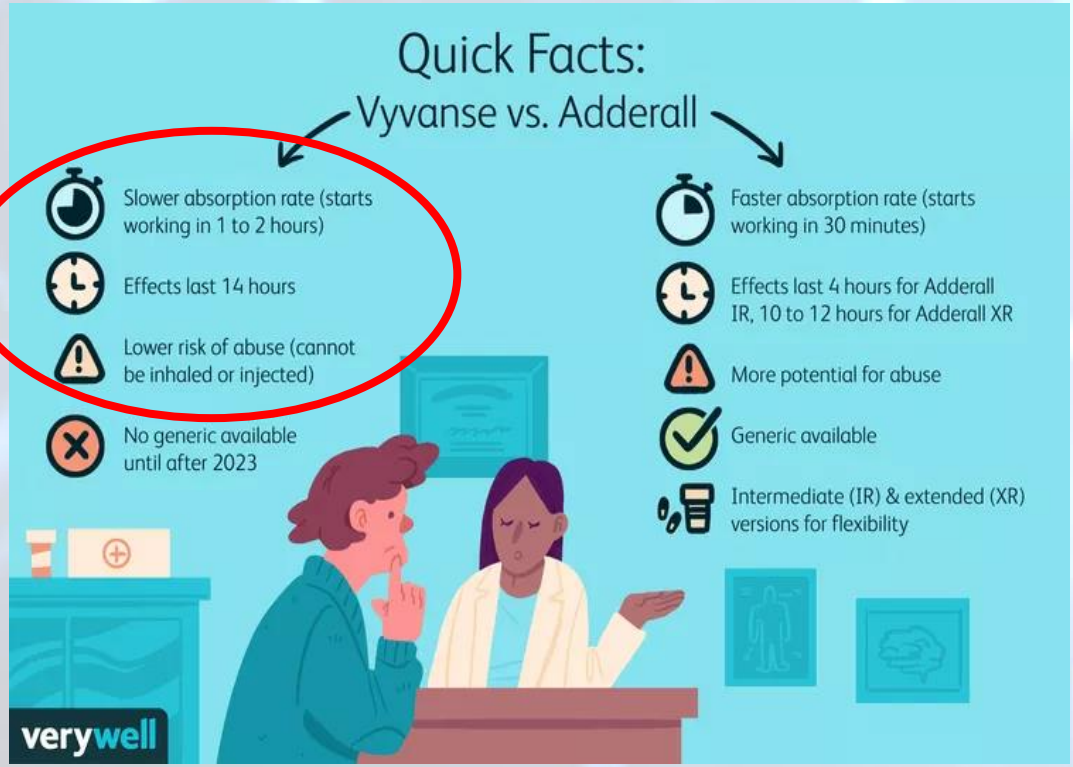
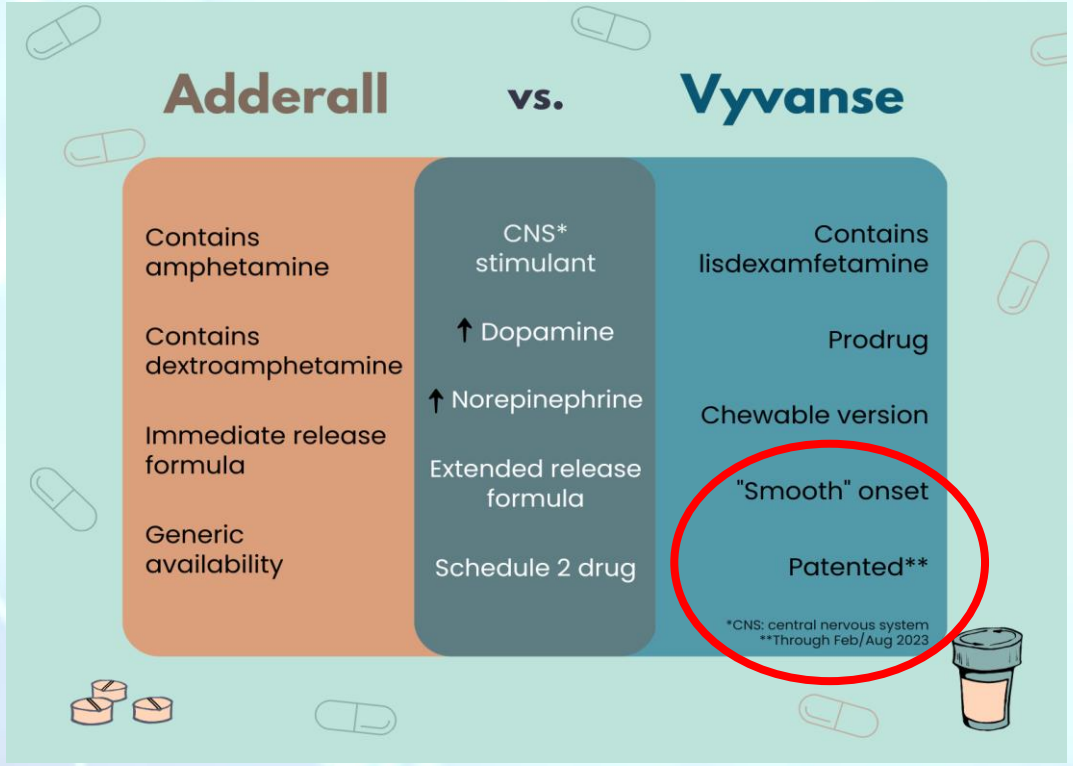
The Vyvanse story – model for our MDMA-prodrug project = prodrug of amphetamine





