MERIT coursework

Asahi Kanno, D1, Department of Chemistry,
Graduate School of Science
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1. Project title
   - Development of therapeutic agents for advanced or recurrent cancers using synthetic lethality induced by skeletal editing of natural products.

2. Background
   - Our research group has rationally modified the structure of trabectedin, a therapeutic agent for malignant tumors, and designed a series of antitumor macrocyclic molecules. An efficient semi-synthetic method requiring only about one-third the number of steps compared to existing drugs has been demonstrated. While conventional anticancer agents have been limited to 10-membered macrocyclic structures, our invention enables flexible synthesis of novel 14-, 15-, 16-, and 17-membered macrocycles. Compounds synthesized using this method have shown consistently strong activity in cell-based assays, with some exhibiting antitumor potency surpassing that of approved drugs. One related patent has been filed: PCT/JP2022/008664.

3. Objective
   - To explore the feasibility and potential of launching a drug discovery startup based on research seeds from Oguri research group, the University of Tokyo, and to formulate a roadmap for it.

4. Project period
   1) From December 26, 2024, to March 31, 2025

5. Initial hypothesis
   - Although chemotherapy using anticancer agents is highly effective as a first-line treatment for cancer, resistance often develops, forcing discontinuation of therapy. For advanced or recurrent cancers, second-line treatment options remain limited, representing a significant unmet medical need. One breakthrough addressing this issue was AstraZeneca's Olaparib, a PARP inhibitor. By leveraging the concept of "synthetic lethality"—inducing selective toxicity in cancer cells with specific genetic abnormalities through small-molecule protein inhibition—this drug provided a novel therapeutic strategy. Since its emergence in 2014, the market has grown to 7.2 billion USD by 2023, with a projected CAGR of 9.15%, indicating sustained growth.
   - In 2024, a Korean research group reported that trabectedin inhibits the DNA incision enzyme XPG in the transcription-coupled nucleotide excision repair (TC-NER) pathway, exhibiting potent antitumor activity. This suggests that trabectedin has potential as a synthetic lethality-inducing agent targeting cancers with hyperactivated TC-NER, positioning it as a next-generation molecular targeted therapy. However, the synthetic complexity of trabectedin has posed a barrier to drug development during the hit-to-lead optimization phase. To address this, the applicant proposes a drug discovery initiative based on proprietary IP and know-how accumulated in his laboratory regarding novel synthetic methods for trabectedin analogs. The project envisions exploratory research targeting XPG and other related target proteins, followed by subsequent drug development.

6. Evaluation methods
   - Desk research through literature and book review
   - Strategy sessions with AMED-certified venture capitalists
   - Interviews with key opinion leaders (KOL) at the University of Tokyo Medical Faculty
   - Participation in on-campus pitch events and feedback from multiple venture capital firms
   - Attendance at PMDA seminar on the latest GMP, and site visit to NIPRO Pharma plant in Nara.
   - On-site visits and founder interviews at TargaGenix Inc. and Recurve Pharma.
   - Series of interviews to tech-transfer division at Stony Brook University
   - Visit to Harvard University Myers Laboratory and founder interview to Kinvard Bio Inc.

7. Detailed findings
   - Detailed in the attached presentation materials. Selected excerpts from interviews and investigations are appended.

Schedule for the visit of Mr. Asahi Kanno
Ph.D. Candidate, The University of Tokyo, Japan

Tuesday, March 4, 2025

Arrival: 5:28 PM by Delta Shuttle from Boston.
Transportation reservation made by Asahi Kanno (confirmation #76550380)

Wednesday, March 5, 2025

9:00-10:00 AM	Zoom Meeting with Mr. Junji Takegami, Advisor, Tiger Pacific Capital LP
10:15	Walk to Biomedical Engineering Bldg from HGI-SB.
10:30 – 11:30 AM	Dr. Louis A. Peña Center for Biotechnology, Biomedical Engineering Bldg., Room 204, Phone: 631-632-1064 (Walk to Chemistry Bldg. 7th Floor, Room 717) Phone: 631-632-1311
12:10-1:30 PM	Lunch with Prof. Iwao Ojima and graduate students at Simons Café
1:30-2:00 PM	Discussion with Prof. Ojima Room 717, Chem. Bldg.
2:15-3:30 PM	Seminar Room 731 (ICB&DD Director's Conference Room) "Development of a Modular Synthetic Process for Skeletal Diversification of Ecteinascidin 743"
4:00-5:00 PM	Visiting Long Island High Technology Incubator (LIHTI) (Prof. Ojima will escort Mr. Kanno) Mr. Andrew Wooten, Executive Director, LIHTI 25 Health Sciences Drive, Phone: (631) 444 8800
6:30 PM	Dinner with Professor and Mrs. Ojima at "Fifth Season Restaurant", Port Jefferson

Thursday, March 6, 2025

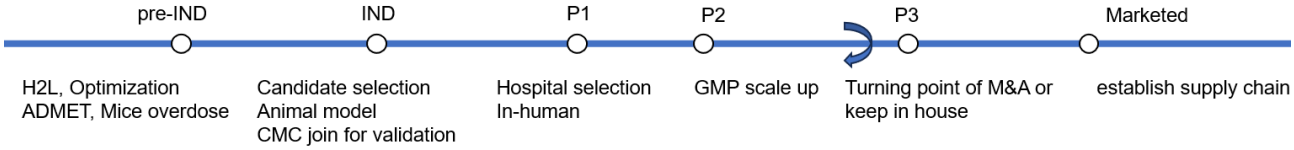
10:00-10:45 PM	Ms. Kate Hutchinson, Assistant Director, Center for Biotechnology Biomedical Engineering Bldg, Room 204, Phone: 631-632-1743
11:00-12:00 PM	Dr. James Egan, Recurv Pharma/TargaGenix, Room 731, Chem. Bldg.
12:15-1:15 PM	Lunch with Dr. Egan and Professor Ojima (Hilton Garden Inn, Northern Coast Restaurant)
1:30-2:15 PM	Dr. Sean Boykevisch, Director, Intellectual Property Partners (IPP) Room N5002, Frank Melville Jr. Memorial Library, Phone: 631-632-9009
3:00 PM	Leaving for La Guardia Airport. Transportation reservation made by Asahi Kanno (confirmation #76550380) (Delta Shuttle departure time 6:00 PM)

