

FY2022 Business Results

May 15, 2023

Perseus Proteomics Inc.
(Securities code: 4882)



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03	Review of FY2022 and Future Plans
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01 **FY2022 Business Results**

FY2022 business results

Profit & Loss highlights

(million yen)

	FY2021	FY2022		FY2022		
	Results	Forecasts	Results	vs FY2021	vs forecasts	
Sales	71	77	94	31.0%	21.9%	Ab/reagent sales Ab research support
Gross profit	67	72	86	27.7%	19.3%	
SG & A	539	776	784	45.3%	1.0%	PPMX-T003 P1 cost Adjustment of SG&A and non-operating expenses
R&D cost	308	522	494	60.3%	-5.4%	
Other	231	253	289	25.2%	14.3%	
Operating income	(472)	(703)	(697)	-	-	
Ordinary income	(481)	(736)	(689)	-	-	Foreign exchange gains
Extraordinary loss	117	116	95	-19.0%	-17.7%	Impairment loss due to restoration and capex increase
Net income	(599)	(854)	(786)	-	-	

- Sales: JPY 13 million increase Y on Y. Recovered to the pre COVID-19 level.

FY2022 business results

Balance Sheet highlights

(million yen)




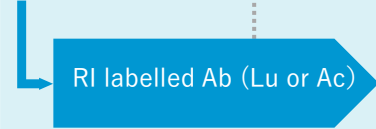

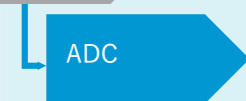
Assets		
	2022/3/31	2023/3/31
Cash & deposits	3,214	2,444
Total current assets	3,290	2,514
Non-current assets	9	51
Total assets	3,300	2,566

Liabilities		
	2022/3/31	2023/3/31
Current liabilities	148	111
Non-current liabilities	-	58
Total liabilities	148	170
Total net assets	3,152	2,396
Total liabilities and net assets	3,300	2,566

- Cash & deposits: decrease mainly due to R&D costs and capex
- Non-current liabilities: long-term deposits due to adoption of PPMX-T003 (ANKL therapeutic drug development) as AMED program
- Capital ratio: 92.1%

02 Pipeline

Pipeline progress

Code	Indication	Region	Drug discovery/ Research	Preclinical	P1	P2	P3	Notes
PPMX-T003	PV*1	Japan						P1 ongoing in-house
	ANKL*2	Japan						<ul style="list-style-type: none">• Adopted as AMED program• Investigator-led clinical trial will start after patient registry
PPMX-T002 → New code	Solid tumor	USA	 					<ul style="list-style-type: none">• Accumulation of Ab confirmed in P1 expansion• Lead development (agreed w/PDRadiopharma)• Change of RI to Lu or Ac under study
PPMX-T004 → New code	Solid tumor		 					<ul style="list-style-type: none">• Study of optimization of therapeutic drugs and linkers

*1 PV: polycythemia vera *2 ANKL: aggressive NK-cell leukemia

03 **Review of FY2022 and Future Plans**

Achievements of FY2022 plans and FY2023 plans

FY2022 Initial Plans/ Achievements

- 1 PPMX-T003
Start and finish administration in P1 among PV patients
⇒ × : **Extended P1 period**
- 2 PPMX-T003
Develop medical drug for ANKL – finish preparation for investigator-led clinical trial
⇒ ✓ : **Submitted clinical trial notification, PMDA examination finished**
- 3 PPMX-T002
Determine new partner
⇒ △ : **Determined partner candidates**
- 4 PPMX-T004
Plan re-development
⇒ ✓ : **Finished re-development plan. Verifying optimization of drug/linker with animal models**

Plans of FY2023

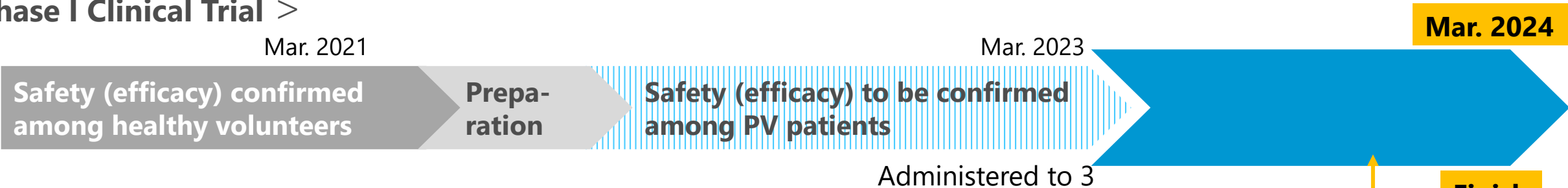
- Finish P1 in FY2023**
Licensing out in FY2024
- Promote investigator-led clinical trial**
- Formulate development plans for licensing out in FY2024**
- Narrowing down linker/drug.**
Start preliminary toxicity tests

