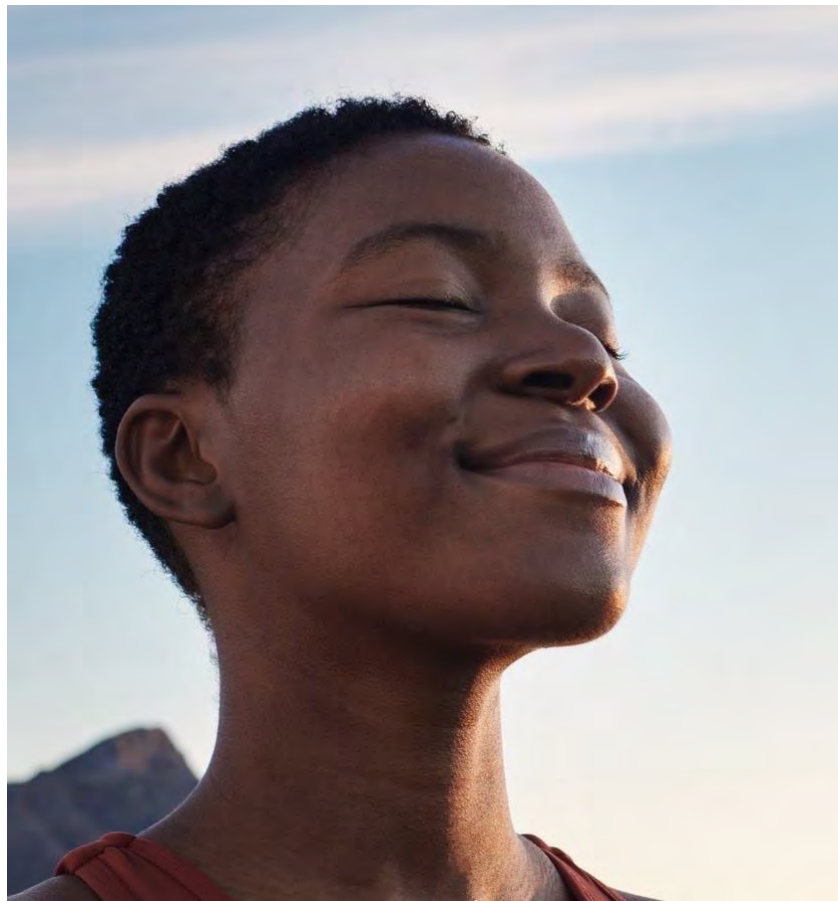


# **BREAKTHROUGH MEDICINES**

WITH LONG-ACTING INJECTABLES (LAI)



#### IMPORTANT NOTICE - YOU MUST READ THE FOLLOWING BEFORE CONTINUING

This presentation contains forward-looking statements, including statements regarding Company's expectations for (i) the timing, progress and outcome of its clinical trials; (ii) the clinical benefits and competitive positioning of its product candidates; (iii) the ability of its products to obtain regulatory approvals, commence commercial production and achieve market penetration and sales; (iv) its future product portfolio; (v) its future partnering arrangements; (vi) its future capital needs, capital expenditure plans and ability to obtain funding; and (vii) prospective financial matters regarding our business. Although the Company believes that its expectations are based on reasonable assumptions, any statements other than statements of historical facts that may be contained in this presentation relating to future events are forward-looking statements and subject to change without notice, factors beyond the Company's control and the Company's financial capabilities.

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UZEDY® is a trademark of Teva Pharmaceuticals.

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- **UZEDY<sup>®</sup>** (*marketed by Teva Pharmaceuticals*)  
Monthly and every 2 months subcutaneous risperidone for treatment of schizophrenia

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- **mdc-TJK**  
Monthly subcutaneous olanzapine LAI for treatment of schizophrenia  
*Submission expected in 2025*
- **mdc-CWM**  
Intraarticular celecoxib for post-operative pain and inflammation management  
*Next clinical development expected in 2025*
- **mdc-WWM**  
Best-in-class contraceptive LAI (preclinical)
- **mdc-STM**  
Global Health program to fight malaria (preclinical)

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# CORPORATE OVERVIEW

BEPO®

**Pioneering Long-Acting Injectable (LAI) innovator with breakthrough technology platform**

UZEDY®

**First product marketed by Teva Pharmaceuticals in the U.S. since May 2023**

- UZEDY®, monthly and every 2 months subcutaneous risperidone for treatment of schizophrenia
- Approved by the FDA in April 2023
- Targeting primarily U.S. \$4.4 billion 12% CAGR market, up to \$105m milestones + royalties for MedinCell
- 2024 sales forecast by Teva: \$100m - Actual sales as of Sept 30, 2024: \$75m



**Rich R&D pipeline including first-in-class therapies and potential blockbusters**

- 2 products already in phase 3
- Growing number of products at formulation and preclinical stages

**Tier one partners**

- Teva Pharmaceuticals
- AbbVie
- Bill & Melinda Gates (*\$23m grant, Global Health*)
- Joint venture with Corbion (*GMP commercial Polymer*)



**Return to profitability**

- Royalties from UZEDY®, ramp-up in progress
- Strong commercial potential of mdc-TJK, next product expected to reach market in 2026
- Active ongoing discussions for new strategic partnerships driven by booming interest for LAIs

**MEDCL**  
LISTED  
EURONEXT

# PRODUCT PORTFOLIO AND R&D PIPELINE

FORMULATION → PRECLINICAL → CLINICAL PHASE 3 → MARKET →

10

in-house and partnered programs



mdc-WMM  
**Progestin 6-Month Contraception**  
BILL & MELINDA GATES foundation

mdc-STW  
**Ivermectin 3-Month Malaria**  
Unitaid

**AbbVie (1/6)**  
abbvie

mdc-TJK  
**Olanzapine 1-Month Schizophrenia**  
teva

mdc-CWM  
**Celecoxib - Intraarticular Postoperative pain**  
AiC

mdc-IRM  
**UZEDY® Risperidone 1- & 2-Month Schizophrenia**  
teva

April 2024

# STRATEGIC COLLABORATION WITH ABBVIE

## CO-DEVELOPMENT AND LICENSING AGREEMENT

### Up to 6 Long-Acting Injectable therapies

- Multiple therapeutic areas and indications
- First program candidate selected; preclinical and CMC activities underway

**Medincell to conduct formulation and preclinical activities**

**AbbVie to conduct clinical development**

**AbbVie responsible for commercialization globally**

## FINANCIAL METRICS

**\$35 million upfront payment**

**up to \$1.9 billion in potential commercial and development milestones including \$X million payment upon initiation of each of the 5 next programs**

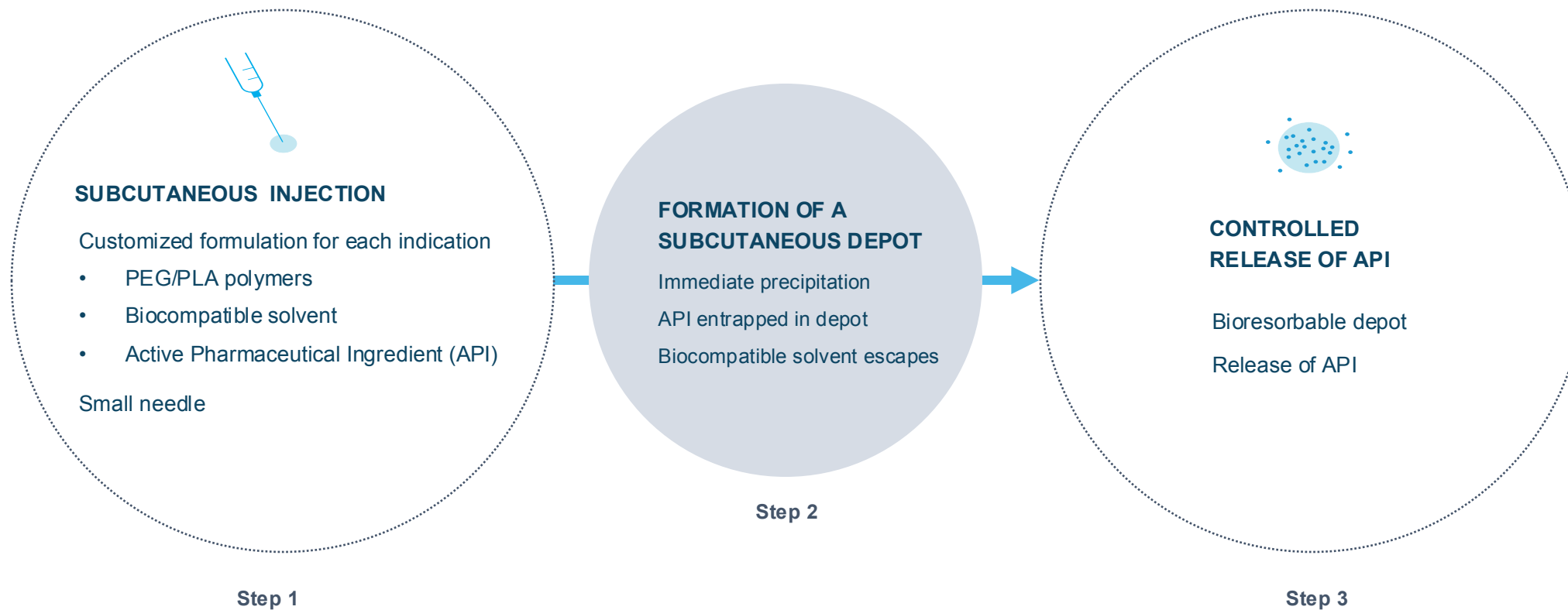
**Tiered mid-single to low-double digit royalties**



