molecure

Fate can be altered

April 10, 2024

Presenting Team

Marcin Szumowski
Chairman of the Board & CEO

Zbigniew Zasłona
Chief Scientific Officer

Samson Fung
Chief Medical Officer

Sławomir Broniarek
Chief Financial Officer

Summary | Molecure on the path of continued growth

OATD-01: FDA and MHRA approval for Ph2 clinical trial, new application for approval in the countries of the EU and Norway. Recruitment initiated in the US and UK; **First patient dosed in UK.**

OATD-02: Ph1 clinical trial: progression to 20 mg cohort. Increase in PD marker with no toxicity

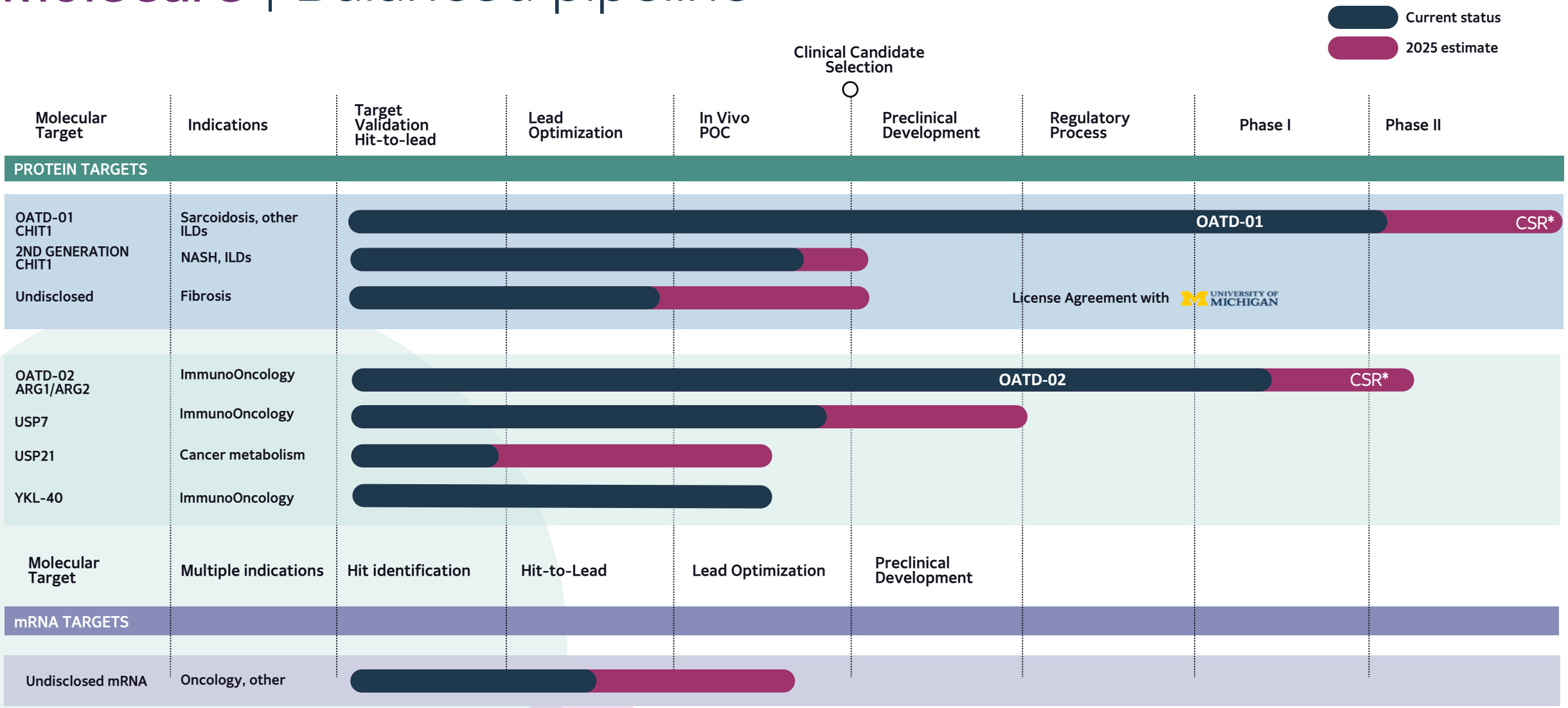
Implementation of AI tools in drug discovery; First AI-derived molecules.

50 m PLN raised in SPO (July 2023)

PoC in the mRNA discovery platform

Progress in the deubiquitinase platform

Molecure | Balanced pipeline



*Clinical Study Report

OATD-01: Disease modifying potential in sarcoidosis

10.04.2024

OATD-01 | Phase 2 in sarcoidosis

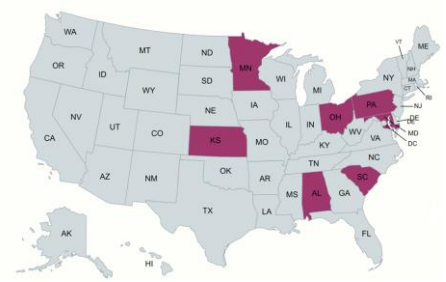
Double-blind, randomized, placebo-controlled multi-center study to assess the safety and efficacy of an oral inhibitor of CHIT1 (OATD-01) in patients with active pulmonary sarcoidosis.