1

PPMX-T003:

Measurements for finishing P1 clinical trial among polycythemia vera patients

< Phase I Clinical Trial >



< Reasons for delay >

- Extremely few patients who do not use existing drugs

< Measurements against solutions for delay >

1) Protocol amendment (expansion of subjects)

Before	After
Exclude patients w/high EPO *	Increase in EPO * due to phlebotomy ⇒ Include patients w/high EPO
PV judgment: Prioritize WHO standards	PV judgment: Prioritize clinicians' judgment

* EPO (Erythropoietin):

Hormone to create RBC. EPO increases in case of anemia and functions to increase RBC.

2) Addition of clinical trial locations

- Kansai Medical Univ. Hospital
- Osaka Metropolitan Univ. Hospital
- Shimane Univ. Hospital
- +
- TOKAI Univ. Hospital
- Hayama Heart Center
- Miyazaki University Hospital (Apr)
- Shonan Kamakura General Hospital (Apr)
- Iwate Prefectural Central Hospital (Jul: planned)

Finish P1 in FY2023

1

PPMX-T003 :

Phase 1 3 patients after administration progressing smoothly

Progress report of P1

May 27, 2023

Prof. Ito, chief investigator, will present progress report at JSH Kinki Association (Osaka)

Abstract

- Administration to 3 patients
- **Safety and efficacy confirmed** in all the 3 patients
- Side effects were fever and decrease in lymphocytes; same level as HV

● Abstract (Japanese only)

http://www.jshem.or.jp/uploads/files/local%20branch/%E7%AC%AC118%E5%9B%9E%E8%BF%91%E7%95%BF%E8%A1%80%E6%B6%B2%E5%AD%A6%E4%BC%9A%E3%83%97%E3%83%AD%E3%82%B0%E3%83%A9%E3%83%A0_0502.pdf

2

PPMX-T003 :

Development of Aggressive NK-cell Leukemia (ANKL) drug

What's
ANKL?

- **Poor prognosis**

50% survival period = 58 days (about 2 months)

- **Ultra rare disease**

- 13 cases in Japan in 2020
- Many cases in east Asia and Latin America
- Cases may increase when advances in medical technology will enable easier diagnosis

- **Many cases in AYA generation** (age 15 to 39) and **40s**

- **No effective medical drug available**

Fulminant and poor prognosis.

Discovery of causes and establishment of treatment required.

Title: "Development of Therapeutic Drug for Aggressive NK Cell Leukemia"

(Patent application filed in Apr. 2022)



Found that **transferrin** is related to **proliferation and treatment of tumor**

Anti-TfR Ab
PPMX-T003
obtained by PPMX

Found that **cancer cells exist not in bone marrow but in liver**

FY2022:	50M yen	Received
FY2023:	100M yen	
FY2024:	100M yen	
Subsidy (max) total:	250M yen	