**BEPO<sup>®</sup>**

Long-acting injectables  
cutting-edge technology platform

## Long-Acting Injectable cutting-edge technology platform



# BEPO® POLYMERS SECURED THROUGH INDUSTRIAL JOINT VENTURE WITH CORBION



## Limited scale-up risk

*Research and clinical batch polymers come from same production line as commercial polymers*

**Secure supply, ensure quality & preserve manufacturing IP**

**Dual GMP manufacturing facilities – Europe and U.S.**

**DMF filed in the US and Canada**

**50/50 Joint-Venture**



Leading manufacturer of biomedical polymers worldwide

Pharma production standards (ICHQ & GMP)

Listed on Euronext Amsterdam (CRBN - market cap: ca. €1.1B as of January 1, 2023)



# PRODUCT ON MARKET

## UZEDY®

Monthly and every 2 months subcutaneous risperidone  
for treatment of schizophrenia

# UZEDY®



Market authorization by U.S. FDA on April 28, 2023

Commercialization by Teva Pharmaceuticals since May 2023

Targeting primarily US \$4.4 billion 12% CAGR market

Medincell eligible for

- mid-to high-single digit royalties on net sales
- up to \$105m in commercial milestones

2024 Teva's revenue outlook: ~\$100 million

2024 sales (as of September 30)

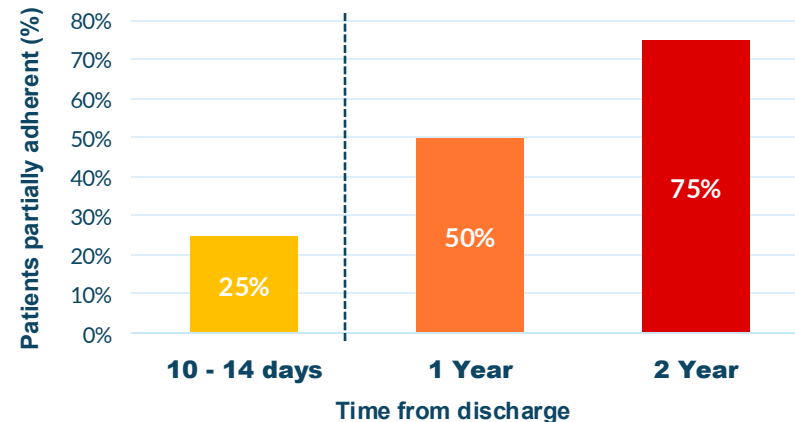
Q1	Q2	Q3	Q4
\$40M		\$35M	n/a

# ADHERENCE TO TREATMENT IS CRUCIAL IN SCHIZOPHRENIA

ca. 1% of the worldwide population will develop schizophrenia in their lifetime<sup>1</sup>

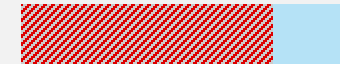
Approximately 80% of patients experience multiple relapses during the first five years of treatment<sup>2</sup>, and each relapse carries a biological risk of loss of function, treatment refractoriness, and changes in brain morphology<sup>3,4</sup>

Treatment compliance worsens over time<sup>5</sup>



<sup>1</sup> SSPAA, About Schizophrenia, Available at: [schizophrenia.org/about-schizophrenia/](http://schizophrenia.org/about-schizophrenia/) - Accessed June 2023; <sup>2</sup> Emsley, R., & Kilian, S. (2018). Efficacy and safety profile of paliperidone palmitate injections in the management of patients with schizophrenia: an evidence-based review. *Neuropsychiatric disease and treatment*, 14, 205-223; <sup>3</sup> Emsley, R., Chhiza, B., Asmal, L., et al. (2013). The nature of relapse in schizophrenia. *BMC Psychiatry* 13, 50; <sup>4</sup> Andreasen, N. C., et al. (2013). Relapse duration, treatment intensity, and brain tissue loss in schizophrenia: a prospective longitudinal MRI study. *The American journal of psychiatry*, 170(6), 609-615; <sup>5</sup> Velligan DI, et al. *Psychiatr Serv*. 2003;54(5):655-667. Weinstein PJ, et al. Medication noncompliance in schizophrenia: I. assessment. *Journal of Practical Psychiatry and Behavioral Health*. 1997;3:106-110; <sup>6</sup> Comprehensive understanding of schizophrenia and its treatment, Maguire GA. *Am J Health Syst Pharm*. 2002; <sup>7</sup> Analysis Group, Otsuka, Lundbeck LLC - 2016

75%



of patients had discontinued medication within 2 years due to insufficient efficacy, intolerable side effects or for other reasons

In the U.S., schizophrenia accounts for 20% of all hospital bed-days and over 50% of all psychiatric beds<sup>6</sup>

Annual schizophrenia costs are estimated between \$134 and \$174 bn<sup>7</sup>

# UZEDY<sup>®</sup>, STRONG DIFFERENTIATION THANKS TO BEPO<sup>®</sup>



## SUBCUTANEOUS INJECTION (vs. intramuscular)

- Smaller needle (16mm; 21 gauge)
- Multiple injection sites (upper arm and abdomen)
- Lower injection volume (0.1 –0.7 ml)

## PREFILLED SYRINGE

- Ready-to-use (no reconstitution needed)
- Can be left out of the refrigerator for up to 90 days












## IMMEDIATE ONSET OF ACTION

- Achieves therapeutic levels within 24 hours of first injection
- No loading dose or oral supplementation required

## DESIRABLE PHARMACOKINETICS

- Multiple dosing options corresponding to oral risperidone
- Can be dosed every month or every two months

# UZEDY<sup>®</sup>, DIFFERENTIATED PROFILE FOR SCHIZOPHRENIA PATIENTS

	 UZEDY <sup>™</sup>	Invega Sustenna <sup>®</sup>
Molecule	Risperidone	Paliperidone
Efficacy	 Efficacy profile consistent with risperidone	 Efficacy profile consistent with paliperidone
Safety	 Safety profile consistent with risperidone	 Safety profile consistent with paliperidone
Dose frequency	1-Month, 2-Month	1-Month
SC injection (and volume)	 (0.1-0.7 mL)	 <sup>1</sup> (0.25-1.5 mL)
Therapeutic levels in 24h	 	 <sup>2</sup> 
No oral supplement / loading dose	 	 <sup>2</sup> 