FDA approval	Central Bioethic Committee (BC) approval	Application submissions in EU/UK	MHRA approval	FPFV (US/UK)	EU approval / FPFV (EU)	Intermediate checkpoint	LPLV (US & EU)
Jul 2023	Sep 2023	Sep 2023	Nov 2023	Q1 2024	Q2/Q3 2024	Q1 2025	H2 2025

H2 2025
Results and CSR

Treatment goals

- Stop disease progression and organ damage
  - Quantification of the change in granulomatous inflammation
- Improve symptoms
  - Boost lung function/ prevent lung dysfunction
  - Forced Vital Capacity (FVC) and radiographic sarcoidosis
- Improve Quality of Life (QoL)



Each patient treated for 12 weeks

~100 male and female patients with active pulmonary sarcoidosis

20-30 outpatient sites in the EU and US

OATD-01 | current status

THE KITE STUDY

[Study Details | Efficacy and Safety Study of OATD-01 in Patients With Active Pulmonary Sarcoidosis | ClinicalTrials.gov]

www.thekitestudy.com

First patient dosed in Phase II clinical trial at Edinburgh Hospital in the UK

Study active in UK and US (1 active site in each country)

Approval from the U.S. FDA and Central Bioethics Committee

Clinical trial in Europe:
- Approval of Medicines and Healthcare products Regulatory Agency (MHRA) in UK
- Resubmission for EU and Norway

Grant application to PARP (FENG program) for a total amount of PLN 16m and NIH for 2.2m USD in review

Branding activities started (WASOG participation, established FSR collaboration, ERS & AASOG participation), Study Website active,
Social media campaign in US and EU ready to launch

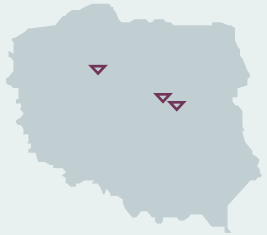
FDA's green light paved the way for Molecure to initiate the study in the United States becoming **only the second Polish biotech company** ever to do so

OATD-02: A first in class dual arginase inhibitor for cancer applications

OATD-02 | Phase I clinical study overview

Design: First-In-Human (FIH)
Open-label single-arm dose-escalation monotherapy study

Location: 3 sites in Poland:
Warsaw, Otwock, Bydgoszcz



OATD-02

Patient population: Relapsed/refractory advanced and/or metastatic solid tumors

Colorectal cancer, platinum-resistant serous ovarian cancer, pancreatic ductal cancer, renal cell carcinoma

Study Duration: Approx. 2 years
(Q1 2023 – Q1 2025)

OATD-02 taken once daily orally as monotherapy

Each patient treated for six 28-day cycles in FIH

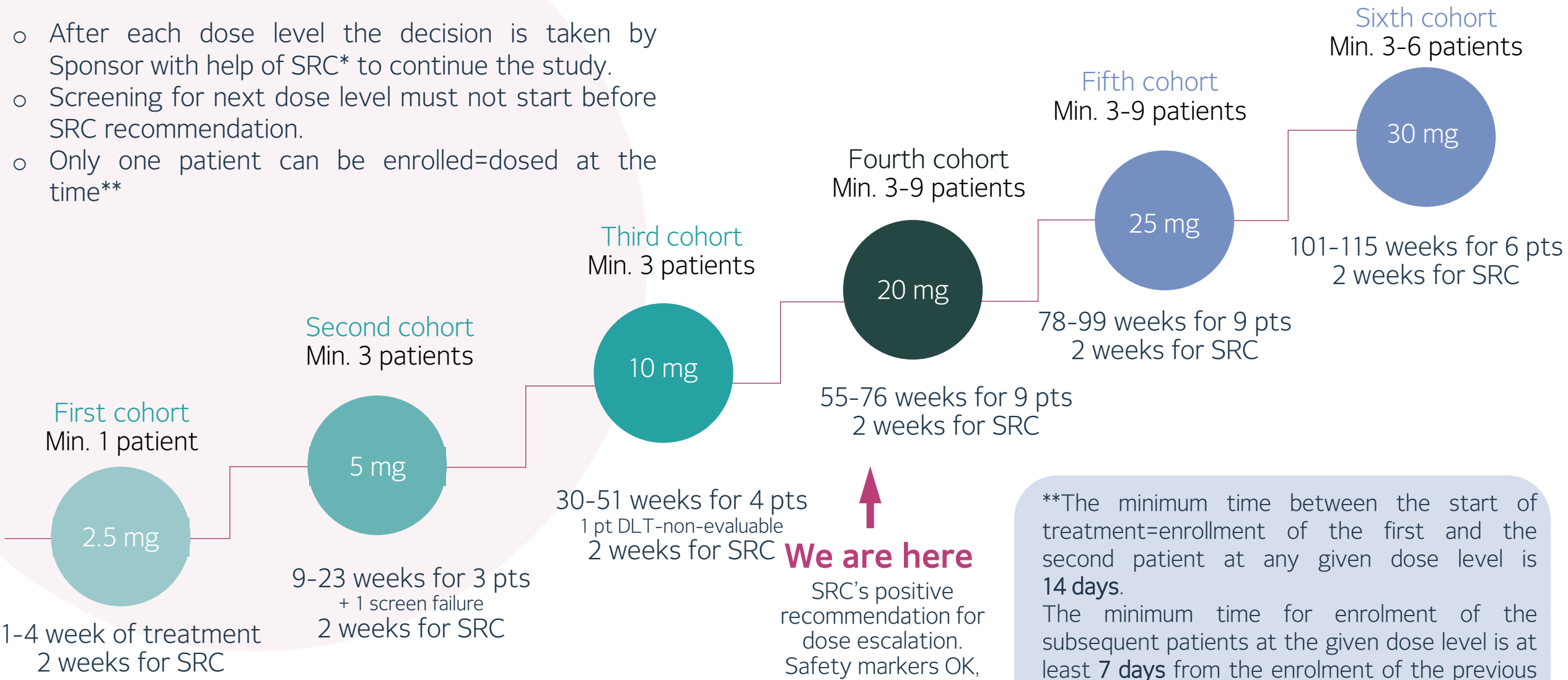
~30-40 male and female patients with advanced cancers