PPMX-T003
administered



Model mouse



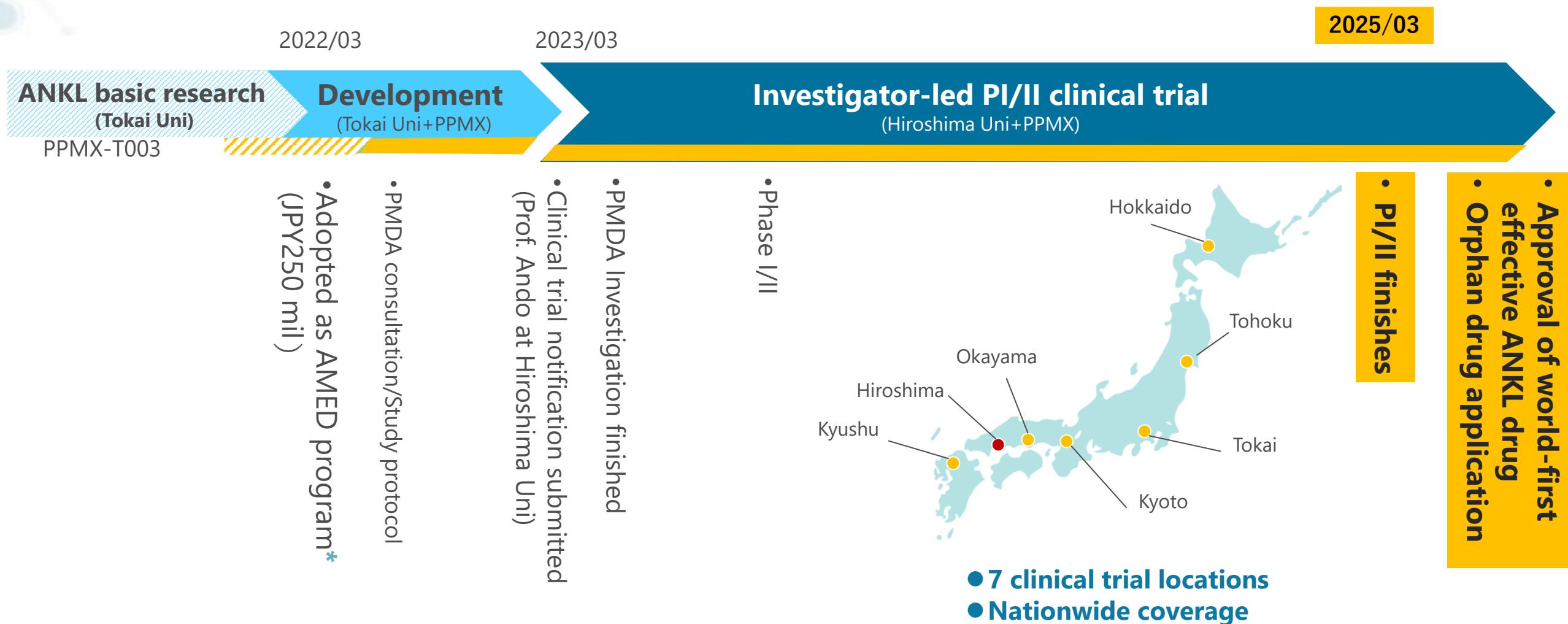
Tumor disappeared



Aim at approval of world-first effective therapeutic drug for ANKL

2

PPMX-T003: ANKL drug investigator-led clinical trial started



Nationwide coverage of patients by 7 clinical trial locations

2

PPMX-T003 :

Overcame difficulty of drug development of ultra rare disease
Favorable effects on entire T003 development plan

Hurdles for drug development of ultra rare disease

High cost

Slow recruitment

Long time



Measurements for success

Utilize T003 investigational drug (no CMC cost)

JPY 250 Mil subsidy from AMED

Establish nationwide core hospital network for smooth clinical trial

Apply for orphan drug, possibly apply for approval in house (high drug price)

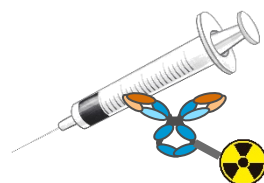
Promote PPMX-T003 entire development plan through ANKL drug approval

3

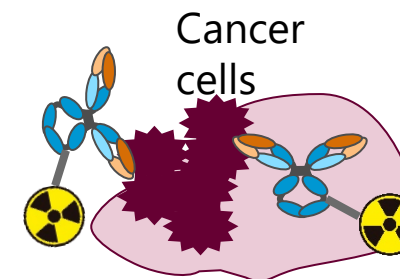
PPMX-T002:

Function of RI labelled Ab and structure of new PPMX-T002

1 Function of RI labelled Ab



Dose PPMX-T002
to a patient

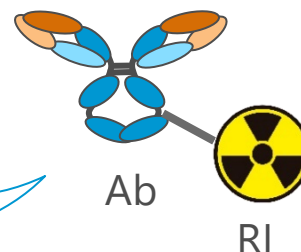


PPMX-T002 Ab accumulates on CDH3 on cancer cells
and RI kills cancer cells

2 Structure of new PPMX-T002

Confirmed accumulation on cancer cells

Use it as is

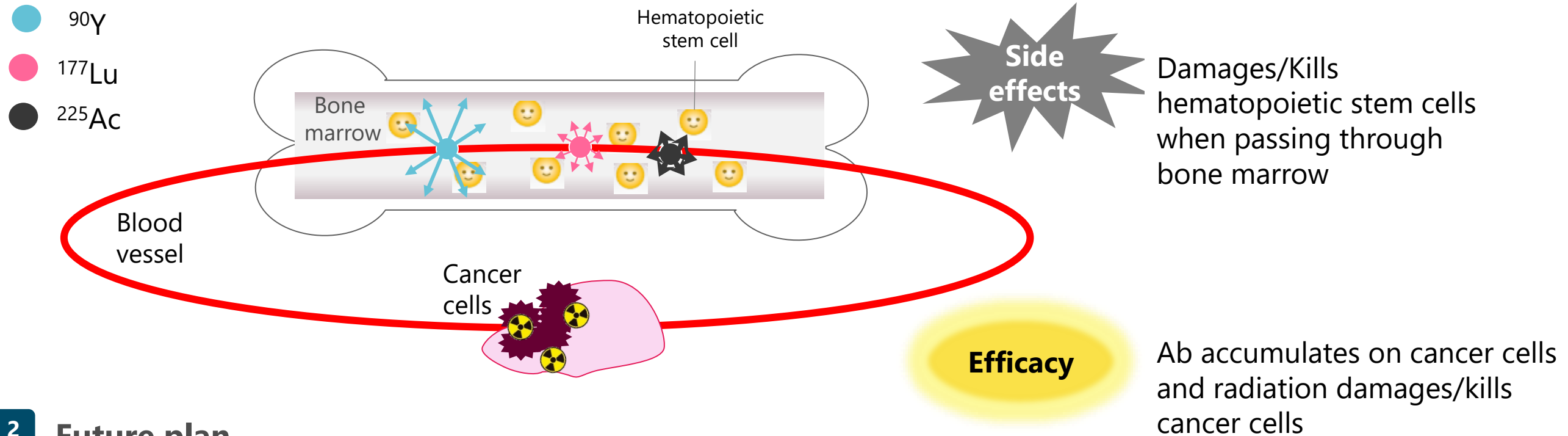


^{90}Y (β emitter) \gggg ^{177}Lu (β emitter)
or
 ^{225}Ac (α emitter)

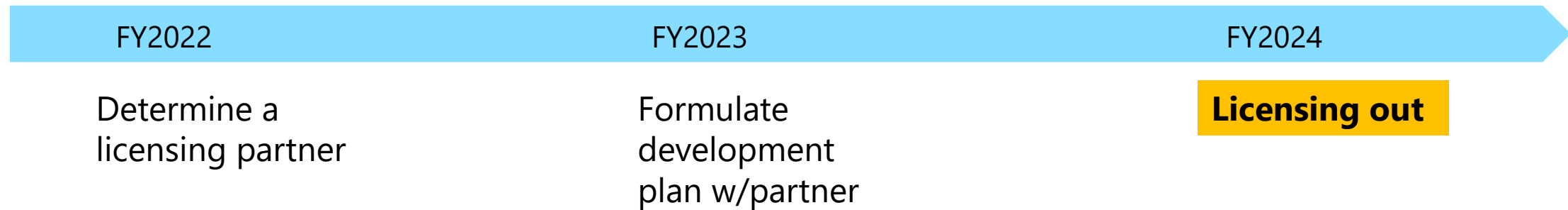
Utilize Ab as is and change RI to that w/higher effectiveness