The way to startup from academic research of natural products chemistry

Technology's criteria
1. Evident compounds in mice model, disease indication
2. Capable in scale up (> 5 g)
3. Granted as an intellectual property

Founder's criteria
1. Indispensable, irreplaceable and overwhelming expertise in organic synthesis
2. Ability to absorb and catch up with comprehensive knowledge of drug discovery
3. Management skills to oversee contractors
4. Proficiency in English communication

Must-read literature, available on amazon.jp



H2L, Optimization
ADMET, Mice overdose

Candidate selection
Animal model
CMC join for validation

Hospital selection
In-human

GMP scale up

Turning point of M&A or keep in house

establish supply chain

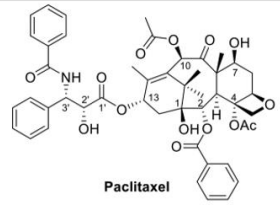
First or best in class must be indicated and evident in mice model, and exposed to academic paper of Nature or Science.
Mice overdosing require > 5 g amount, hence fundamental process chemistry be better proved in patent or academic OPRD paper.

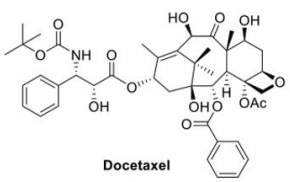
New co. would engage in pre-IND to P2.
Fabless development using proper CRO and CMO could enable low burn rate, with as lean team as possible. Namely, CEO and CTO is enough before P1, and then CMC manager would be hired later, in total 3 members.

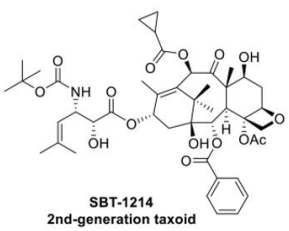
Case 1

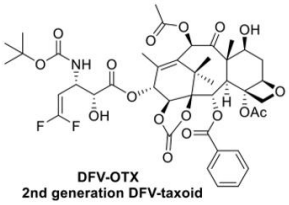
Recurv Pharma/ TargaGenix inc. (Stony Brook Univ.)

- TargaGenix is a clinical-stage biotech company focused on developing next-generation taxoid-based cancer therapeutics.
- Its lead program centers on NE-DHA-SBT-1214, a DHA-conjugated taxoid originally developed at Stony Brook University and licensed to TargaGenix in 2016.
- Designed as a nanoemulsion formulation, the compound targets multidrug-resistant (MDR) tumors and cancer stem cells (CSCs) with enhanced tumor selectivity.
- Backed by up to $24 million in funding from TVM Capital Life Science, TargaGenix has advanced preclinical development and is preparing for clinical proof-of-concept studies.