Rollover study for patients with clinical benefit

Bayesian Optimal Interval design, 2.5-30mg

OATD-02 | start of 4th cohort

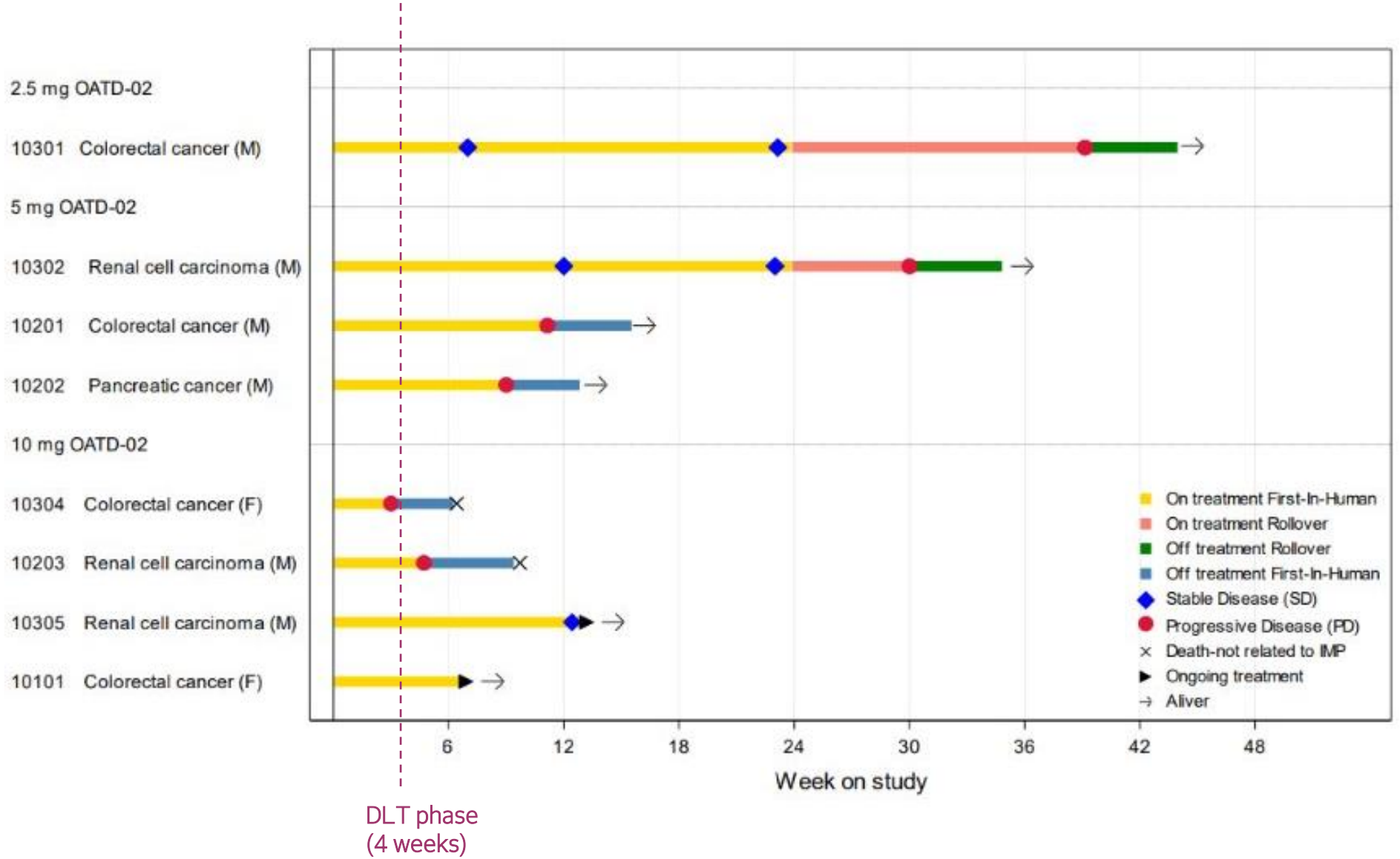
- After each dose level the decision is taken by Sponsor with help of SRC* to continue the study.
- Screening for next dose level must not start before SRC recommendation.
- Only one patient can be enrolled=dosed at the time**



*SRC – Safety Review Committee

The minimum time between the start of treatment=enrollment of the first and the second patient at any given dose level is **14 days.
The minimum time for enrolment of the subsequent patients at the given dose level is at least **7 days** from the enrolment of the previous patient.

OATD-02 | Swimmer plot – all enrolled patients*



cut-off date 04 April 2024

molecure

OATD-01 and OATD-02: to learn more about mechanism of action (MoA)

OATD-01 | New publication

frontiers

- Examples presented in this review demonstrate that protein glycosylation regulates metabolism-driven immune responses in macrophages, with implications for fibrotic processes and granuloma formation.

- Targeting proteins that regulate glycosylation, such as fucosyltransferases, neuraminidase 1 and CHIT 1 could effectively block immunometabolic changes driving inflammation and fibrosis, providing novel avenues for therapeutic interventions.