3 PPMX-T002: Formulate development plan for licensing out in FY2024

1 Determine RI: consider impacts and efficacy on hematopoietic stem cells



2 Future plan

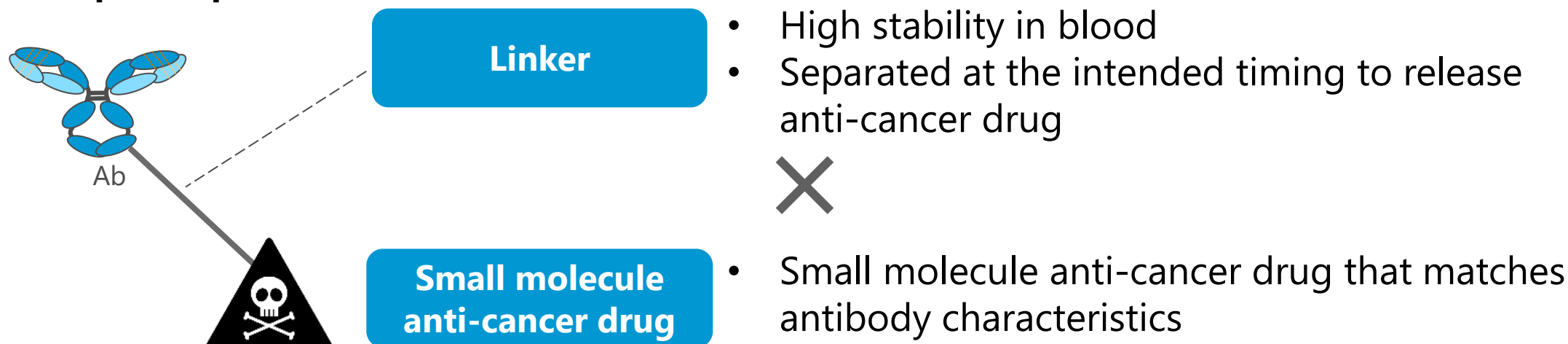


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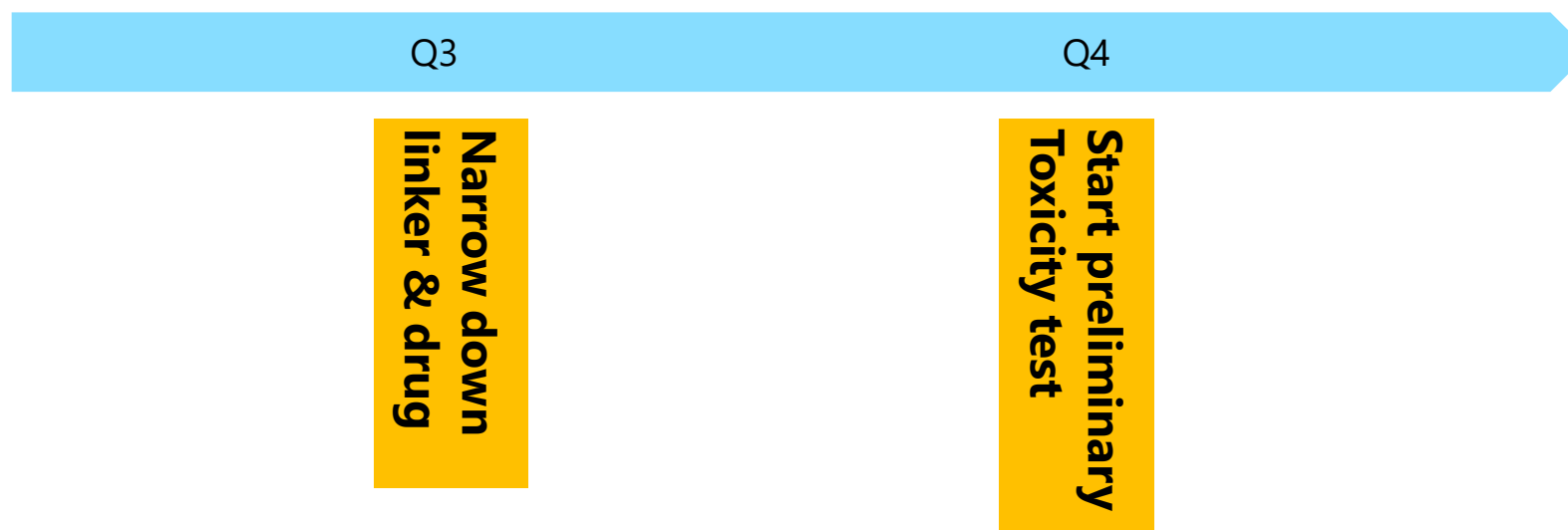
PPMX-T004:

Finished formulation of redevelopment plan, develop as a new ADC

1 Re-development plan



2 FY2023 Plan



Development of super neutralizing antibody UT27K

May 2022 Signed MoU on joint research w/Toyama University and Toyama Prefecture

“UT28K”

Treatment drug candidate for COVID-19

Ab effective for all variants

Toyama University

Generated UT28K



Business partner

Toyama Prefecture

Toyama Pharmaceutical
Valley Development
Consortium Office

Now

Confirmed efficacy in vitro



Verify by animal experiments



Obtain subsidies from government, etc.