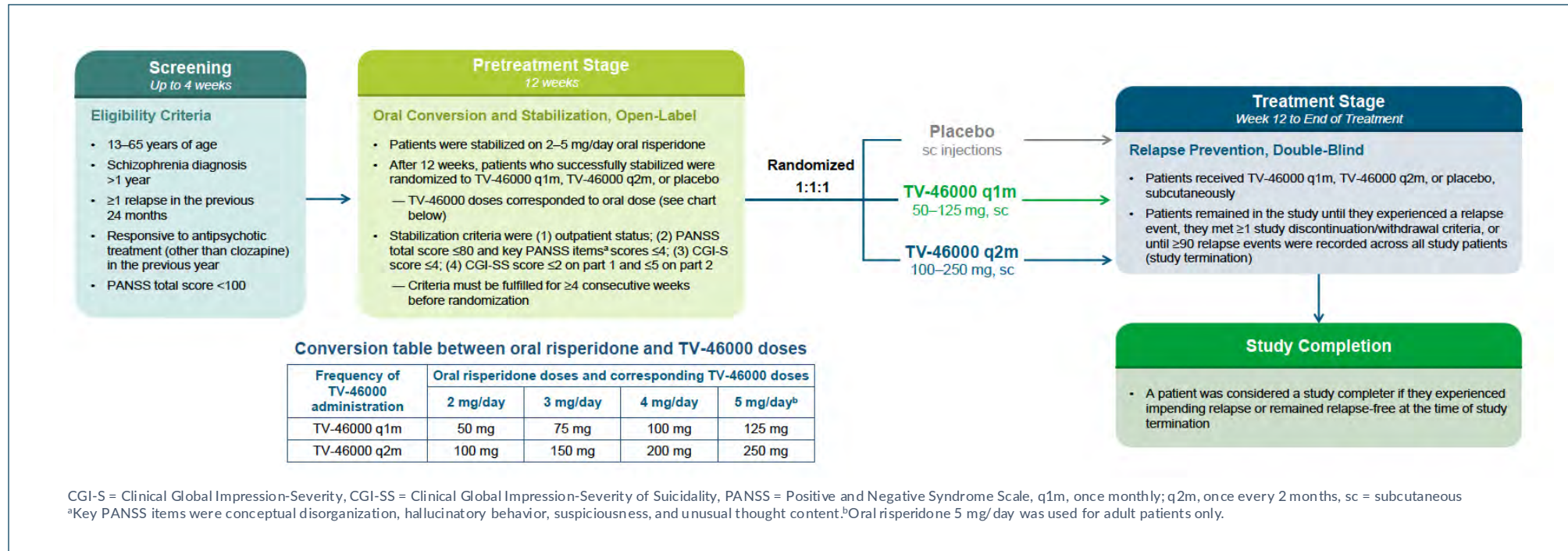
3M Invega Trinza<sup>®</sup> and 6M Invega Hafyera<sup>®</sup> formulations also available

← **70% of target LAI patients<sup>3</sup> are on 1M formulation (*preferred by psychiatrists for patient monitoring*)**

1. Intramuscular injection 2. As per prescribing information, Invega Sustenna requires two initial deltoid IM injections of 234mg on day 1 and 156mg on day 8 to help attain therapeutic levels rapidly 3. U.S. patients on risperidone/paliperidone LAIs  
Note: No head-to-head studies have been conducted comparing UZEDY with any other therapy. The information on this slide should not be construed to imply any difference in safety, efficacy, or other clinical outcome. All trademarks referenced are properties of their respective owners  
Sources: UZEDY RISE Phase III pivotal study and prescribing information; Invega Sustenna Phase III pivotal study and prescribing information

# UZEDY<sup>®</sup>, EFFICACY AND SAFETY IN SCHIZOPHRENIA

## Phase 3, Randomized, Double-Blind, Relapse Prevention Study (RISE Study)



In total, 1 267 patients were screened, 863 were enrolled, and 544 were randomized

The primary endpoint was time to impending relapse and secondary endpoints included proportions of patients with impending relapse at week 24 and proportion of patients who maintained stability at week 24

TV-46000 is the investigational product codename used by Teva during regulatory development of mdc-IRM

Source: Subcutaneous Risperidone (TV-46000) Efficacy and Safety in Schizophrenia: a Phase 3, Randomized, Double-Blind, Relapse Prevention Study (RISE Study)

John M. Kane,<sup>1,3</sup> Eran Harary,<sup>4</sup> Oma Tohami,<sup>4</sup> Roy Eshet,<sup>4</sup> Avia Merenlender-Wagner,<sup>4</sup> Nir Sharon,<sup>4</sup> Mark Suett,<sup>5</sup> Kelli R. Franzenburg,<sup>6</sup> Christoph U. Correll<sup>1,3,4</sup>

<sup>1</sup>Zucker Hillside Hospital, Northwell Health, Department of Psychiatry, Glen Oaks, NY, United States; <sup>2</sup>Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, Department of Psychiatry and Molecular Medicine, Hempstead, NY, United States; <sup>3</sup>Feinstein Institutes for Medical Research, Institute of Behavioral Science, Manhasset, NY, United States; <sup>4</sup>Teva Pharmaceutical Industries, Global Specialty Research & Development, Netanya, Israel; <sup>5</sup>Teva Pharmaceutical Industries, Global Medical Affairs, West Chester, PA, United States; <sup>6</sup>Charité–Universitätsmedizin Berlin, Department of Child and Adolescent Psychiatry, Berlin, Germany  
Presented at Psych Congress 2021, October 29–November 1, 2021

# UZEDY<sup>®</sup>, KEY OUTCOMES FROM THE PIVOTAL PHASE 3 STUDY

## EFFICACY

mdc-IRM significantly prolonged time to impending relapse compared to placebo<sup>1</sup>

- 80.0% and 62.5% reduction in risk of relapse vs placebo for monthly and every two-month UZEDY<sup>®</sup>, respectively
- x5 and x2.7 increase in time to impending relapse with monthly and every two-month UZEDY<sup>™</sup>, respectively
- 7% and 13% of patients using monthly and every two-month UZEDY<sup>®</sup>, respectively, relapsed within 24 months vs 28% of placebo patients

mdc-IRM provided continued symptom improvement in patients with schizophrenia<sup>2</sup>

## SAFETY

No new safety signals versus accumulated safety data for oral risperidone and other long-acting risperidone formulations<sup>3</sup>



TV46000 is the investigational product codename used by Teva during regulatory development of mdc-IRM

<sup>1</sup> Subcutaneous Risperidone (TV-46000) Efficacy and Safety in Schizophrenia: a Phase 3, Randomized, Double-Blind, Relapse Prevention Study (RISE Study) - John M. Kane, Eran Harary, Oma Tohami, Roy Eshet, Avia Merenlender-Wagner, Nir Sharon, Mark Suett, Kelli R. Franzenburg, Christoph U. Correll ; <sup>2</sup> TV-46000 Provided Continued Symptom Improvement in Patients With Schizophrenia in the Phase 3, Randomized, Double-Blind Relapse Prevention RISE Study - John M. Kane, Christoph U. Correll, Oma Tohami, Roy Eshet, Avia Merenlender-Wagner, Nir Sharon, Mark Suett, Kelli R. Franzenburg, Eran Harary ; <sup>3</sup> Behavioral-, Metabolic-, Endocrine-, and Cardiovascular-Related Adverse Events in Patients With Schizophrenia Treated With TV-46000 - Christoph U. Correll, Helena Knebel, Eran Harary, Roy Eshet, Oma Tohami, Mark Suett, Nir Sharon, Kelli R. Franzenburg, John M. Kane ; Presented at Psych Congress 2021, October 29–November 1, 2021

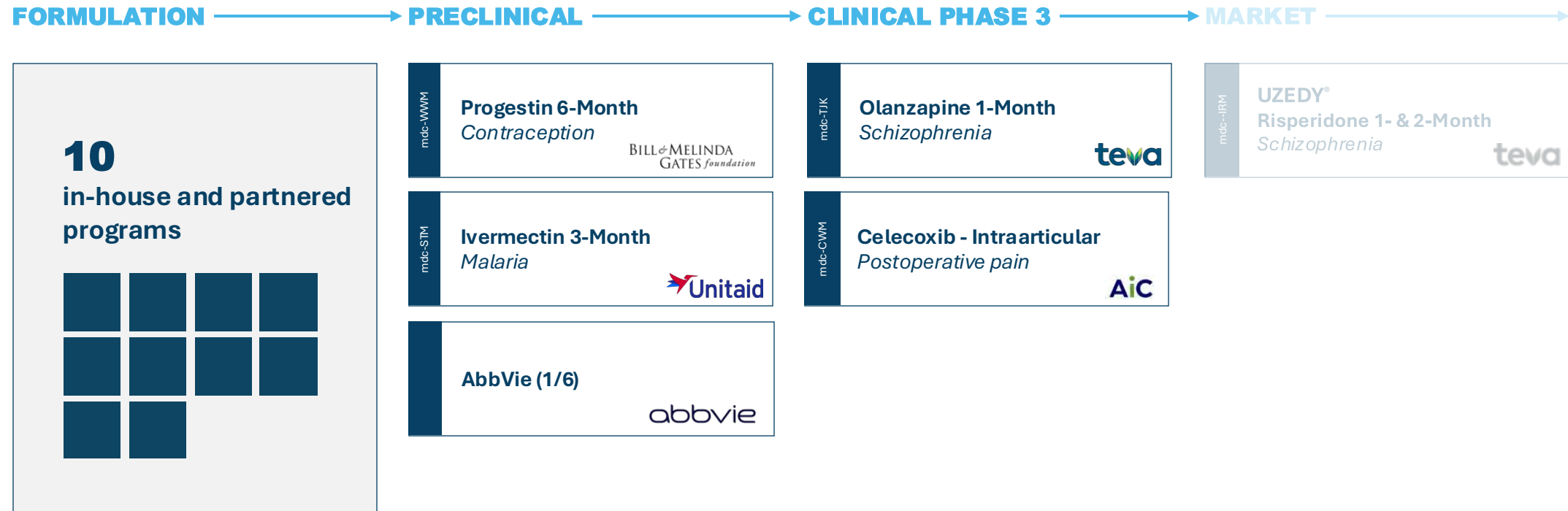


# R&D PIPELINE

Long-acting injectables based on BEPO

# R&D PIPELINE

## Long-acting injectables based on BEPO®





CLINICAL PHASE 3 | mdc-TJK

## Olanzapine 1-Month

Once-monthly subcutaneous long-acting injection of the atypical antipsychotic olanzapine