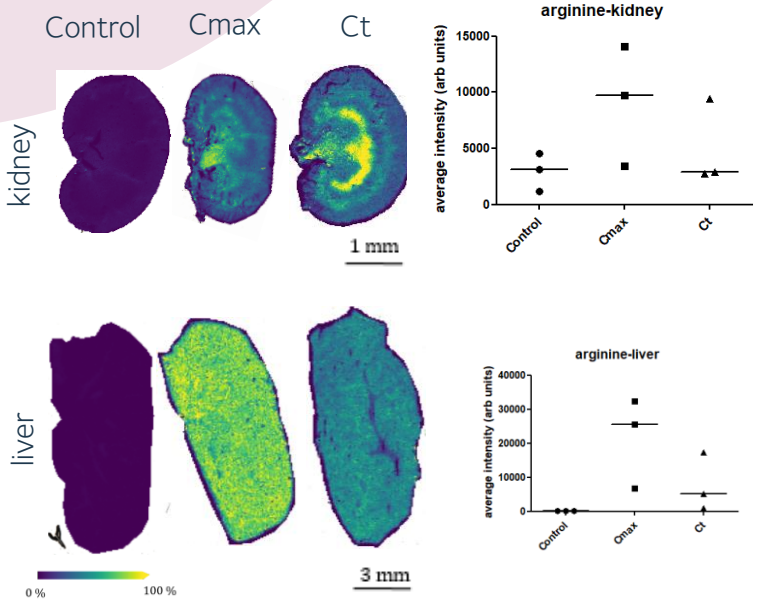
Frontiers | Link to the article

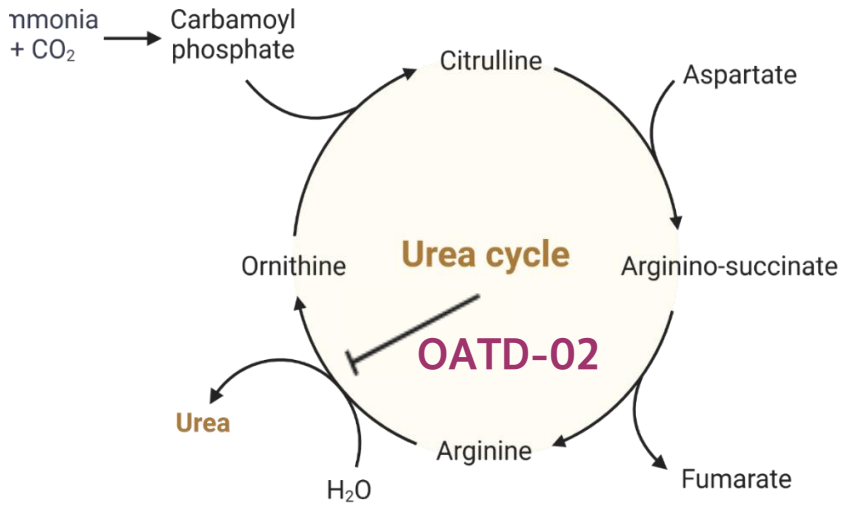
OATD-02 MoA | proof of intracellular activity

- collaboration with a research group from the University of Mannheim to use Mass Spectrometry Imaging (MSI) to assess metabolites

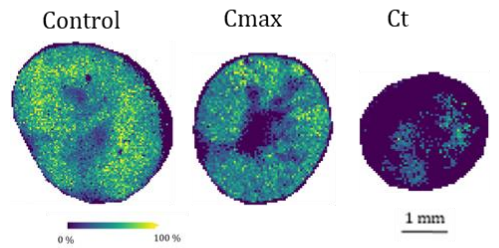
Conclusions:
the metabolic activity of OATD-02 demonstrates significant changes in tissue distribution of important **metabolic biomarkers** **confirming intracellular inhibition of ARG2 activity explaining anti-cancer effects**

Arginine

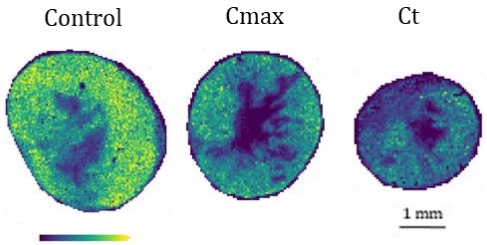




Proline



Spermidine



- Systemic increase of arginine level after OATD-02 administration

- Inhibition of polyamin synthesis in TME illustrates direct inhibition of cancer metabolism

A promising pre-clinical pipeline

USP7 inhibitor | T cell activator with proven anti-cancer potential

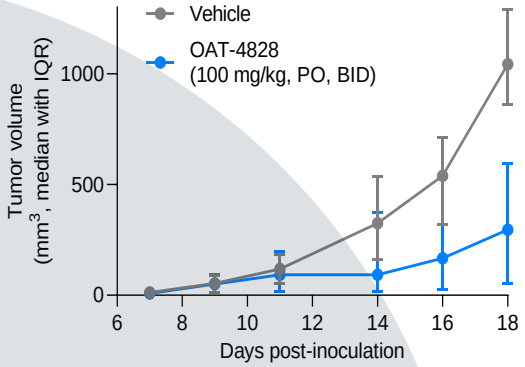
- The USP7 inhibitor program is at an advanced stage of optimization of the lead compound (medicinal chemistry work is focused on the search for an advanced lead compound with improved pharmacological properties over OAT-4828)
- First AI-derived compounds tested to improve the pharmacological properties of the lead compound - minimizing the risk of future DDI

Validated translational potential

Mechanism of action explains efficacy in various models

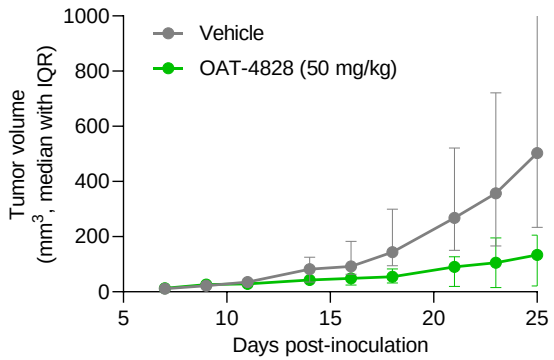
Significant efficacy as monotherapy and in combinations