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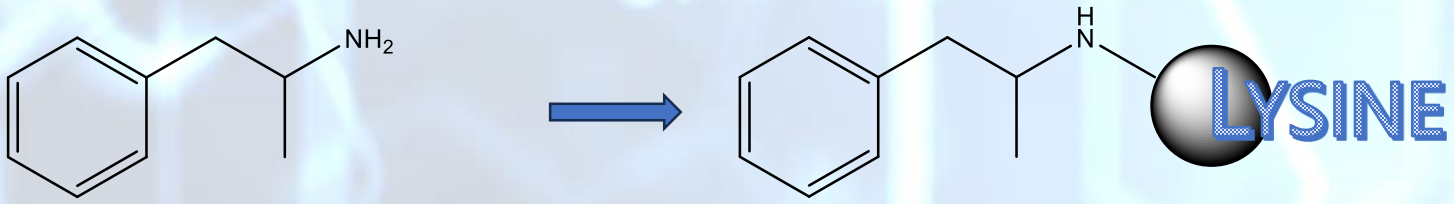
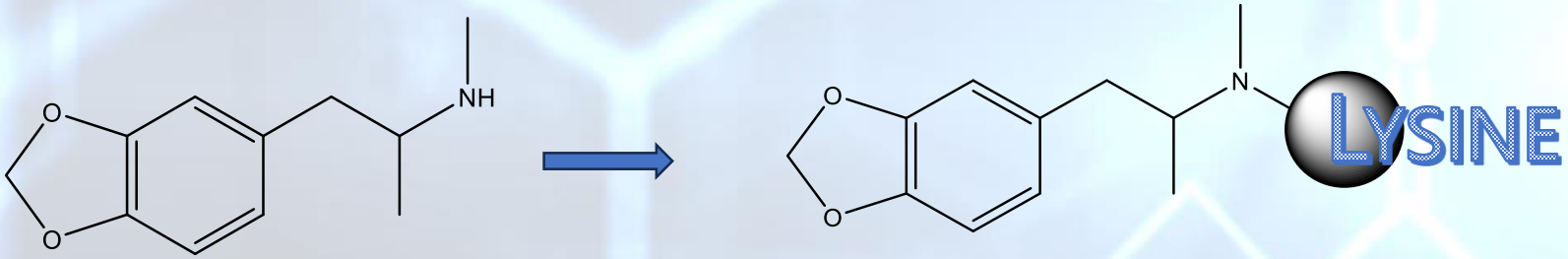
Our similar approach (patent WO2022053696) in compliance with the Vyvanse story



Takeda / Shire

Vyvanse

Amphetamine



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MDMA
(Methylenedioxymethamphetamine)

MiHKAL prodrug MKL001 **(= new molecular entity (NME))**

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Our unique product: «Best in class»

MAPS
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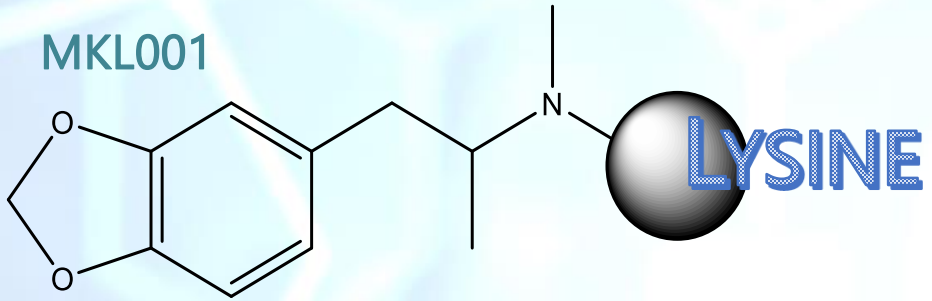
«First in class»

MDMA oral
120 – 180 mg
patented in 1912 !