May 2024: Positive Phase 3 efficacy results in adult patients with schizophrenia

Phase 3 safety data topline readout expected in H1 2025

**May be the first long-acting olanzapine with a favorable safety profile**

# mdc-TJK, MEDICAL NEED AND PRODUCT RATIONALE

## Impact of relapse and psychosis in schizophrenia

High non-adherence rates with oral medication, eg 64% of patients assigned to olanzapine discontinued treatment within 18 months<sup>1</sup>

## Approved Olanzapine IM LAI

Existing olanzapine LAI has limited use:

- Black box warning for PDSS as a result of dose dumping hypothesized to be caused by a combination of IM route of administration and formulation characteristics<sup>2</sup>
- Only available through restricted distribution (REMS) program
- IM injection, requires a loading dose for low and middle doses

## Envisaged mdc-TJK

Monthly long-acting subcutaneous injectable :

- SC administration & formulation characteristics of mdc-TJK may mitigate the hypothesized causes of PDSS
- No complex initiation program with no need for loading

LAI = long-acting injectable,

PDSS = post-injection delirium/sedation syndrome,

REMS = Risk Evaluation and Mitigation Strategy

Product characteristics are aspirational, and the product is still in development

References: 1. Lieberman JA, et al. N Engl J Med. 2005;353(12):1209-1223 2. McDonnell, D.P., Delke, H.C., Bergstrom, R.F. et al. BMC Psychiatry 10, 45 (2010). <https://doi.org/10.1186/1471-244X-10-45> 3. Correll CU, et al. Am J Psychiatry. 2020;177(12):1168-1178. doi:10.1176/appi.ajp.2020.19121279; 4. Citrome L. CNS Spectr. 2021;26(2):118-129. doi:10.1017/S1092852921000243; 5. Roberge C, et al. Journal of Controlled Release. 2020; 319: 416-427.

# mdc-TJK - POTENTIAL TO BE THE FIRST LAI OLANZAPINE WITH FAVORABLE SAFETY PROFILE

	1990's ▼		Today ▼
	Oral olanzapine	Zyprexa Relprevv® (LAI)	mdc-TJK Target profile
Efficacy	✓	✓	✓ Expect efficacy consistent with olanzapine
Safety	Well characterized safety profile <sup>1</sup>	Well-characterized safety profile <sup>1</sup> with PDSS occurrence	Expected in line with oral olanzapine <sup>2</sup> BEPO <sup>®3</sup> technology controls the steady release of API, as demonstrated with UZEDY <sup>®</sup>
Convenience	✗ Once daily	≈ Once every 2 weeks	✓ Once monthly

PDSS: Post-Injection Delirium/Sedation Syndrome PK: Pharmacokinetics

<sup>1</sup> With boxed warning for increased mortality in elderly patients with dementia-related psychosis <sup>2</sup> Expected boxed warning for increased mortality in elderly patients with dementia-related psychosis

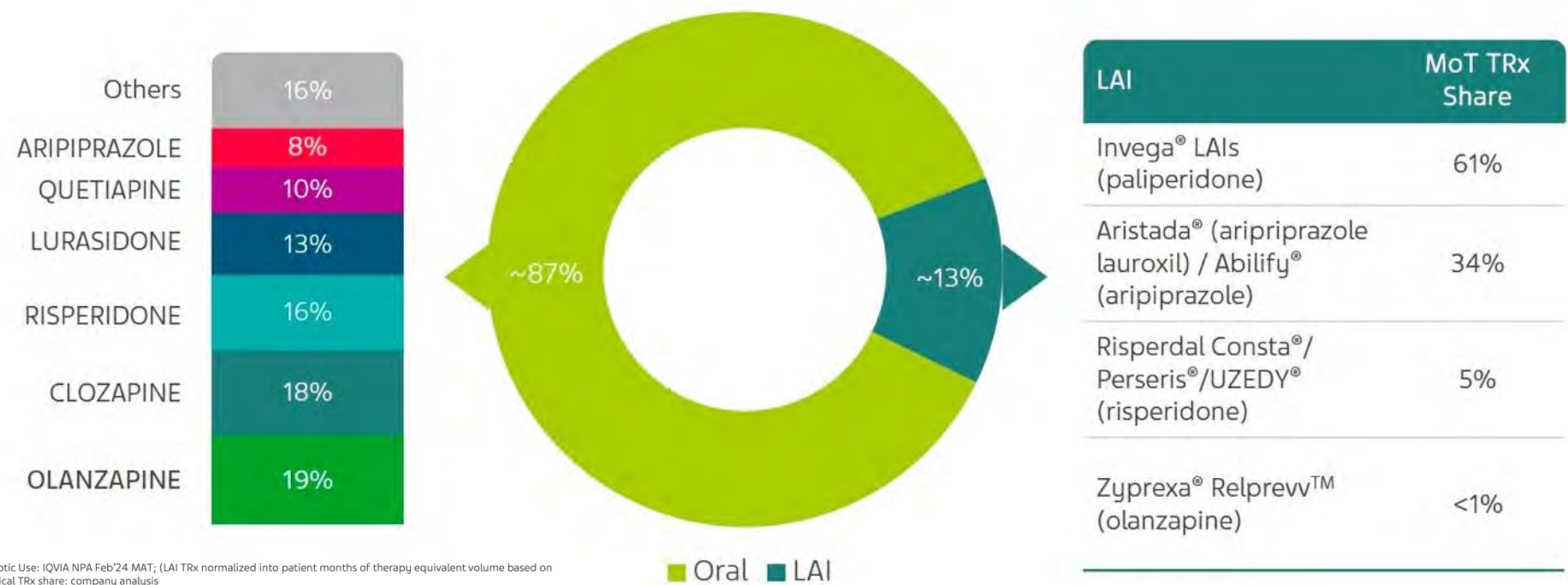
Note: No head-to-head studies have been conducted comparing olanzapine (749) with any other therapy. The information on this slide should not be construed to imply any difference in safety, efficacy, or other clinical outcome. Olanzapine (749) is an asset under investigation, not approved by regulators. SteadyTeq<sup>®</sup> is a registered trademark of Teva Pharmaceuticals USA, Inc.

<sup>3</sup> Licensed under the name SteadyTeq<sup>™</sup> to Teva

# OLANZAPINE LAI SIGNIFICANT POTENTIAL

Olanzapine is the most prescribed antipsychotic for schizophrenia in the U.S.