B16F10 melanoma



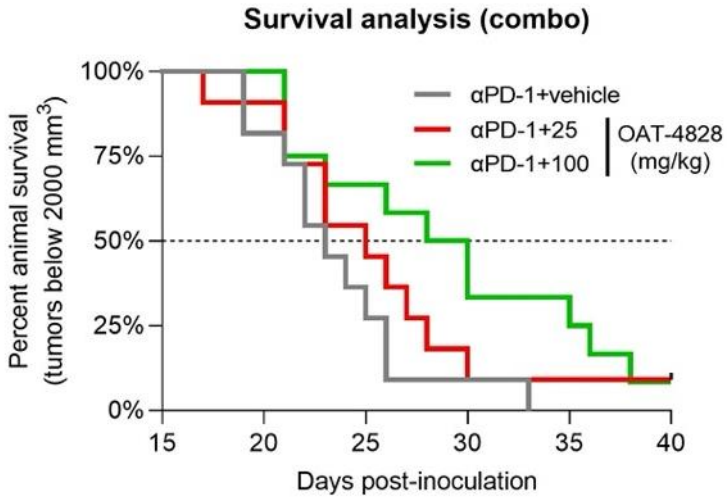
TGI 72% (100 mg/kg)

E0771 breast



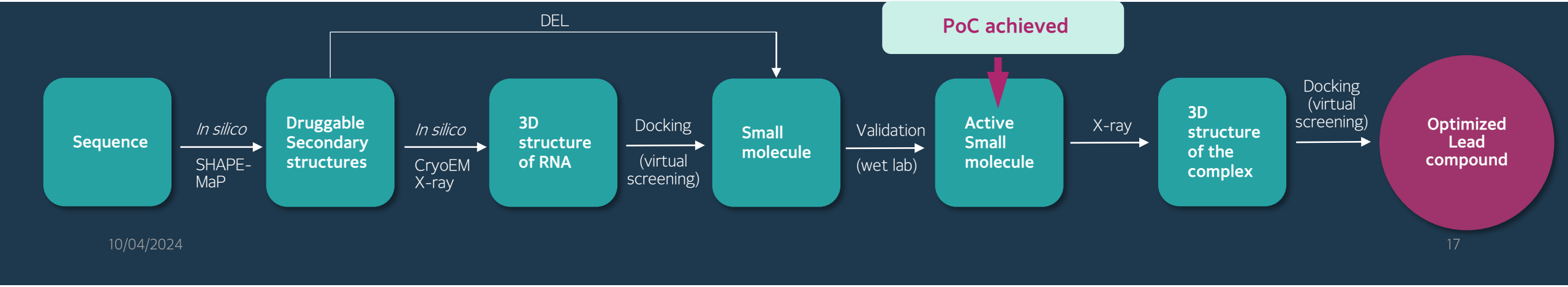
TGI 62% (50 mg/kg)

Survival analysis (combo)



mRNA Platform | discovering medicines of the future

Small molecules targeting mRNA to prevent downstream mRNA translation

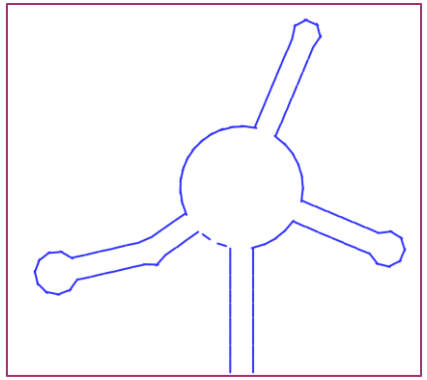


- Continued development of this novel platform, with a range of biochemical and biophysical techniques being applied to assist structural biology studies of RNA
- In-house investment in both cellular and molecular screening capabilities
- Ongoing collaborations with global leading RNA centers to further leverage the company's expertise and alternative approach to identify compounds interacting with selected mRNA regions
- Proof of Concept (PoC) achieved, in vitro study confirmed the success of mRNA platform - demonstrated the inhibition of protein translation using meticulously designed compounds that target mRNA encoding specific proteins

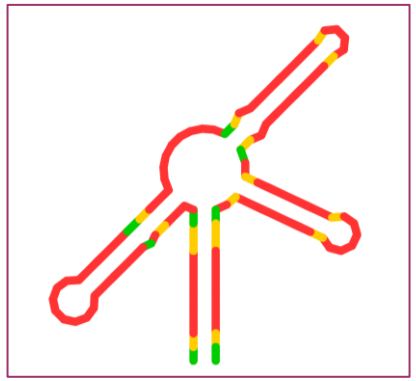
mRNA platform | first step - druggable region selection