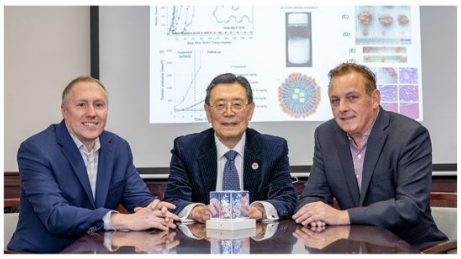

Paclitaxel


Docetaxel


SBT-1214
2nd-generation taxoid

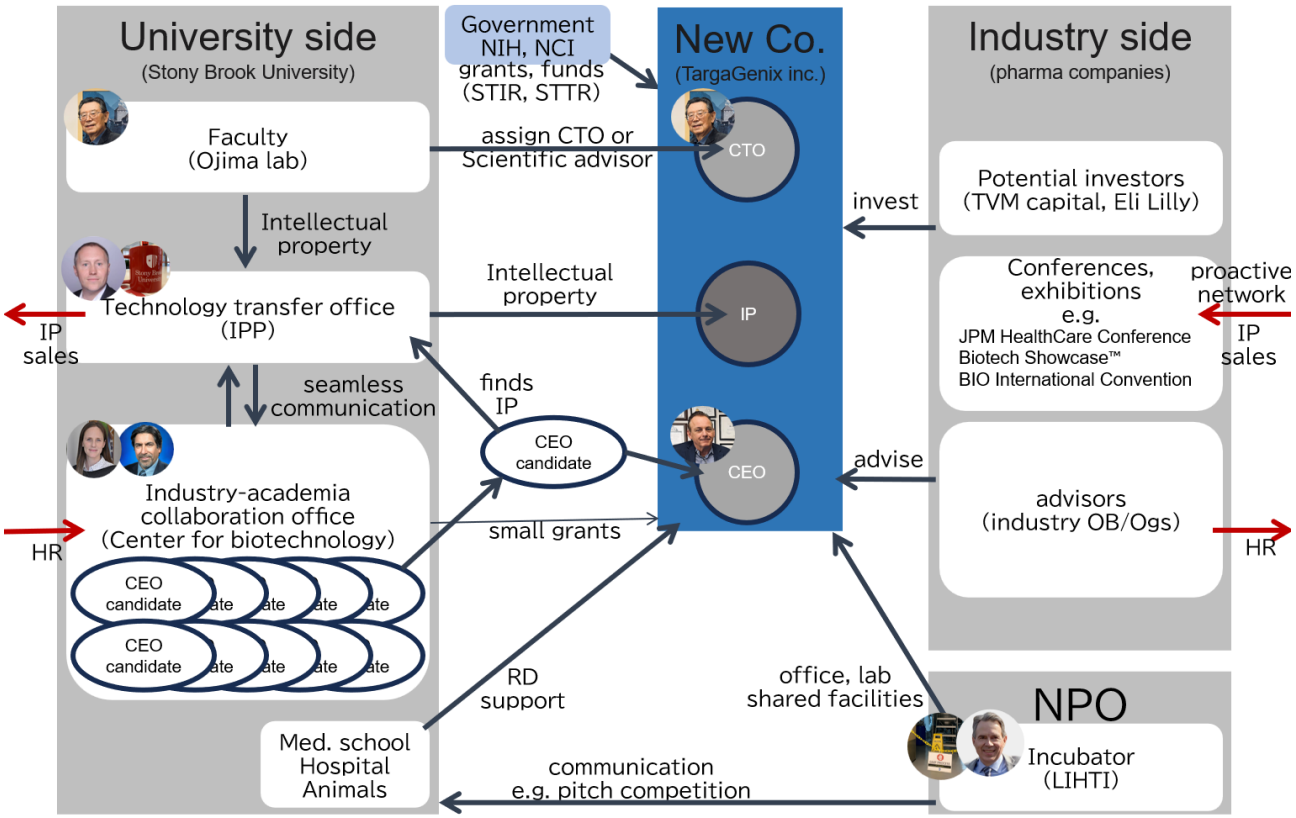

DFV-OTX
2nd generation DFV-taxoid

Stony Brook University × TARGAGENIX

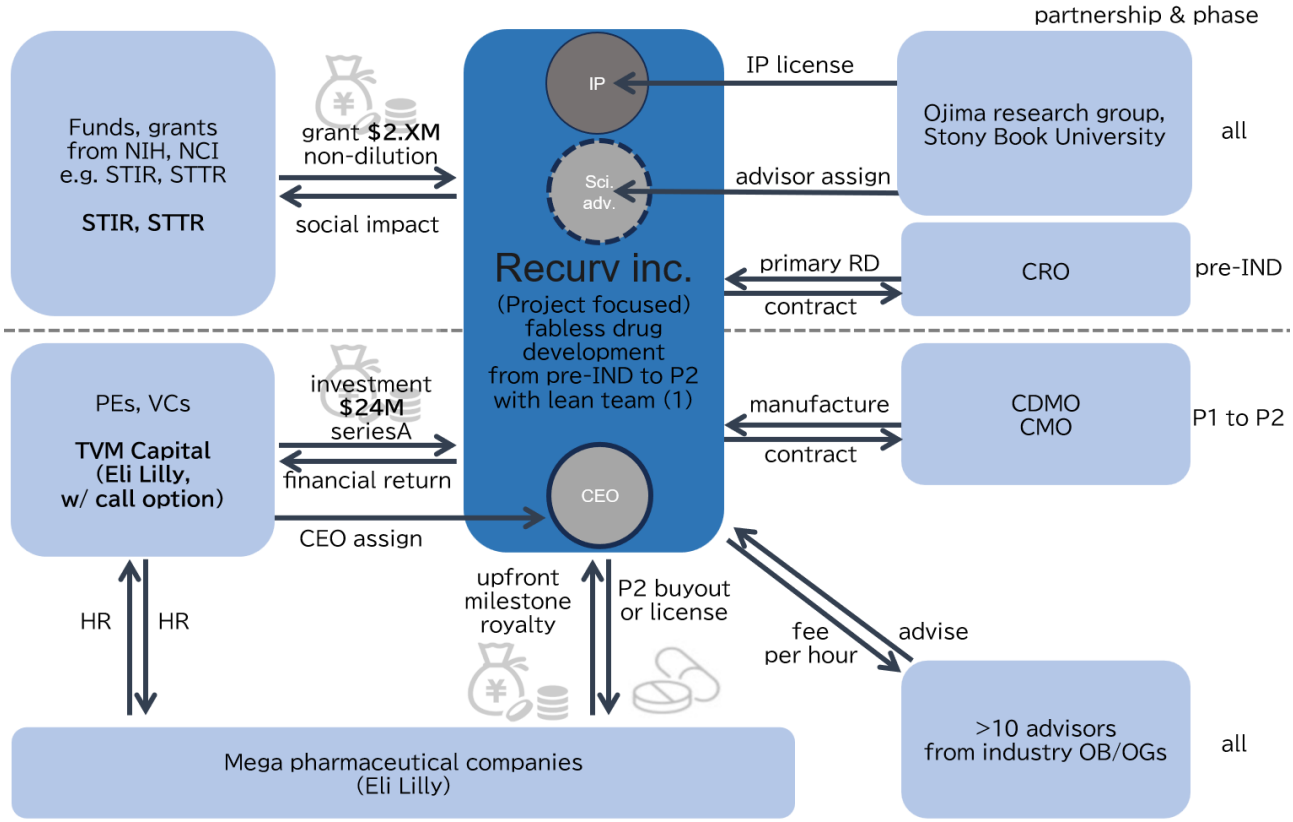

TargaGenix with Prof. Iwao Ojima

1. Jayanetti, K.; Takemura, K.; Bendale, H.; Garg, A.; Ojima, I. *J. Fluorine Chem.* **2023**, *267*, 110106. Recent Advances in the Strategic Incorporation of Fluorine into New-Generation Taxoid Anticancer Agents.
2. Stony Brook University News: New Anti-Cancer Compound Originally Discovered at Stony Brook Takes a Major Step Towards Clinical Development

Seamless tech transfer from Univ. to TargaGenix inc.



Recurv Phrama, a SPV of TargaGenix inc.



CEO, Dr. James Egan

Experience

Chief Executive Officer
Recurv Pharma, Inc. · Full-time
Nov 2022 - Present · 2 yrs 5 mos
Newark, Delaware, United States · Hybrid

Developing novel oncology therapies

President & CEO
TargaGenix, Inc.
Jun 2013 - Present · 11 yrs 10 mos
Greater New York City Area

TargaGenix, Inc. ("the Company") was founded in 2013 to develop novel compounds that are effective on both drug-resistant tumors and cancer stem cells. In numerous preclinical models of cancer, including colo ...see more

IRX Therapeutics, Inc.
7 yrs

Vice President
Dec 2015 - May 2016 · 6 mos
Greater New York City Area

Director, Business Development
Jun 2009 - Dec 2015 · 6 yrs 7 mos

-Served on Executive Management Team of a clinical stage biotechnology company
-Reported directly to CEO and CFO... ...see more

Post Doctoral Fellow
Cold Spring Harbor Laboratory
May 2001 - May 2002 · 1 yr 1 mo

☒ Directed drug development platform for novel compounds involved in cancer and immune system therapeutics. ... ...see more

Education

Stony Brook University
MBA, Finance
2008 - 2011

PhD, Molecular Pharmacology
1995 - 2000
Activities and societies: Sigma Xi

Qualification of CEO
Comprehensive experience/ Pharma dev.