U.S. Schizophrenia Rx market, current atypical antipsychotic use

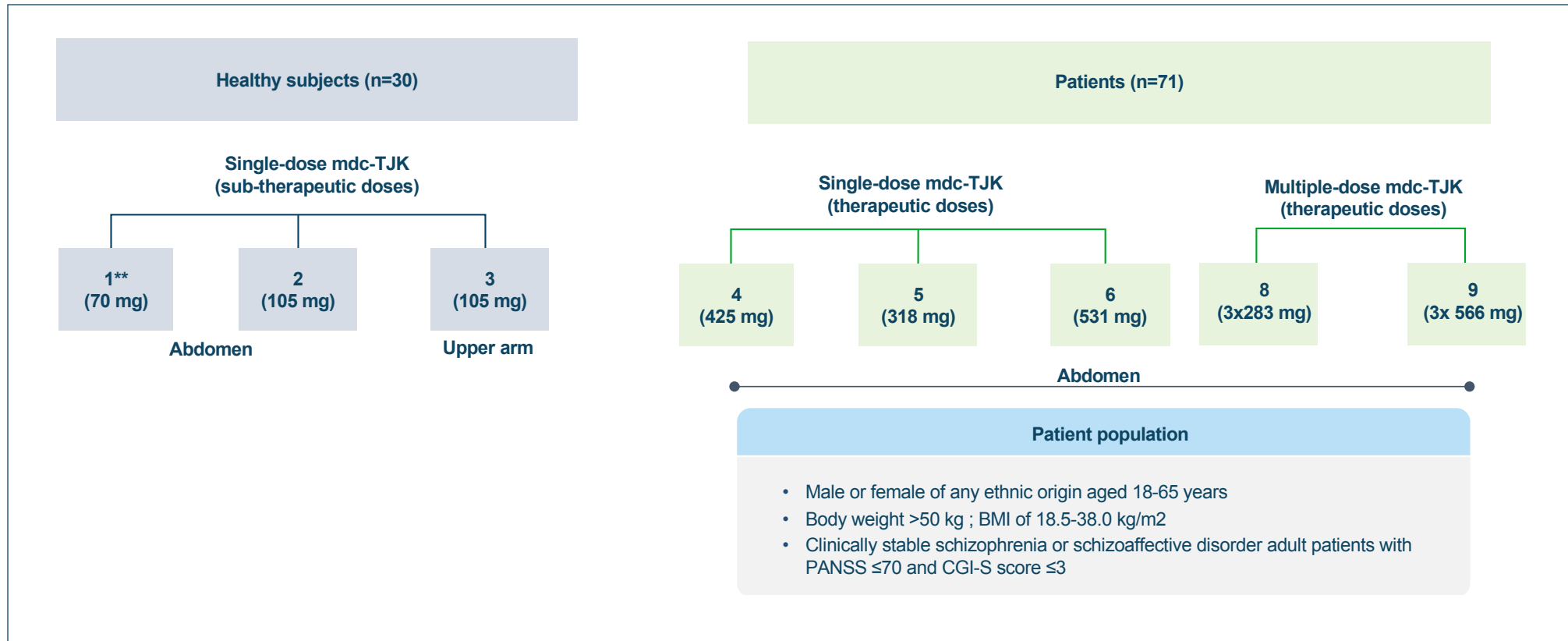


Current Atypical Antipsychotic Use: IQVIA NPA Feb'24 MAT; (LAI TRx normalized into patient months of therapy equivalent volume based on dosing regimen), Oral atypical TRx share: company analysis  
Global peak sales source: Evaluate pharma complete data extract for LAI antipsychotics  
Trademarks mentioned are the property of their respective owners

Source: Teva earnings call presentation - May 8, 2024

# mdc-TJK PHASE 1 SAD/MAD STUDY DESIGN

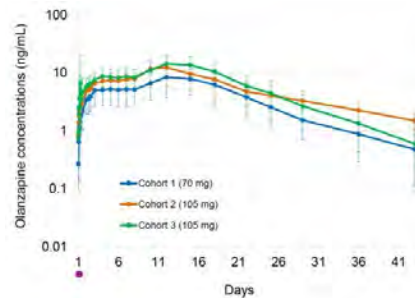
- Overall, 127 participants enrolled
- 101 participants were administered mdc-TJK



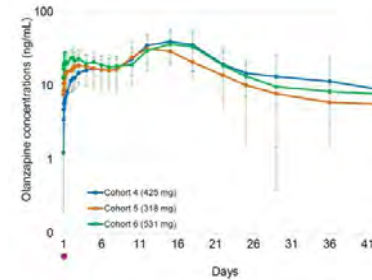
# mdc-TJK PHASE 1 SAD/MAD

## Pharmacokinetics in healthy volunteers and patients with schizophrenia or schizoaffective disorder

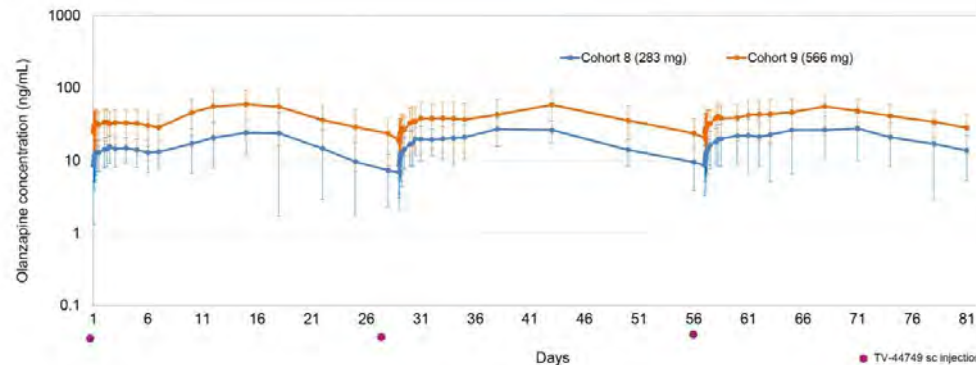
Mean ( $\pm$ SD) olanzapine plasma concentrations following single dose TV-44749 sc injections in healthy subjects



Mean ( $\pm$ SD) olanzapine plasma concentrations following single dose TV-44749 sc injections in patients with schizophrenia



Mean ( $\pm$ SD) olanzapine plasma concentrations following three once monthly TV-44749 sc injections in patients with schizophrenia



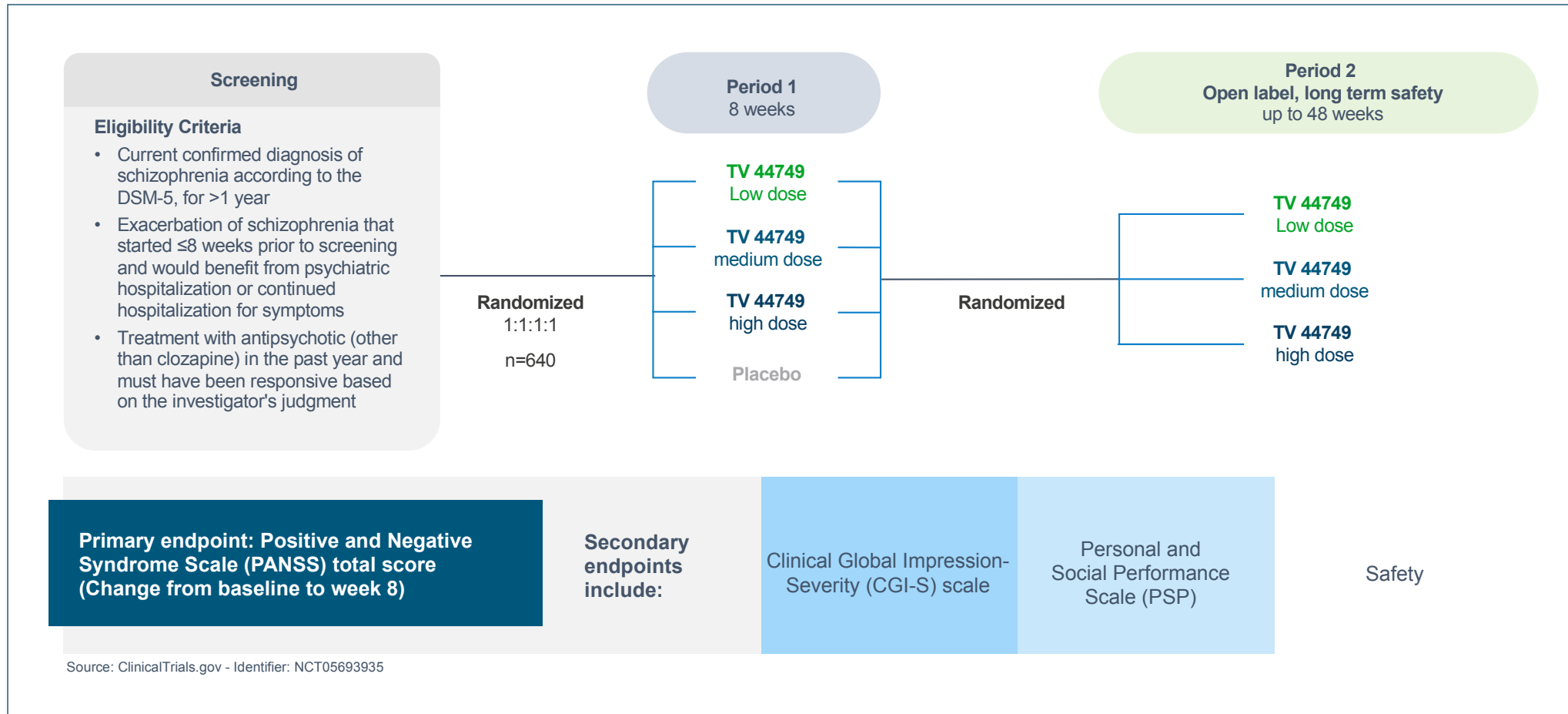
### mdc-TJK exhibited favorable characteristics of extended-release profile:

- By reaching clinically relevant therapeutic olanzapine plasma concentrations ( $\geq 10$  ng/mL) within a 1 to 2 day and maintaining them during the 28-day dosing interval
- At steady-state conditions over 28 dosing interval, the systemic exposure of mdc-TJK at doses 318, 425 and 531 mg were comparable to oral daily corresponding doses 10 mg, 15 mg, and 20 mg respectively
- No burst or uncontrolled rise in olanzapine plasma concentrations following mdc-TJK subcutaneous administration was observed

**The results of this study, supported dose selection of mdc-TJK in ongoing Phase 3**

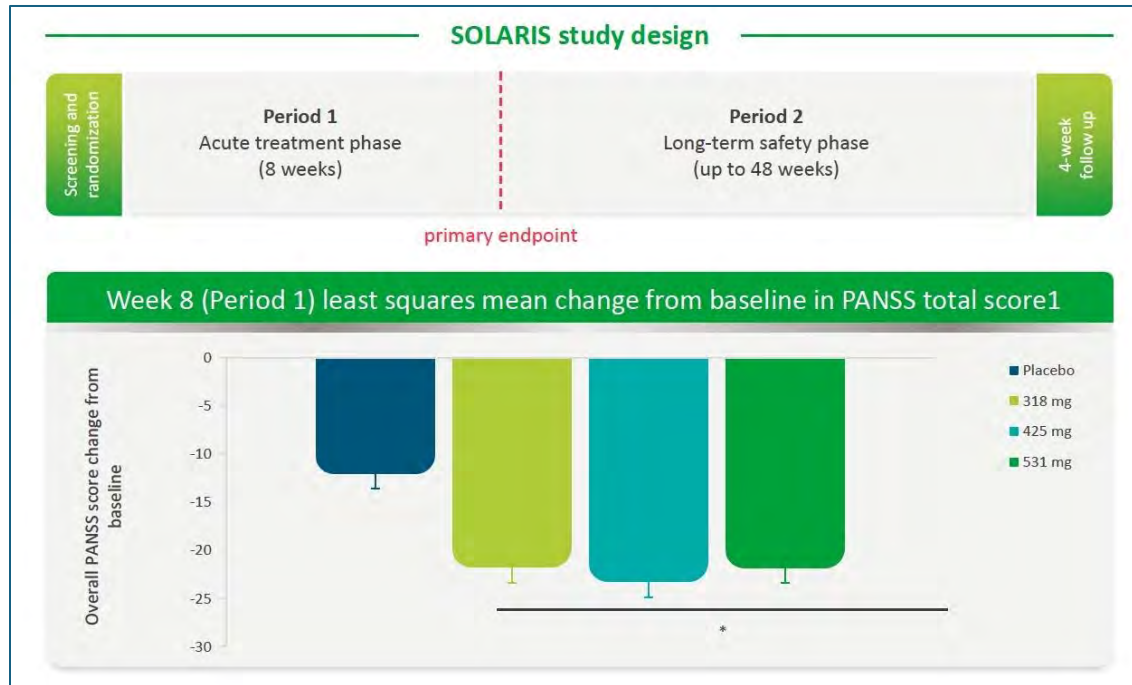
# mdc-TJK, EFFICACY AND SAFETY IN SCHIZOPHRENIA

- A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study (SOLARIS)



# mdc-TJK, EFFICACY AND SAFETY IN SCHIZOPHRENIA

May 2024: Positive Phase 3 efficacy results in adult patients with schizophrenia



Source: Teva earnings call presentation - November 6, 2024

**Olanzapine LAI for all doses demonstrated statistically significant greater efficacy versus placebo<sup>1</sup>**

## Primary endpoint

Significantly greater change from baseline to week 8 in PANSS total score versus placebo

## Secondary endpoints

Significantly greater change from baseline to week 8 in CGI-S scale score and PSP scale score versus placebo

## Other positive results

- Significant improvement in social functioning and quality of life across multiple validated measures from baseline to week 8 <sup>2</sup>
- Results from the 8-week double-blind Period 1 indicate that the systemic safety profile of all three doses was consistent with other approved formulations of olanzapine <sup>3</sup>

<sup>1</sup> Efficacy Demonstrated With Olanzapine Extended-Release Injectable Suspension (TV-44749) for Subcutaneous Use in Patients With Schizophrenia: Initial Results From a Randomized, Double-blind, Placebo-Controlled Trial (SOLARIS); Presented at the European College of Neuropsychopharmacology 2024, 21-24 September 2024; Milan, Italy; © Teva Pharmaceutical

<sup>2</sup> Improvement in Personal/Social Functioning and Quality of Life in Adults With Schizophrenia Following 8 Weeks of Once-Monthly Olanzapine Extended-Release Injectable Suspension for Subcutaneous Use (TV-44749; Phase 3 SOLARIS); Presented at Psych Congress 2024, October 29– November 2, 2024; Boston, USA; © Teva Pharmaceuticals

<sup>3</sup> Safety and Tolerability of Olanzapine Extended-Release Injectable Suspension (TV-44749) for Subcutaneous Use: Initial Results From a Randomized, Placebo-Controlled Phase 3 Trial in Patients With Schizophrenia (SOLARIS); Presented at the European College of Neuropsychopharmacology 2024, 21-24 September 2024; Milan, Italy; © Teva Pharmaceuticals

# mdc-TJK, ADDRESSING THE PDSS CHALLENGE

The use of the only available Olanzapine LAI is limited by a risk of serious side effect (PDSS) due to injection method

- PDSS: Sudden and unexpected onset of delirium or sedation after injection
- <0.1% of injections and ≈2% of patients
- Risk remains for each injection

FDA Blackbox and monitoring requirement on existing Olanzapine LAI

- Restricted distribution program
- Patients must stay at healthcare facility for 3 hours after each injection

Phase 3 (SOLARIS)

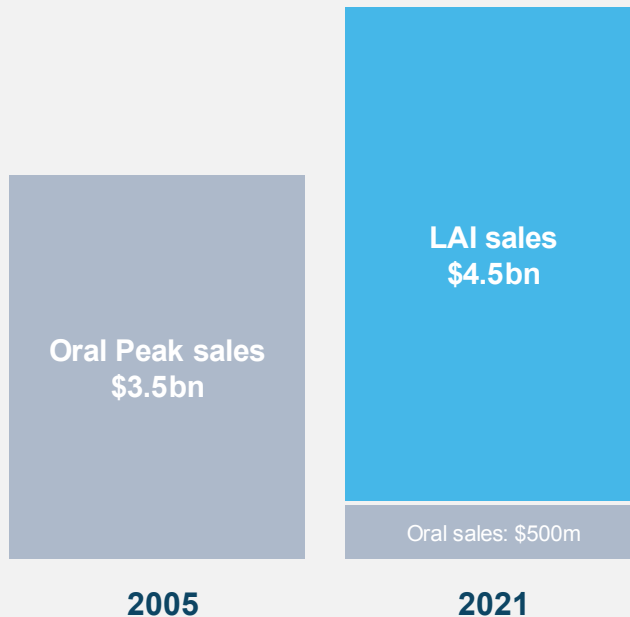
**No PDSS observed**  
**After 100% of 3600 injections**  
**required for submission**

(November 2024)

# STRONG OPPORTUNITY FOR OLANZAPINE LAI WITH FAVORABLE SAFETY PROFILE

LAI franchise was successfully built with risperidone + paliperidone<sup>1</sup>...