Region with a stable structure

Predicted robust structure



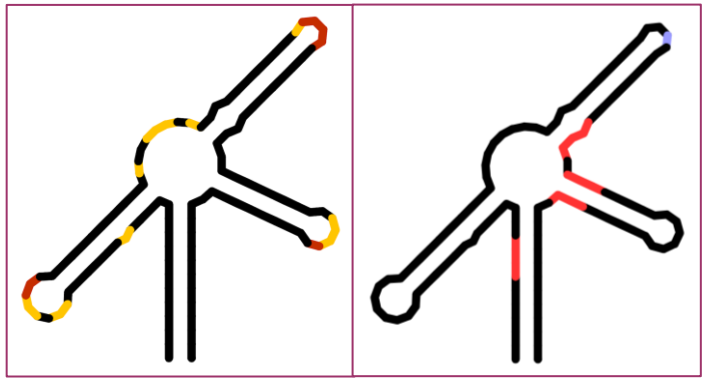
Shannon entropy



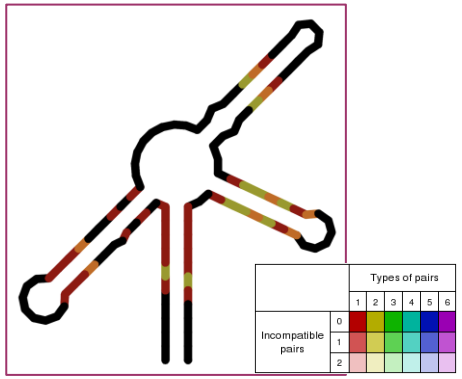
SHAPE-MaP

In vitro

In vitro – in cellulo

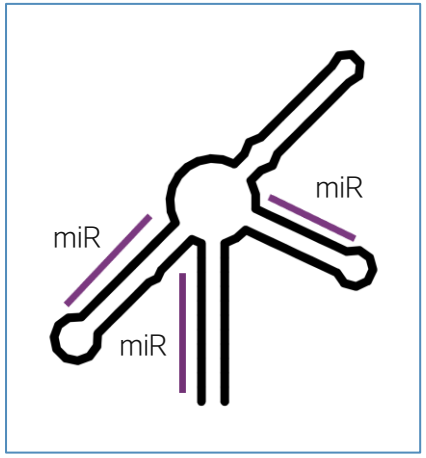


Conservation

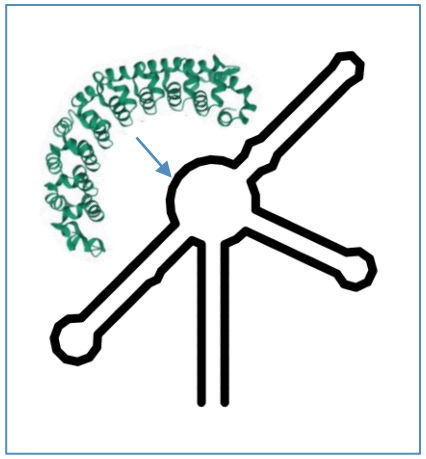


Functionality

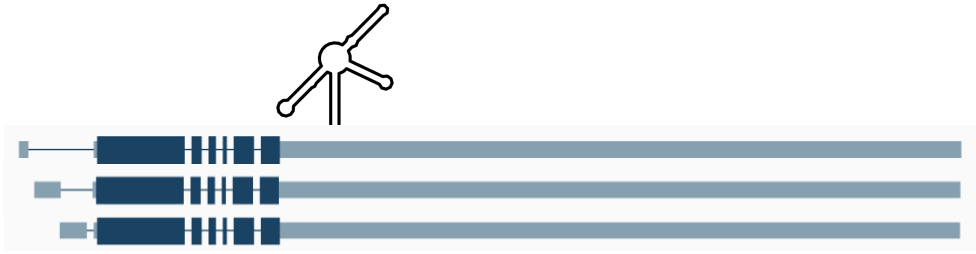
Publications



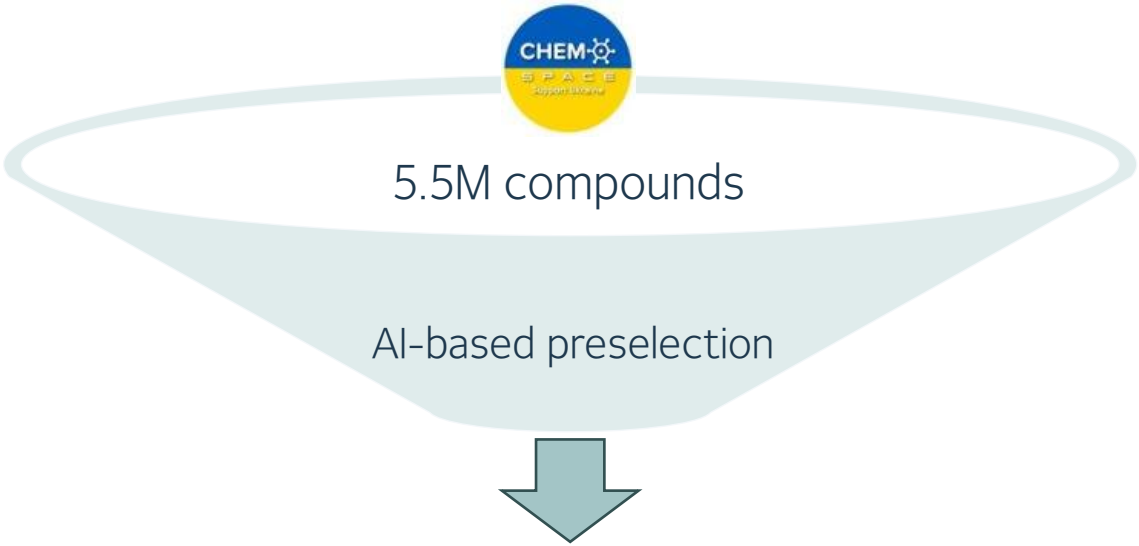
CLIP-seq



Protein coding RNA isoforms
from patient's tissues and cell lines contain the target region