Manufacture investigational drug



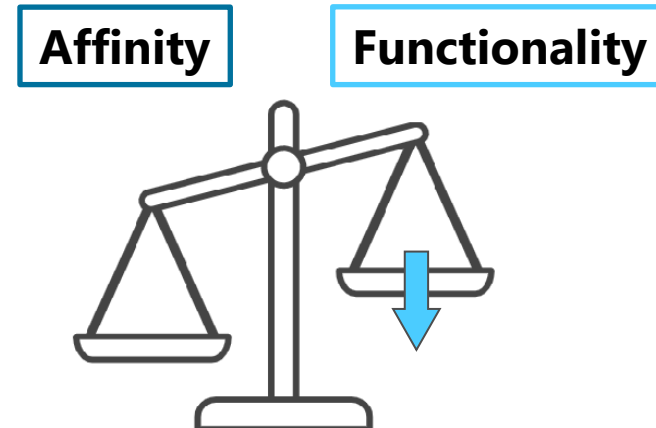
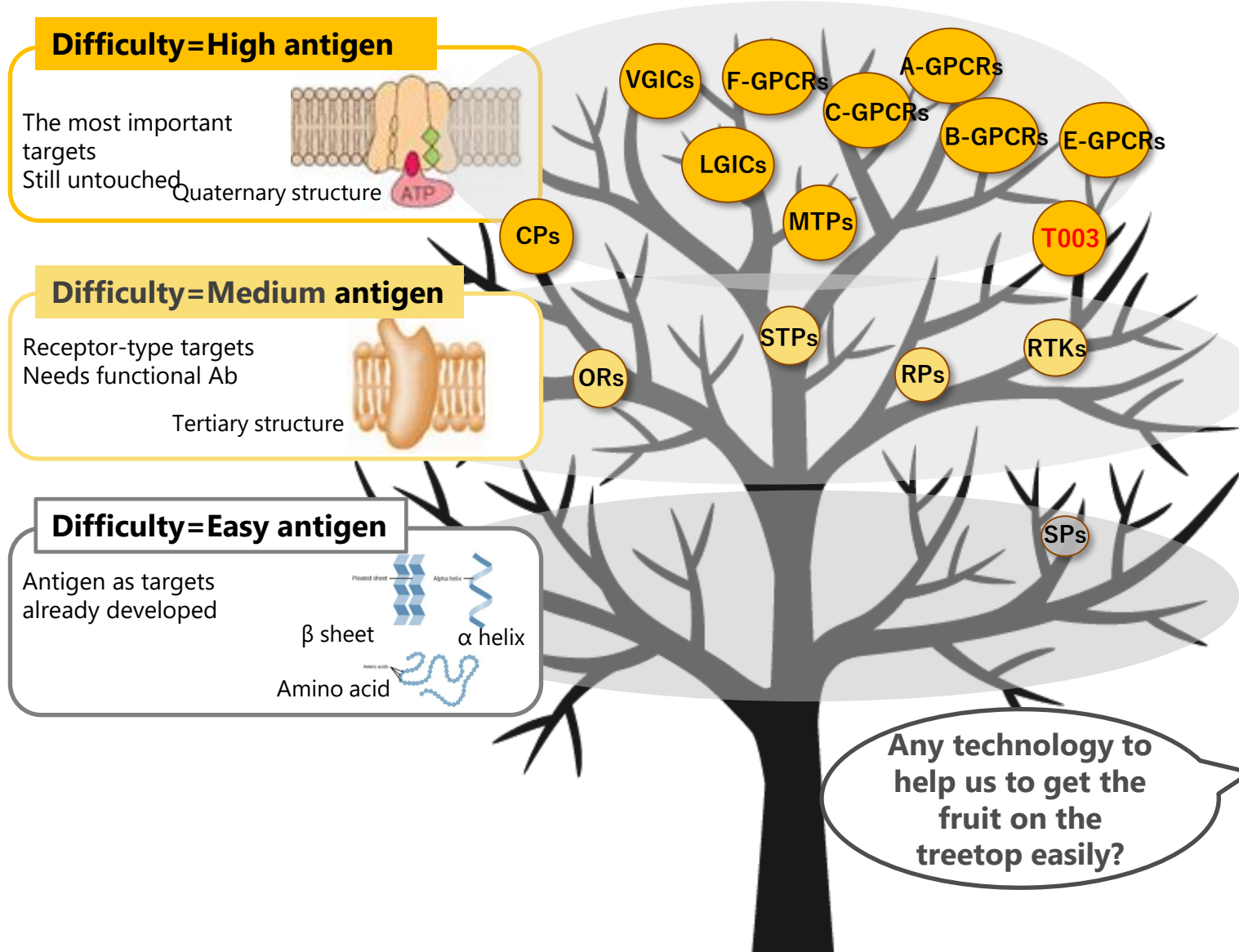
Confirm safety in healthy volunteers