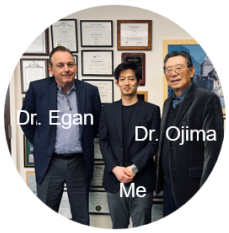
After acquiring PhD Pharmacy, Post Doc, joined a Pharma venture company (IRX). Initially as researcher, in the middle MBA, and eventually business development as vice president.
Developed comprehensive skill sets;

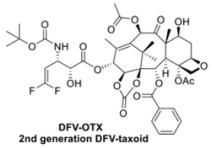
- Regulatory
- Clinical development
- Manufacture
- Finance, pitch deck

- ➢ After the series of experience above,
- ➢ Stayed as entrepreneur resident at Stony Brook University
- ➢ Met an innovation by Professor Ojima, which is reduced toxicity of Taxol derivative tethered with DHA to enable DDS system.
- ➢ Brought it together with nano-formulation technology.
- ➢ Established TargaGenix inc. out of Stony Brook University.
- ➢ The counterpart of University side,Intellectual Property Partner, Dr. Sean Boykevisch, was a junior from the same laboratory as Dr. Egan.

Burn of the inc. was well designed. Lean team, asset light, minimum rounds of finance, minimum contract (more to be confidential base)

Scientific advisor, Professor Iwao Ojima





DFV-OTX
2nd generation DFV-taxoid

- 1968 B.S., 1970 M.S.
- 1973 Ph.D. from the University of Tokyo, Japan.
- 1970 Sagami Chemical Research Institute, director
- 1983 Joined the faculty as Associate Professor,Department of Chemistry, State University of New York at Stony Brook
- 1984 promoted to Professor
- 1991 promoted to Leading Professor
- 1995 promoted to University Distinguished Professor
- >440 papers, >100 patents, >8 books, >58 PhD students, >64 Postdocs, >11 awards

Current position:
Distinguished Professor, State University of New York
Director, Institute of Chemical Biology and Drug Discovery (ICB&DD) Stony Brook University

Translational research

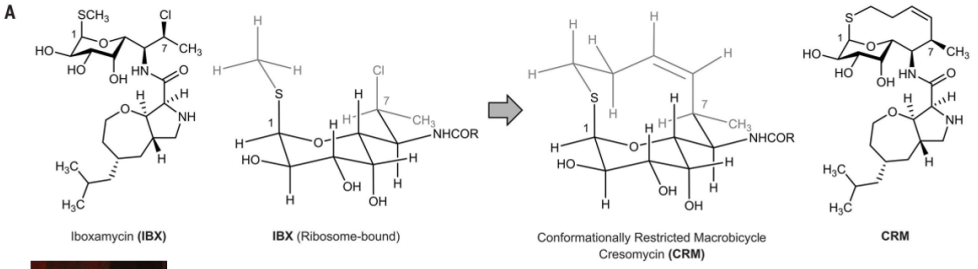
- In 2001, Professor Iwao Ojima received the ACS Award in Medicinal Chemistry. Stony Brook University (SBU) requested him to stay, prompting his proposal to create a research institute combining chemical biology and drug discovery. By fall 2003, the establishment of ICB&DD was finalized.
- Aiming to create an interdisciplinary "Center of Excellence" bridging basic and clinical research, focusing on translational research.
- Main research areas include drug development for cancer, infectious diseases, and diabetes/obesity. A tenure system ensures organizational fluidity. Starting with 20 members in 2004, the team has grown to over 35.
- Secured $3 million in initial funding. Raised approximately $13 million in research funding over five years. Some projects have reached clinical trial stages.

- A novel generation of taxane-based anticancer agents developed in a research lab at SBU was licensed or sublicensed to companies such as Sanofi-Aventis, Indena, Bayer, and Spectrum. One of these compounds, Ortataxel, underwent clinical trials at Spectrum. For the new series, refer to Targagenix.
- SBU's Intellectual Property (IP) office handles 80–90 invention disclosures annually by faculty and staff, submits 50–80 patent applications, and licenses 25–50 technologies each year. Considering SBU's status as a mid-sized state university and SUNY RF's nonprofit structure, these figures represent commendable achievements.

Case 2 Kinvard bio inc. (Harvard Univ.)

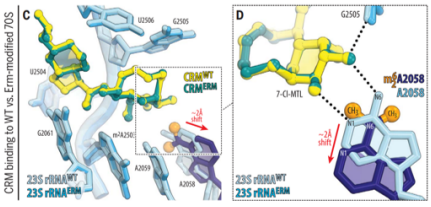
Company Establishment & Business
- Establishment: Founded in February 2025 by Kineticos Life Sciences.
- Background: Based on research from Harvard University's Myers Lab.
- Focus: Developing oxepanoprolinamides (OPPs), a new class of lincosamide antibiotics.
- Target Infections: Bacterial pneumonia, cUTI, and NTM-LD.
- Formulations: Oral and IV.

Team & Investment
- CEO: Dr. Lloyd Payne, with extensive experience in drug discovery and development.
- Research Base: Myers Lab at Harvard University.
- Funding: Supported by the Kineticos AMR Accelerator Fund I.
- Additional Support: Blavatnik Biomedical Accelerator and CARB-X.
- Licensing: Exclusively licensed technology from Harvard University.