mRNA platform | wet lab screening cascade – biophysical tests



500k
RNA-Targeted Library

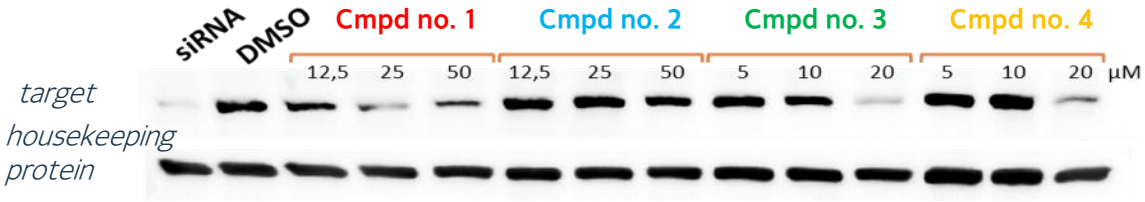
VS → 376 VS HITs

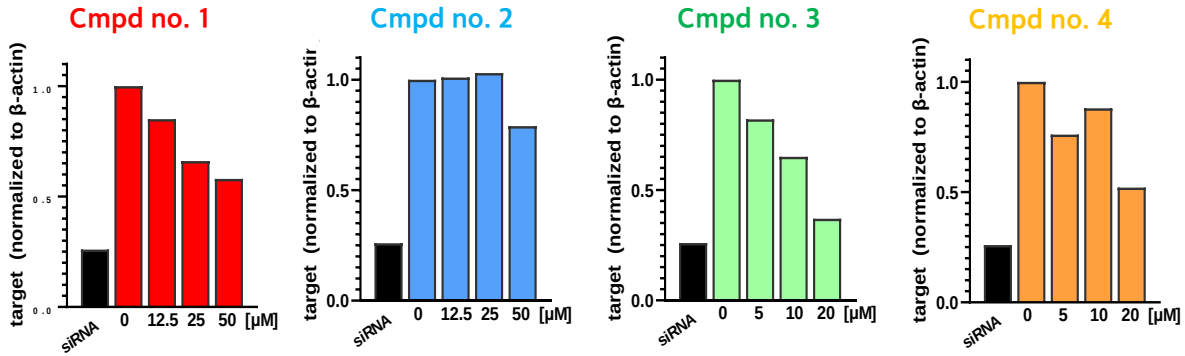
SPR →

~ 30 HITs with K_D < 100 µM
5 Different chemotypes
6 HITs with K_D ≤ 10 µM

mRNA Platform | Proof-of-Concept

We confirmed that small molecules designed to target mRNA inhibit translation of the encoded protein relevant in cancer.





Compound no. 1, 3 and 4 causes downregulation of protein target in cells

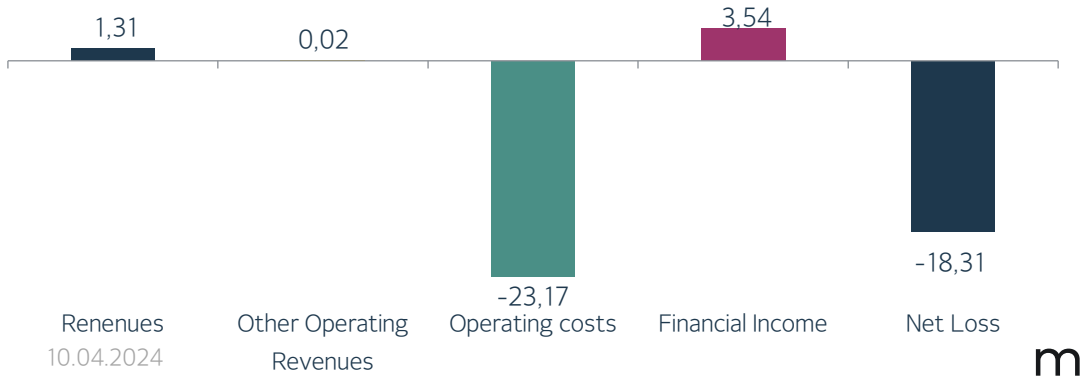
Reaching the PoC stage for the first mRNA target provides evidence of the effectiveness of our strategy in identifying mRNA-binding compounds with therapeutic potential