04 **Summary of FY2023 plans and business results forecasts**

Summary of FY2023 plans

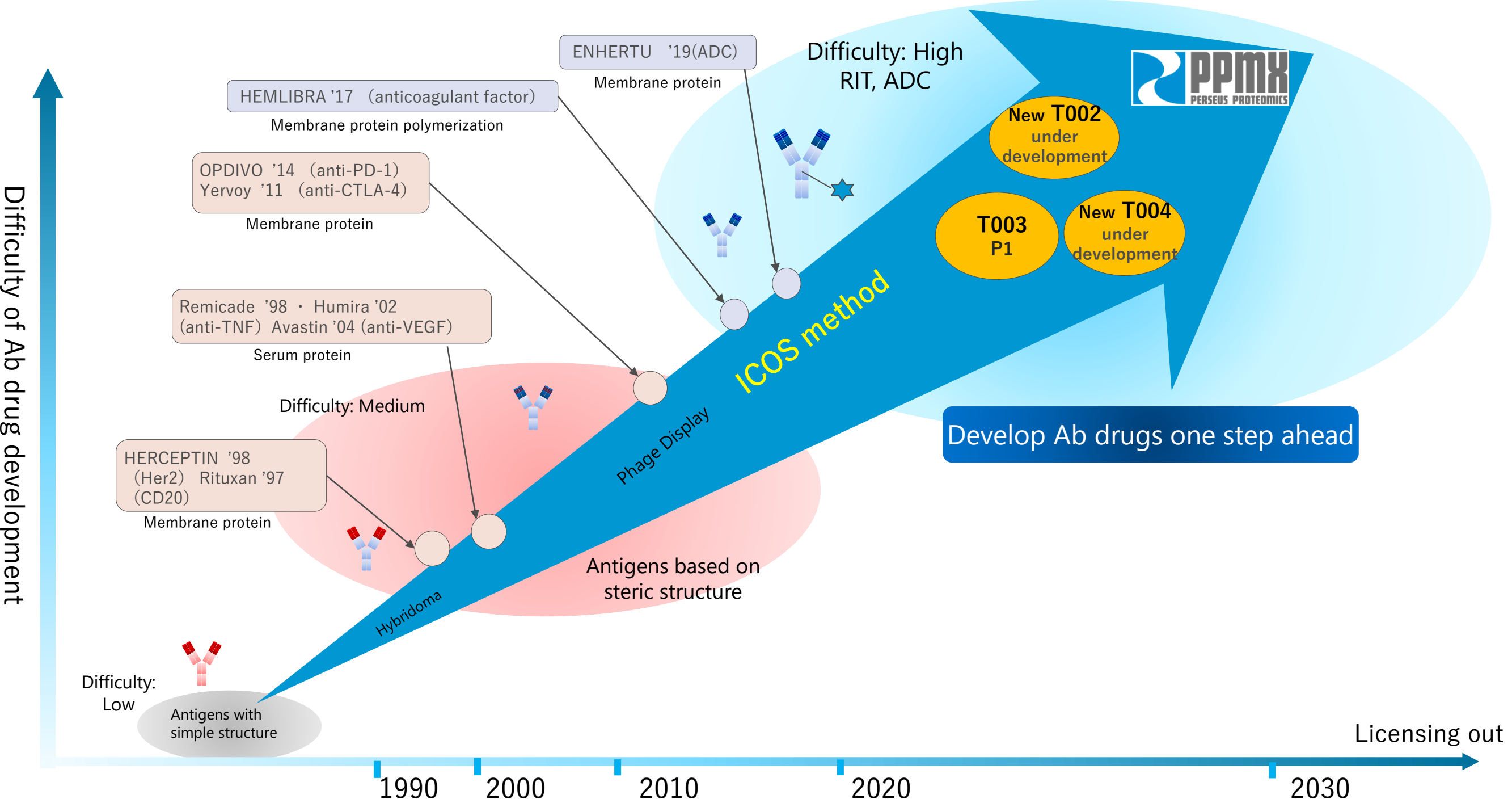
- 1** PPMX-T003 :
Finish P1, licensing out in FY2024
- 2** PPMX-T003 :
Promote ANKL investigator-led P1/2
- 3** PPMX-T002 :
Formulate development plan for licensing out in FY2024
- 4** PPMX-T004 :
Narrowing down linker/drug. Start preliminary toxicity tests

Ab creation technology now required



Technology required for obtaining Abs efficiently against medium to high level antigens

Bring more Ab drugs to patients



FY2023 business results forecast

(million yen)

	FY2022 results	FY2023 (forecast)	Vs. FY2022 Incr/decr rate	
Sales	94	100	6.5%	
Gross profit	86	91	5.8%	
SG & A	784	1,082	38.1%	
R&D cost	494	752	52.2%	PPMX-T003 PV P1 ANKL P1/2 PPMX-T004 development PPMX-T002 development
Other	289	330	14.0%	
Operating income	-697	-991	-	
Ordinary income	-689	-991	-	
Extraordinary loss	95	192	101.6%	Impairment loss of capex Relocation fee
Net income	-786	-1,185	-	