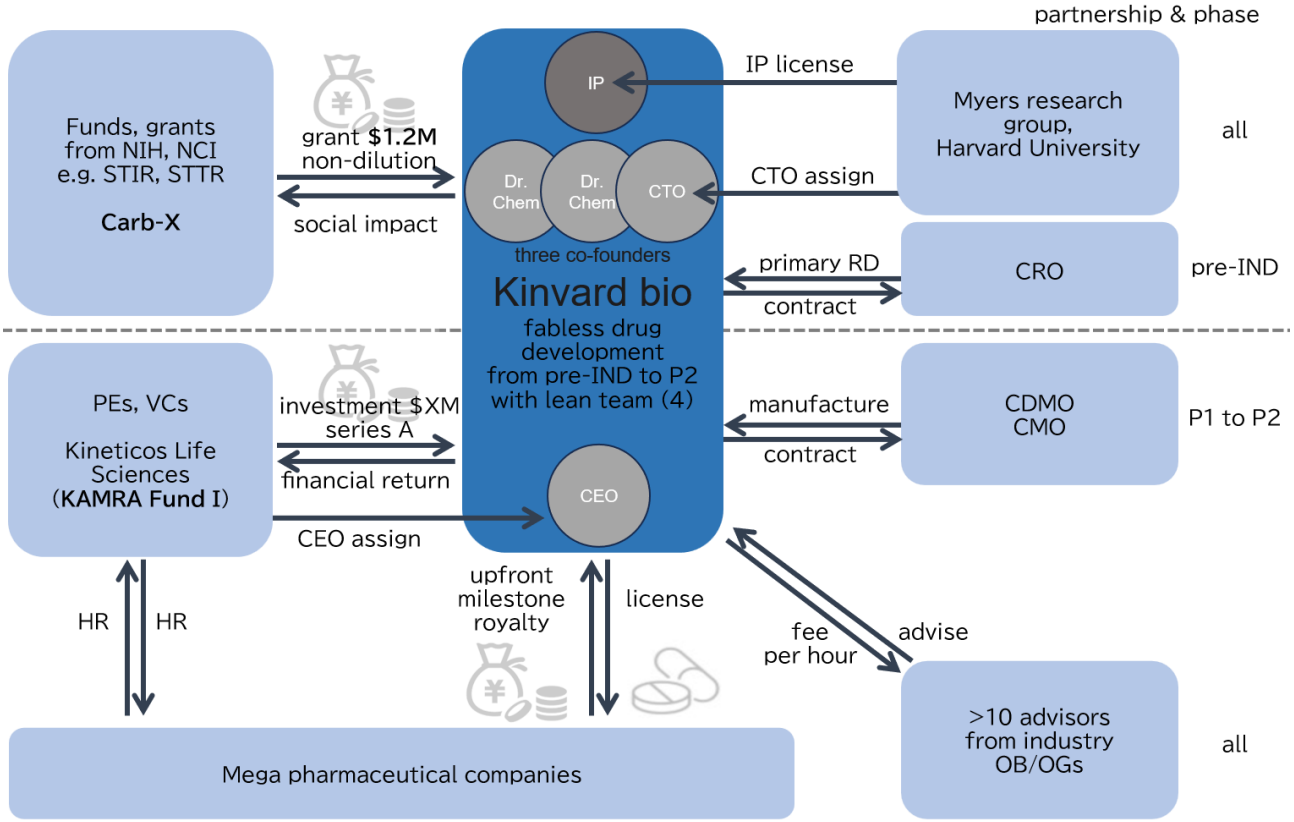
Prof. Andrew Myers

× KinvardBio



1. Myers, A. G. *et al., Nature* **2021**, *599* (7885), 507–512.
2. Wu, K; Myers, A. G. *et al., Science* **2024**, *383* (6684), 721–726.

Fabless drug discovery model, Kinvard bio inc.



Kinvard bio inc. (Harvard Univ.) Co founder, Dr. Kelvin Wu

Career:

- Born in Singapore,
- Bachelor's degree from Cambridge University, UK.
- A*STAR in Singapore for one year,
- PhD at Harvard University under Professor Andrew Myers.

Harvard PhD to Co-founder:

- Natural product chemistry, particularly Iboxamycin (IBX) and its derivatives, as well as chemical biology.
- His work on an Iboxamycin derivative showed strong potential against antimicrobial resistance (AMR).
- Co-founded Kinvard Bio Inc., a Harvard-based startup focused on developing anti-resistant antibiotics

One stop development at Laboratoty

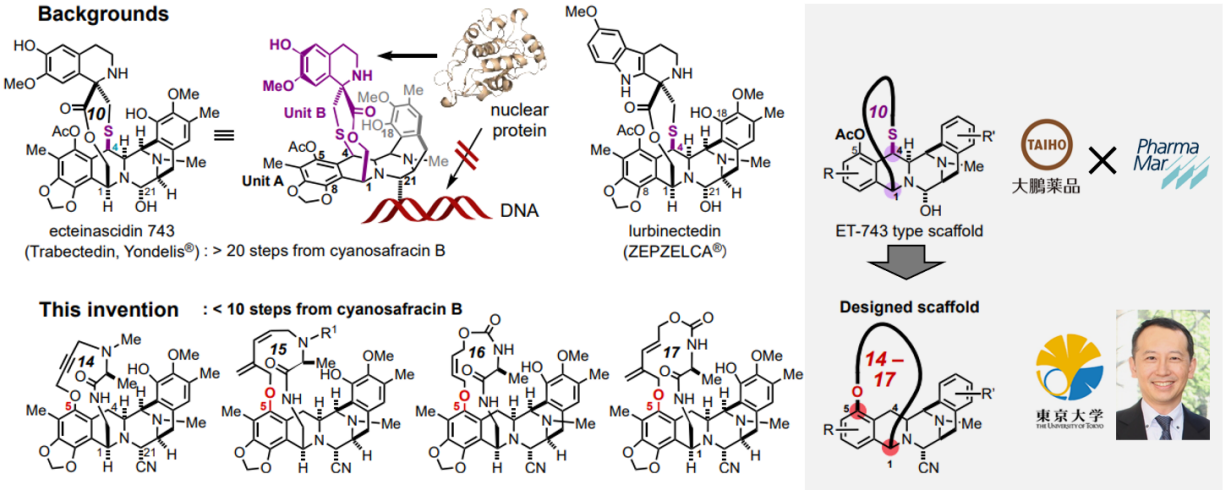
- Synthesis, process, and biological assay (MIC etc.), >6 papers
- BMC Lett. 2021.
- Science 2024, 383 (6684) , 721-726.
- J. Am. Chem. Soc. 2024, 146, 42, 29135–29139
- Chem 2025, 11, 102480.
- Nat. Chem. 2025, 1–8.
- Org. Process Res. Dev. 2025, ASAP

Science paper publication
Media exposure
Carb-X selected
Sponsor pharma company suggested SU
Got together with CEO candidate
As a side note, it was 11:30 PM at that time. The next day, he had his wedding planned. Right after, he headed for a classic and fantastic honeymoon to Las Vegas, the Grand Canyon, and the Aurora.