- Compensates sales fall after patent expiry of oral form of risperidone (2008)



... when current Olanzapine LAI does not reach potential

- Commercial failure of existing Olanzapine LAIs
- Black box warning from FDA



321 000 of U.S. treated patients out of 1,6m use Olanzapine (2022)<sup>1</sup>, mostly with oral administration

**Black box warning on existing LAI of olanzapine**

- Must be injected in certified centers
- Requires continuous observation of patients by healthcare professional for at least 3 hours after each injection
- Patient must be accompanied to their destination from the health care facility

Sources: 7 Major Markets - Companies reported sales, IQVIA

1. Teva investor day presentation– May 2024



CLINICAL PHASE 3 | mdc-CWM (F14)

# Intraarticular celecoxib

50/50 profit collaboration with AIC

Intraarticular celecoxib for post-operative pain and inflammation management

First Phase 3 in Total Knee Replacement (TKR) completed

Next steps of regulatory development in 2025

**Potential “first-in-class” for long-term post-operative pain and inflammation management**

**15%** of TKR patients become long-term opioid users

Source: 2018 Choices Matter Survey - Exposing a silent gateway to persistent opioid use

# **mdc-CWM (F14), MEDICAL NEED AND PRODUCT RATIONALE**

## **GROWING TKR MARKET**

### **Up to 1 million procedures performed annually**

- Procedures have doubled over the past two decades
- 90% are primary (first-time) TKR
- Number of procedures is expected to grow to between 1.5 million and 3 million annually by 2040

### **Rising trend toward outpatient settings (Hospitals or Ambulatory Surgical Centers)**

- Currently, 30-40% of procedures are performed in outpatient settings
- This percentage is expected to increase to 70% by 2040

### **Opioid crisis remains a significant issue in USA**

- mdc-CWM should be eligible for pass-through status in outpatient settings as a non-opioid drug under the NO PAIN Act

## **CLEAR OPPORTUNITY**

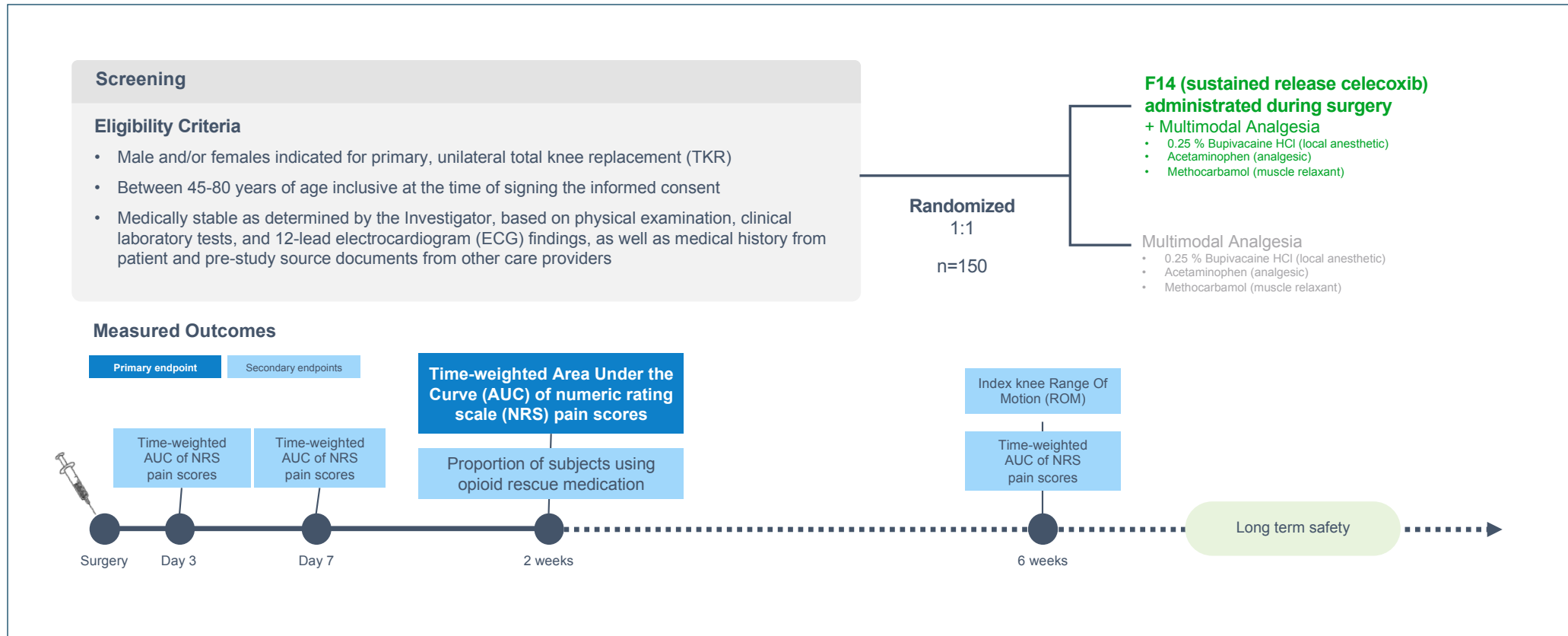
### **Still clear unmet need for greater efficacy in post-operative pain management for orthopedic surgeries**

- Pain control without opioids at greater than 72h where the 15% risk of opioid addiction begins to decline
- Improve measures of inflammation such as ROM, joint swelling, functional activities which drive long term recovery (currently 20% of patients have not returned to normal activities at 6 months post-op)

### **Local exposure only (Intra-articular) avoiding any Celecoxib related systemic safety findings and increasing local efficacy**

# mdc-CWM (F14), EFFICACY AND SAFETY IN TKR

- A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study – Study completed



# **mdc-CWM, EFFICACY AND SAFETY IN TOTAL KNEE REPLACEMENT**

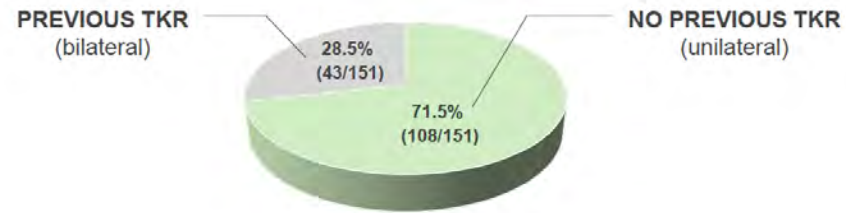
- Phase 3 results

**Primary endpoint not met, but favorable data on measures of inflammation supports differentiation from approved products in this indication as well as therapies in development**

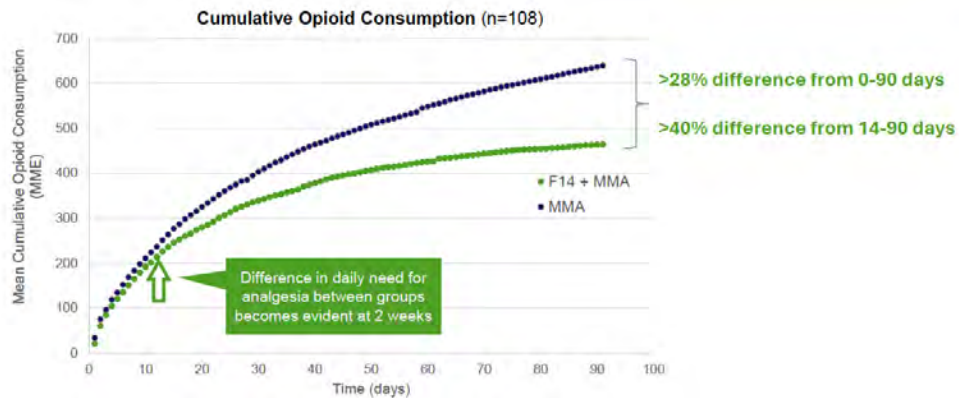
- Statistically significant outcomes related to inflammation
- Far greater improvement in a sub-group of 108 patients who had not undergone prior TKR in the contralateral knee
- No safety signals related to systemic celecoxib were identified and no SAEs were reported as related to F14 treatment
- Human PK shows much lower systemic celecoxib compared to oral formulation

**Clear regulatory path to approval with plans to meet with FDA early in 2025 to confirm primary study population in patients with no prior TKR and revised clinical study design**

# mdc-CWM, SUB-GROUP ANALYSIS



## OPIOID CONSUMPTION (no-TKR subgroup)



At 3 months, 14% of MMA patients were still taking opioids compared to only 4% of F14 patients

## AUC OF NRS PAIN

	ALL		
	F14 (76)	MMA (75)	P-value
3 Days	6.5	6.9	.1566
7 Days	5.8	6.1	.3227
2 Weeks	5.5	5.7	.4949
6 Weeks	4.4	4.6	.5257
3 Months	3.4	3.6	.5194

	NO TKR		
	F14 (51)	MMA (57)	P-value
3 Days	6.2	7.0	.0114
7 Days	5.6	6.3	.0512
2 Weeks	5.1	5.8	.0952
6 Weeks	4.1	4.7	.1624
3 Months	3.0	3.6	.1837

← Primary Endpoint

➤ Adjustment (imputation) made for consumption of opioids

All timepoints were numerically improved for F14

## RANGE-OF-MOTION

	ALL		
	F14 (76)	MMA (75)	p-value
2 Weeks	82.5	78	.1069
6 Weeks	102.4	95	.0027
3 Months	111.6	104.1	.0004