Finance

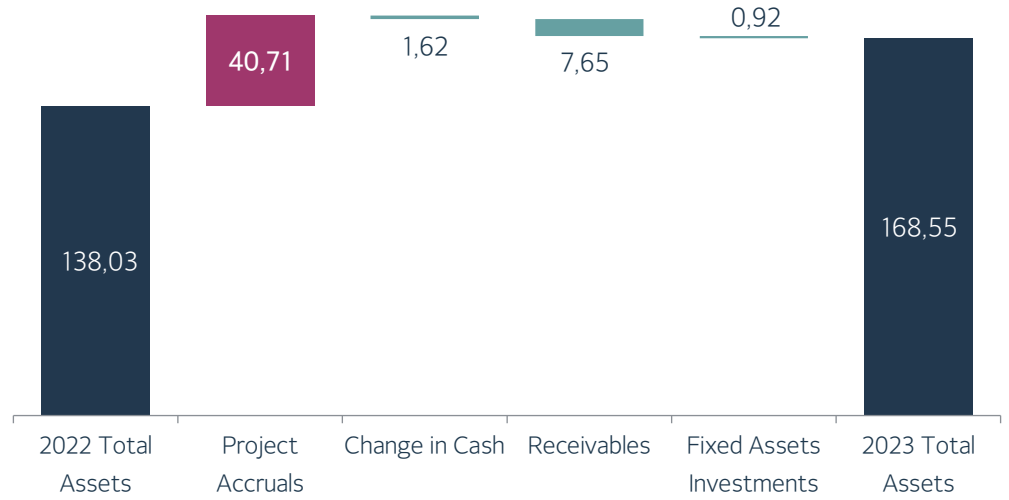
Financial results

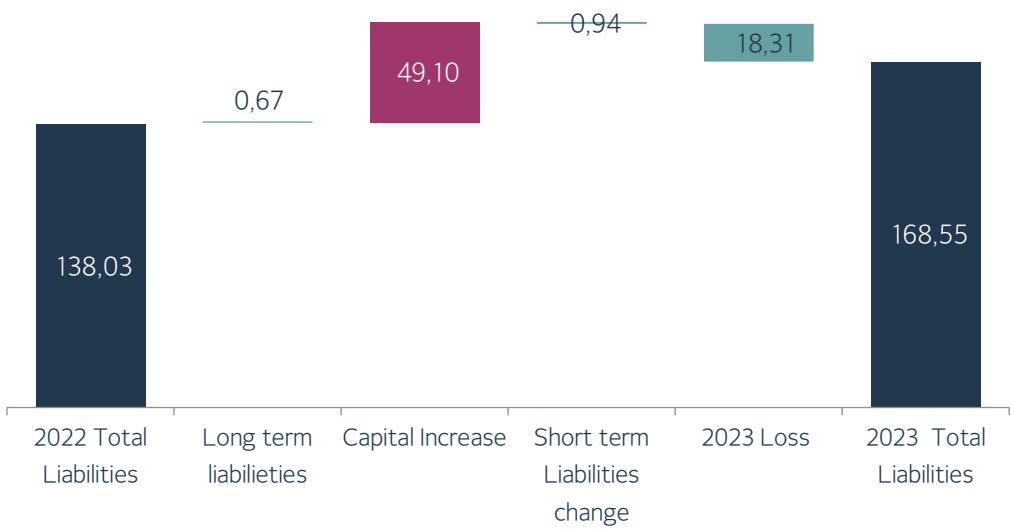
PLN m	2023	2022
Revenue	1 328	1 638
Grants	1 309	1 613
Other	19	25
Cost incl:	23 174	18 407
General & Adm	12 842	13 947
Early stage programs	10 332	4 460
EBIT	-21 846	-16 769
Net Financial income	3 541	1 474
Net loss/profit	-18 305	-15 296

2023 Profit & Loss Breakdown (PLN m)



Assets & Liabilities changes (PLN m)





R&D expenses, CAPEX and employment

PLN m	2023	2022
R&D expenses incl.:	40.71	25.67
Clinical phase programs	30.63	12.92
Discovery and preclinical development programs	10.08	12.75
Early programs	10.33	4.46
General and administrative expenses, including business development & IR	12.84	13.95
other CAPEX	0.36	3.46
Total	64.24	47.54

Cash position (March 2024)
>PLN 54m

114 employees

(incl. >50 PhDs)

- Clinical and early stage projects expenses more than doubled, reflecting the dynamic progress in their advancement
- Other expenses including G&A are on the same or lower level

Grants

Program	Qualified cost [PLN m]	Funding requested [PLN m]	Institution	Filing	Decision		Protest filing	Current status
mRNA platform	52	33	PARP	05.2023	✓	Positive (10.2023)	-	Agreement signed (12.2023)
OATD-01	16	8.2	PARP	07.2023	🕒	Due Q3 2024	-	-
USP21	66	47	PARP	05.2023	⊖	Rejected	-	To be filed within a different funding program
Undisclosed target*	63	44	PARP	07.2023	🕒	Due Q3 2024	-	-
Undisclosed target	62	44	PARP	11.2023	🕒	Due Q3 2024	-	-
USP7 continuation	18	12.5	NCBR	11.2023	🕒	-	03.2024	Awaiting final decision
New service with AI tool**(in consortium)	42	32	NCBR	03.2024	🕒	Due Q2/Q3 2024	-	-
OATD-01 + Undisclosed target*	USD 2.5m	USD 2.5m	NIH	08.2023	🕒	Due Q2 2024	-	-
Total	**244**	**170**						

*project aiming at an undisclosed signaling pathway crucial for the development of pulmonary fibrosis (licensed from the University of Michigan)
** A new service to enable small-molecule drug discovery targeting proteins and mRNA, using an artificial intelligence tool

Finance

Molecure intends to use four possible sources of financing its activites: transaction revenues such as up-front payment(s) from one or more licensing agreements, grants and subsidies, share issue (SPO) and/or debt instruments.

R&D and SG&A expenses in total ~PLN 150 m (2024-2025)	
Clinical phase programs	~ PLN 60 m
Discovery and preclinical programs (including AI tools)	~ PLN 37 m
mRNA platform (including dedicated AI tools)	~ PLN 25 m
General, administrative & BD expenses	~ PLN 28 m

Financing of Molecure's strategic plans:

- Cash
- Non-dilutive grants (already obtained, including the mRNA platform, and anticipated grants) totaling at least PLN 75 m
- Revenues from at least one partnering transaction (approx. PLN 100 m) and funding from the capital market

Business Development and plans

BIO Europe Spring 2024

36 one-on-one meetings

10 high priority Follow-Ups

Number of Discussions per program:

- OATD-01 - **20**
- OATD-02 - **6**
- mRNA – **4**
- other - **6**

Notes:

- The pipeline is perceived as very interesting and with high potential
- Good traction with some new and returning Big Pharma companies across the pipeline
- Smaller companies remain risk averse although there are several promising leads
- Well received mRNA platform offer with follow-up meetings

Molecure | Key milestones 2024-2025

OATD-01

- Interim data analysis by an independent unblinded committee after completion of dosing of approx. 50 patients with lung sarcoidosis (expected early 2025)
- Last patient dosed in the KITE Phase II PoC study (expected late Q3 2025)

OATD-02

- Reaching the therapeutic dose (Ph2RD) (2025)

AI

- Following the implementation of AI tools into our drug discovery process: nomination of the first preclinical development candidate generated by AI engine (2024/2025)

Partnering

- Signing a revenue generating collaboration or licensing agreement in one of the clinical programs or the mRNA platform (ongoing).

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Warsaw, April 10, 2024