CARB-X
Combating Antibiotic-Resistant Bacteria

What we are trying to do

- Ecteinascidin 743 was launched by PharmaMar/Janssen with FDA approval for the treatment of malignant soft tissue tumors (rare disease) in 2015.[1] Its promising mode of action is TC-NER jacking.[2]
- Serious adverse events have prevented it from being widely used in clinical practice, and revenue growth has been sluggish.[1]
- We aim to develop new drugs by improving the structure of the natural product ecteinascidin through structural diversification.

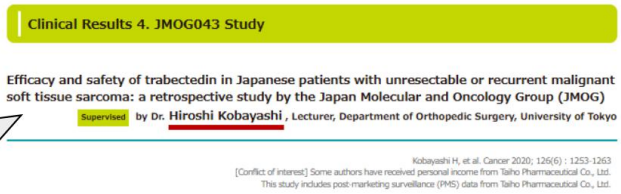


1. Investor relations documents of Taiho Pharma, Pharma Mar Inc.
2. Schärer, O. D.; Sturla, S. J. *et al., Nat. Commun.* **2024**, *15*, 1388.
3. PCT/JP2022/008664 tetrahydroisoquinoline alkaloidal compounds with macrocyclic scaffold exhibiting anti-tumor activities(EP, JP, WO, US)
4. The 16th round of the University of Tokyo GAP Fund Program

- ✓ Designed by Prof. Oguri
- ✓ Structure diversification of ET743
- ✓ 1 Patent (PTC, including US)[3]
- ✓ Selected as GAP fund in JAN 2025[4]

KOL interview
Second-line treatment for soft tissue sarcoma

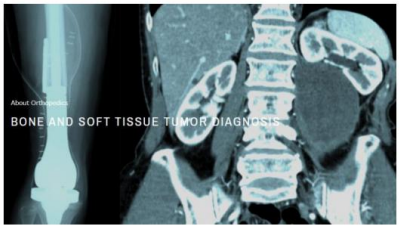
Key Opinion Leader and
Expert who is in charge of post-marketing surveillance of Taiho Pharmaceutical/ PharmaMar's predecessor product, Yondelis® (Ecteinascidin 743)



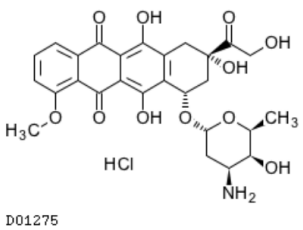
Prof. Hiroshi Kobayashi

The University of Tokyo, Department of Orthopaedic Surgery and Spinal, Surgery

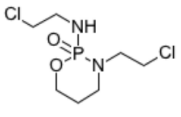
The check points shown on the next page, especially the many **adverse events** reported, make it difficult to spread to clinical practice.



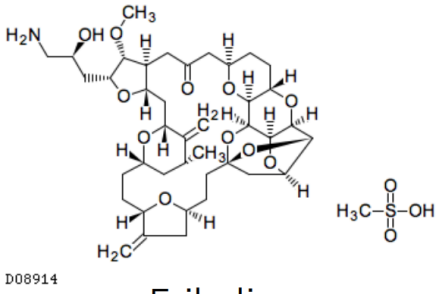
KOL interview
Second-line treatment for soft tissue sarcoma



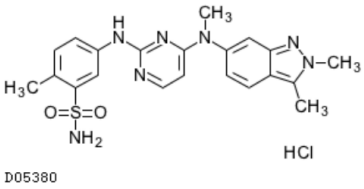
Doxorubicin



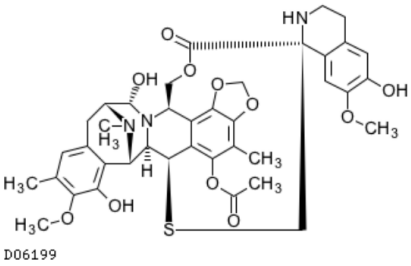
Ifosfamide



Eribulin



Pazopanib



Yondelis®
(Ecteinascidin 743)

Check points

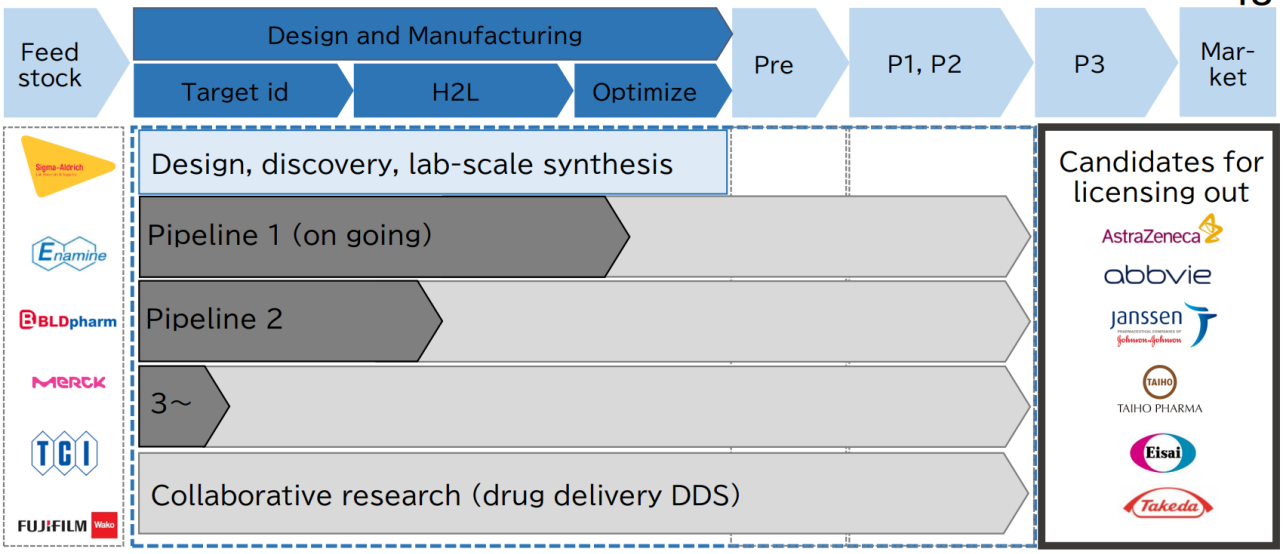
- Efficacy = Extended overall survival (OS)
- Administration
  - Oral
  - Infusion
  - Central venous infusion
- Side effects/adverse events
  - Cytopenia
  - **Liver damage/ rhabdomyolysis**
  - **Extravascular leakage/ tissue necrosis**
  - **Feeling of exacerbation**