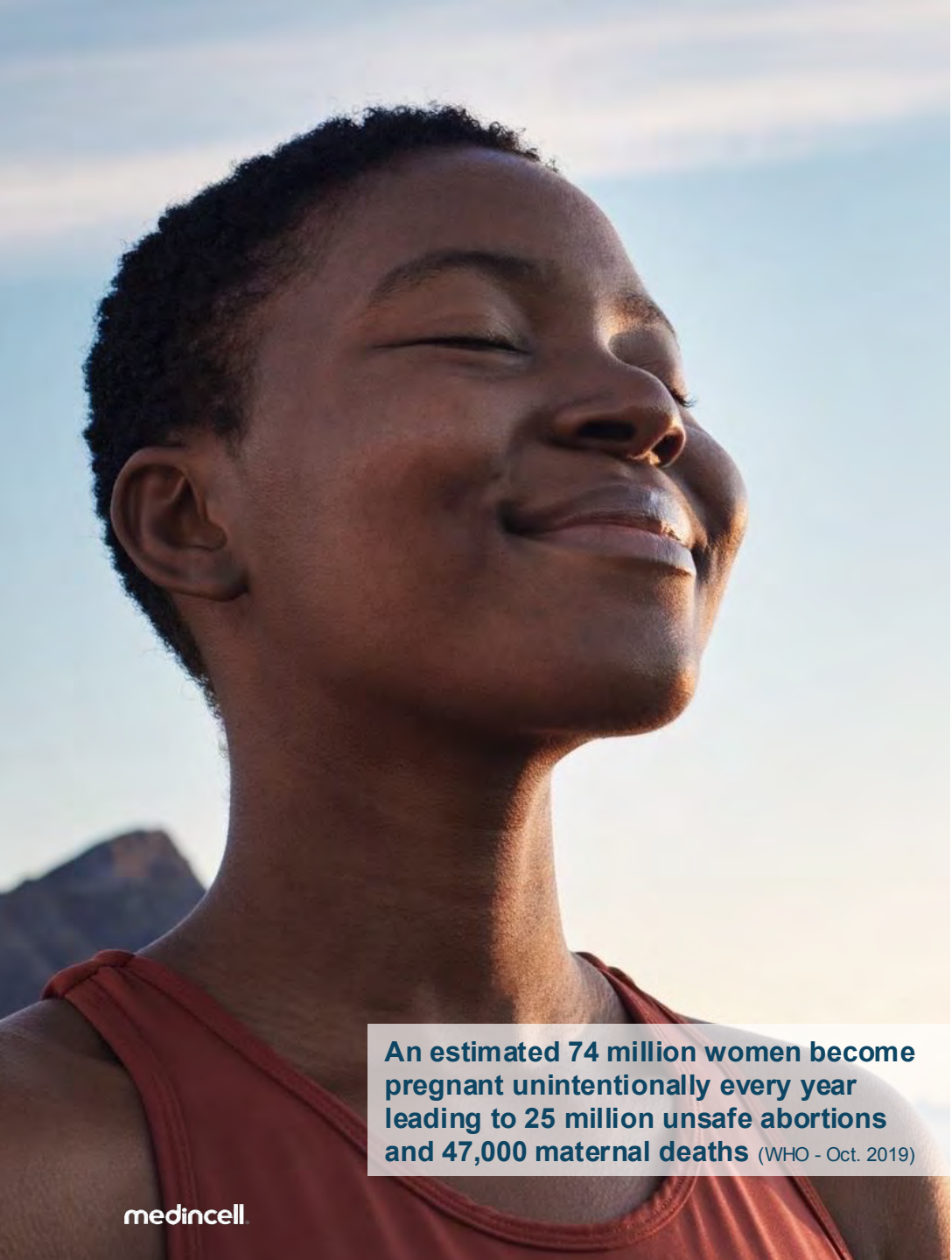
	NO TKR		
	F14 (51)	MMA (52)	p-value
2 Weeks	84.7	79.1	.0877
6 Weeks	104.3	94.6	.0011
3 Months	112.0	104.1	.0028

➤ Range of motion represents direct measurement of knee function

➤ Progression to 100-110 degrees is benchmark for rehabilitation (permits stationary bike)

➤ 1<sup>st</sup> Secondary Endpoint: ROM at 6 weeks

All timepoints were numerically improved for F14



**An estimated 74 million women become pregnant unintentionally every year leading to 25 million unsafe abortions and 47,000 maternal deaths** (WHO - Oct. 2019)

PRECLINICAL | mdc-WWM

## 6-Month contraception

**mdc-WWM could be the first contraceptive to combine essential features to make it a best-in-class product worldwide**

- Progestin molecule (non-MPA)
- 6-month duration
- Subcutaneous injection
- Auto injectable
- Full bio resorption
- Affordability

**All commercial rights owned by Medincell with a significant potential**

- Contraception is a \$5bn market in the U.S.
- LARC (Long-Acting Reversible Contraceptives, primarily solid implants and intrauterine devices) represent 28% of US market, i.e., \$1.4bn with 5- CAGR at 7.8% (Source: IQVIA)

Financial support from  
**BILL & MELINDA**  
GATES foundation

\$22.5m financing grant by the Bill & Melinda Gates Foundation for Global Access rights in low- and middle-income countries



**Malaria in 2020:**

- 627,000 deaths
- 95% in Africa,
- 80% children under 5

(WHO)

PRECLINICAL I mdc-STM

# Ivermectin / Malaria

## Objective: a new tool to fight malaria transmission

- mdc-STM enables sustained release of ivermectin following a single subcutaneous injection
- Administered at beginning of transmission season to people living in malaria-endemic areas
- Mosquitoes feeding on people who have received ivermectin will be killed or made less capable of transmitting malaria parasites further
- Goal is to decrease mosquito numbers, thus benefiting the whole community by lowering the risk of malaria transmission, particularly in children
- Community-based intervention – individuals receiving the injection would not be protected against malaria directly

**\$12m financing by the international Health Agency, Unitaid**

## License agreement with Medicines Patent Pool

Covers all low- and middle-income countries and is royalty free in the public sector. Reasonable royalty in line with industry standards to be agreed in case there would be a private market for the licensed product in low and middle- income countries.



# **FINANCIALS & EXTRA-FINANCIAL PERFORMANCE**

# SELECTED FINANCIALS

€ million	6 month Sept. 30, 2024	Year end March 31, 2024	6 month Sept 30, 2023
<b>Operating result</b>	<b>(7.5)</b>	<b>(20.9)</b>	<b>(9.0)</b>
Revenues	8.6	9.0	7.0
Other income	0.8	2.9	1.2
Operating expenses	(17.0)	(32.9)	(17.1)
<b>Net result</b>	<b>(14.6)</b>	<b>(25.0)</b>	<b>(8.2)</b>
<b>Cash position</b>	<b>31.6</b>	<b>19.5<sup>(1)</sup></b>	<b>26.8<sup>(2)</sup></b>
<b>Non-risky investments</b>	<b>7.2</b>	<b>-</b>	<b>-</b>

<sup>(1)</sup> including 5.2 M€ in the form of non-risky financial assets

<sup>(2)</sup> including 15.0 M€ in the form of non-risky financial assets

Balance sheet € million	6 month March 31, 2024	Year end March 31, 2024
<b>Equity of the consolidated group</b>	<b>(54 030)</b>	<b>(40 824)</b>
<b>Total non-current liabilities</b>	<b>80 236</b>	<b>61 304</b>
<b>Total current liabilities</b>	<b>32 657</b>	<b>16 466</b>
<b>Total non-current assets</b>	<b>11 111</b>	<b>9 690</b>
<i>Of which financial assets and other non-current assets</i>	<i>3 305</i>	<i>1 792</i>
<b>Total current assets</b>	<b>47 752</b>	<b>27 258</b>
<i>Of which cash and cash equivalents</i>	<i>31 636</i>	<i>19 460</i>
<i>Of which non-risky financial investments</i>	<i>7 217</i>	<i>-</i>



**Market Cap: ca. \$500m**  
as of September 1<sup>st</sup>, 2024

**Outstanding Shares: 29.1M**

## Analyst coverage (average TP: €20,36)

**Jefferies**

Brian BALCHIN



Raghuram SELVARAJU



Alex COGUT



Nicolas PAUILLAC



Martial DESCOUTURES



Claire DERAY



Mohamed KAABOUNI

# ESG PERFORMANCE



**C+**  
**51.05/100**



**CSA score: 43** (92<sup>nd</sup> percentile)  
**ESG Score: 51** (Average panel pharma 20/100)



**Medium Risk (high): 25,9**  
(rank 68/430°)



**C**  
(Pharma/Biotech benchmark: B-)



**80/100**



**SUSTAINABLE DEVELOPMENT GOALS**



*"Our mission is to contribute to the improvement and protection of the health of populations across the world.*

*The fair sharing of the value created with all our employees is the foundation of our business model.*

*The sustainability of Medincell an essential condition for achieving our objectives."*

Raison d'être" of Medincell voted by the General Assembly in September 2019