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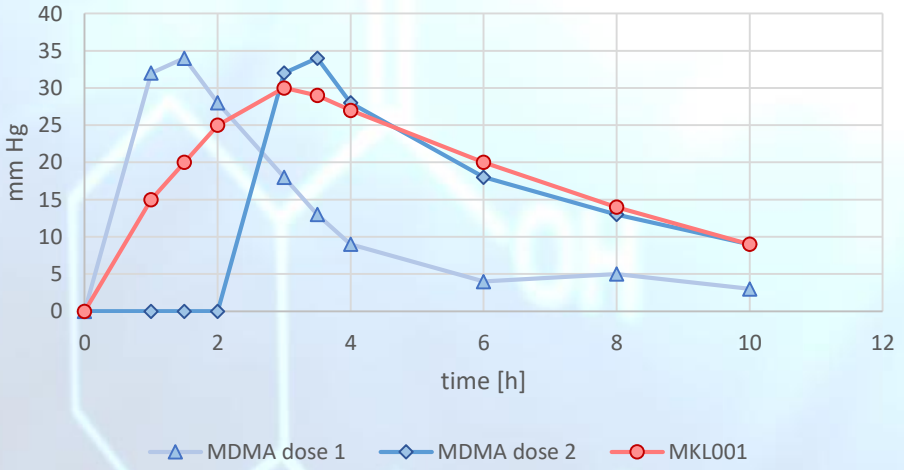
- One dose – one session !
- Distinguishing feature: **Milder onset - Longer effect - Less side effects**

Increase in systolic blood pressure**



* Estimated in analogy to Vyvanse

** Blood pressure as empirically measurable representative for the systemic effects in human as Pharmacokinetics does NOT necessarily equal continuing effect in human!

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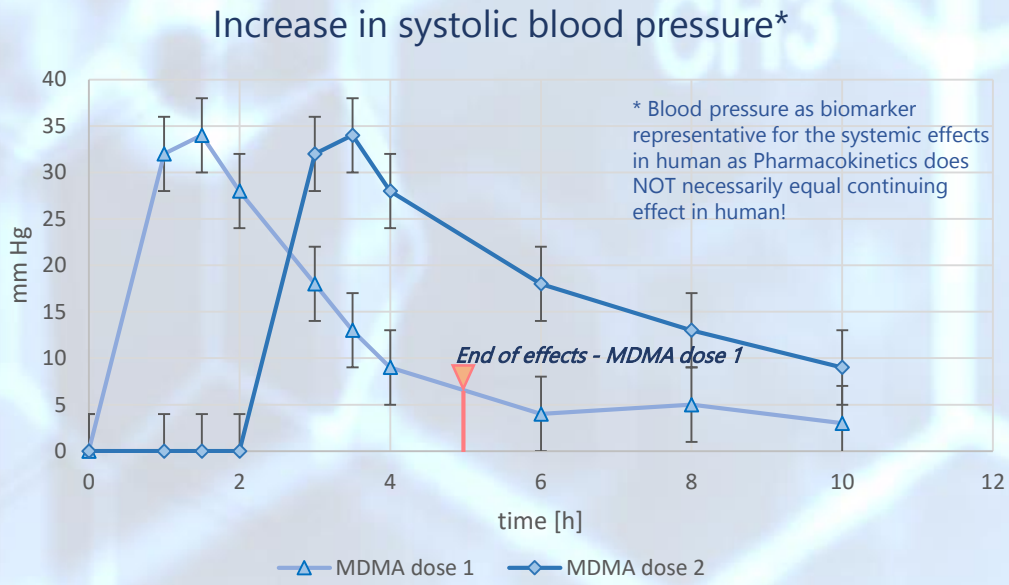
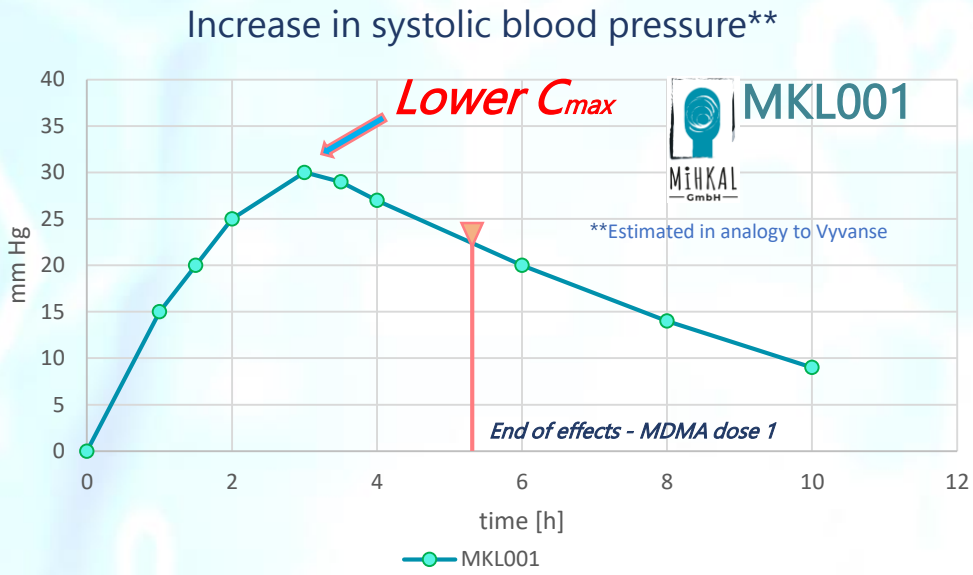
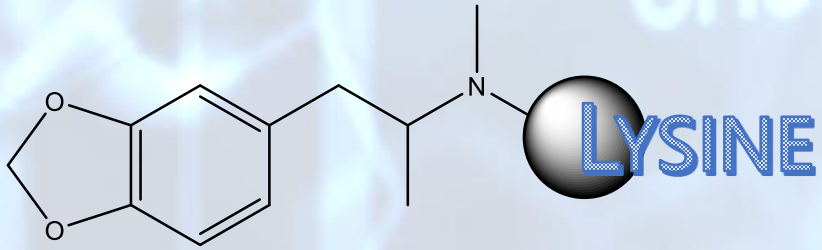
Modeling the PK of MDMA