Comparison with competitor

Comparison	Original PharmaMar Inc.	Our solution
Approach	Natural product Itself/ minor editing	Structural diversification of natural product
Pipeline status	◎marketed (ovarian, sarcoma)	△under development
Intellectual property	>17	1
Adverse events	×Fatal rhabdomyolysis ×Tissue necrosis due to extravasation	○Potentially adjusts hepatic metabolism and alkylation to improve
Administration	×Central venous infusion	○Potentially oral
Hit to lead flexibility	×Scope limited ×Faithful to natural	○Potentially flexible ○Designed with diversification in mind※

PCT/JP2022/008664 tetrahydroisoquinoline alkaloidal compounds with macrocyclic scaffold exhibiting anti-tumor activities(EP, JP, WO, US)

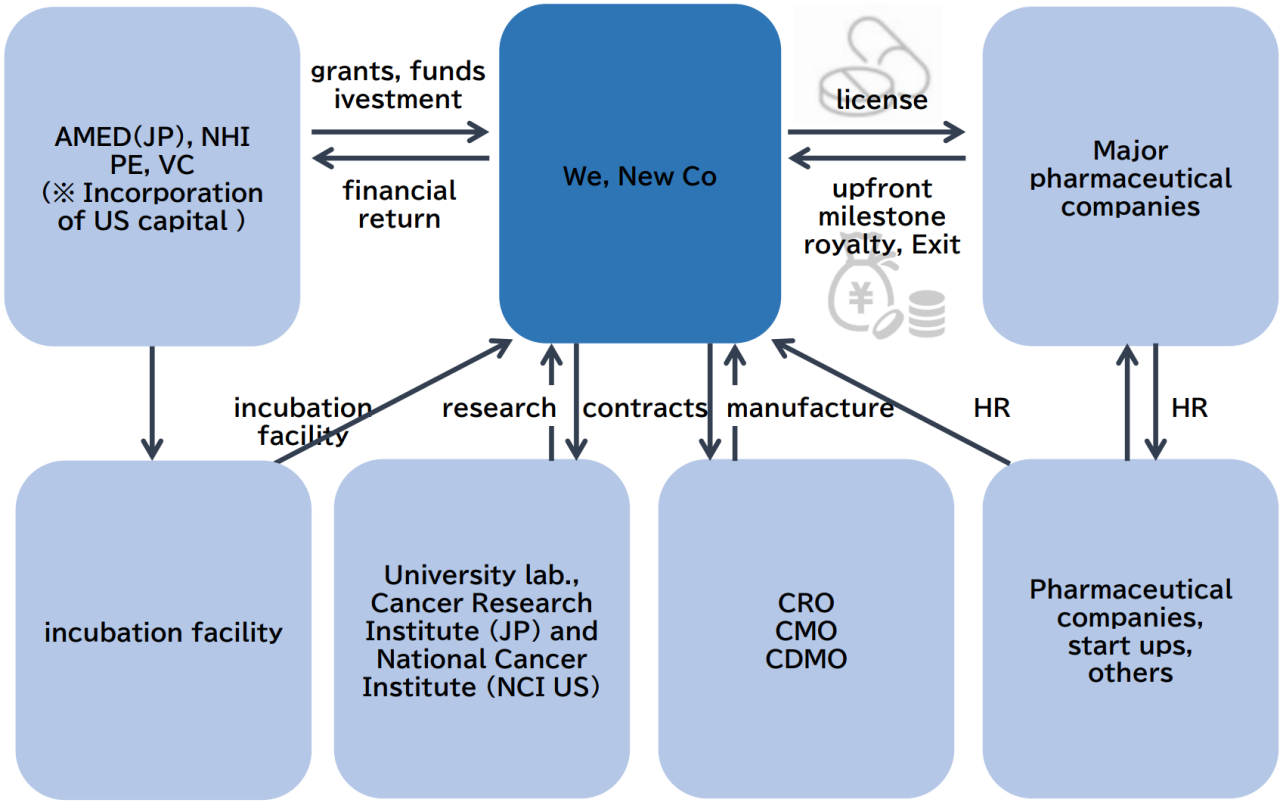
Roadmap

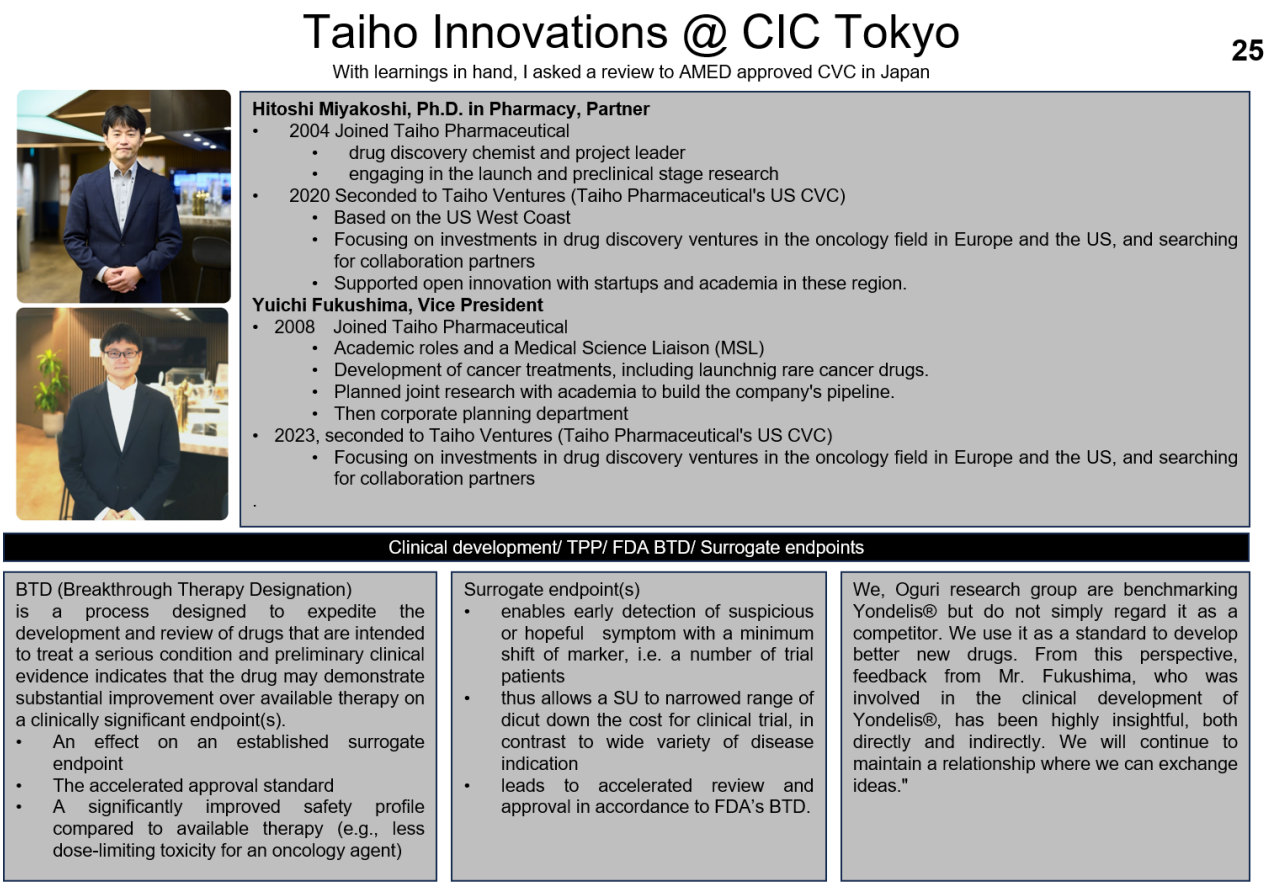


Development issues for the next X years

1. Mode of action	2. Chemical synthesis	3. non-GLP trial
➢ Target id ➢ Tissue types id	➢ Improved throughput ➢ CMC, GMP	➢ ADMET, Toxicity ➢ PDX mouse test

Business model





8. Conclusion

- In exploring academic drug discovery practices, a case study was examined involving small- to medium-sized anticancer agents, developed a foundational understanding of the startup model, and drafted a conceptual framework for launching a venture from corresponding research group.
- For this particular initiative, it is concluded that there is not a significant difference in operational feasibility or ecosystem barriers between establishing a base in Japan or overseas. Notably, Japan offers a favorable market environment, highlighted by integrated efforts among academia, industry, and government to enhance the viability of drug discovery startups—such as the development of the SBIR system and policy recommendations regarding AMED-compliant reliability data.
- Through interviews with the key opinion leader (KOL), some unmet needs in the anticancer drug market were identified, validating our team's initial hypotheses. In particular, anticancer agents with minimal adverse effects are highly valued as end-line therapies from the perspective of patient well-being and quality of life (QOL). These adverse effects are primarily attributed to hepatic metabolism and metabolic antagonism, suggesting room for improvement through molecular design using the technology in our research group.
- It was clarified that the minimum requirements for establishing a new company include efficacy and toxicity data from mouse models At this stage, immediate incorporation is not advisable; instead, the first step should be to steadily advance the research phase through public funding sources such as AMED and GAP funds.
- In parallel with meeting scientific standards, it is essential to enhance engineering feasibility. In natural product-based drug discovery, the cost structure is heavily weighted toward active pharmaceutical ingredient (API) manufacturing, which can undermine competitiveness. Current synthetic routes are considered too complex for contract manufacturing organizations (CMOs) to undertake, given prevailing technical capabilities. Therefore, process development aimed at cost reduction through refined synthetic chemistry is required. Gram-scale synthesis will be established within the university, followed by kilogram-scale and larger CMC development after company formation.
- Regarding financial and human resource acquisition, close communication with relevant stakeholders—including the university's industry-academia collaboration office, technology

licensing organization (TLO), and potential lead venture capitalists—will be key. Ideally, the team should include mid-career professionals with clinical development experience in pharmaceutical companies as CEO or COO candidates. As a self-driven effort, proactive engagement in exhibitions and innovation communities to promote intellectual property will be beneficial. Examples include regular networking events at iPark, LINK-J events, CPHI Japan, Biotech Showcase, JPM HealthCare Conference, and BIO International Convention. Additionally, leveraging talent and IP collaboration networks such as AUTM and UNITT may prove effective.

9. Business plan / Development milestones
   - In FY2025, initial non-clinical studies (PK/PD and safety) will be conducted using budget from the University of Tokyo GAP Fund. While progression to later stages is not guaranteed, the results will inform molecular design and, if necessary, guide further development of synthetic chemistry technologies.
   - In parallel with the acquisition of ADMET data, collaborative research will be initiated to identify biomarkers. This will serve as a critical milestone for obtaining FDA Breakthrough Therapy Designation (BTD) and qualifying for fast-track development.
   - Upon completion of the initial non-clinical studies, a new company will be established. This entity will function as a holding company, with a separate Special Purpose Vehicle (SPV) created to transfer intellectual property from the university. The core team will consist of a CEO and COO, supported by scientific advisors including university faculty and industry experts.
   - A fabless operational model will be adopted, utilizing CROs and CDMOs to complete 100-gram scale synthesis, formulation, and non-clinical testing. Pre-IND activities will be initiated.
   - Approximately 2 million USD in funding will be raised from AMED, SBIR, and AMED-certified venture capital firms to complete Pre-IND documentation. Under a fabless model, kilogram-scale production and Phase 1 and Phase 2 clinical trials will be conducted, with the therapeutic indication finalized during this stage.
   - Upon completion of Phase 2, business development will conclude, and the SPV will be liquidated through M&A or trade sale to a commercial pharmaceutical company.

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