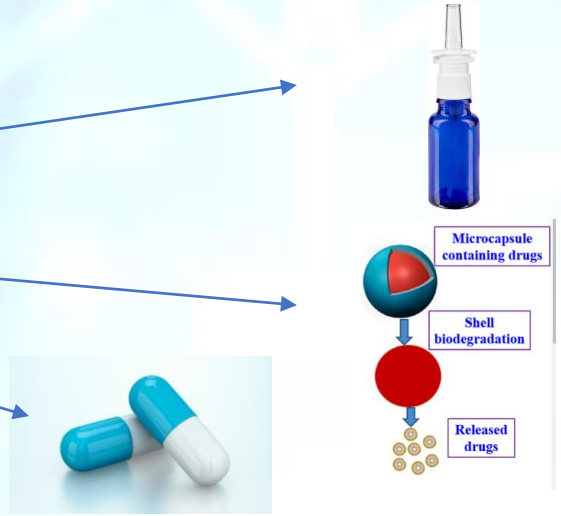




- Instead of two MDMA split doses, only one dose of MKL001 is expected to provide the same duration of effect
- Due to an expected slower on- & offset of the drug and lower Cmax, less side effects and lower addiction profile are expected (slow and steady release and metabolization of the drug)
- Expecting less cardiovascular issues due to slow and steady release and metabolization of the drug

Our unique product MKL001 : 2 independent therapies





MKL001

Fast delivery for short therapy sessions (nasal/mucosal)

Slow release and prolonged effect for persistent treatment regimens (oral)

Target Product Profile

- Less side-effects
- Lower addiction profile compared to MDMA
- Less abuse potential
- Tunable drug release for fast/retarded applications
- Possible indications: PTSD, TRD and anorexia nervosa

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Our Pipeline Overview

Programme	Pre-Lead	Lead / first preclinical data	IND Pack
MKL001			
MKL002			
MKL003			
Analogs/prodrug platform			

Matthias Grill
Designer of new drugs

2021 - 2023 Preclinic drug development for COMPASS
2021 Foundation MiHKAL GmbH
2020 QP & Drug officer Pharmaserv Stansstad
2019 Head of Chemistry Arbolea GmbH Liestal
2013 Project leader Lipomed AG Arlesheim
2012 Head R&D THC Pharm Frankfurt
2011 Lableader LGC Europe Berlin
2010 PhD thesis Max-Planck-Institute Mainz
2005 Diploma LMU München

Our Team

Dr. Matthias Grill

CEO and
Founder of MiHKAL

Tamara Hell

CFO and
Co-Founder

Andrea Marti

R&D Scientist

Richard Troxler

R&D Chemist

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