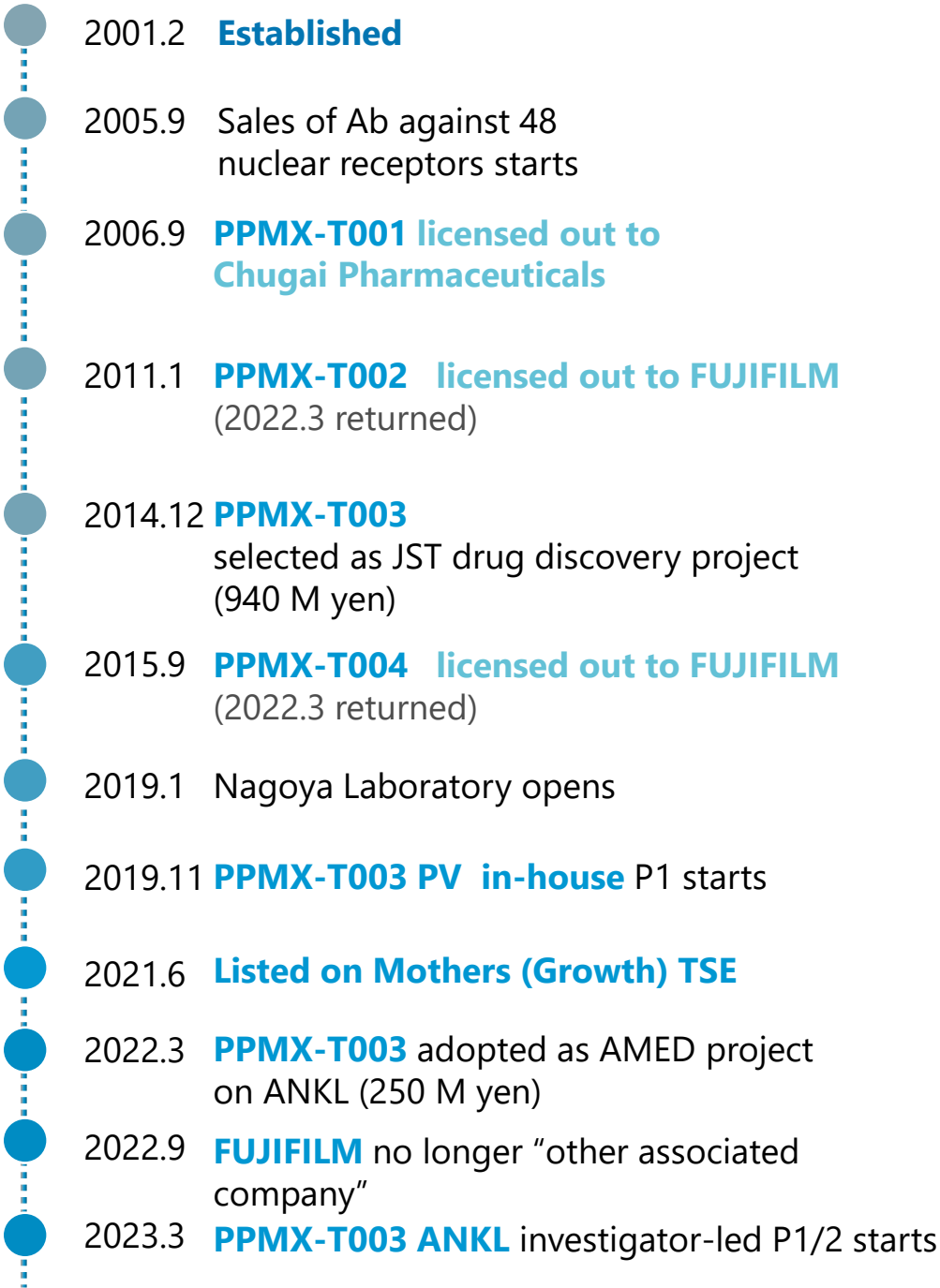
- Sales: JPY 100M expected
- R&D cost: P1 among PV patients, development cost of PPMX-T004 and PPMX-T002
- Extraordinary loss: JPY 192M expected due to impairment loss of capex and relocation fee

Appendix

Company outline

Business	<ul style="list-style-type: none"> Develop Ab drugs Support research on Ab Sales of Abs/reagents
Company name	Perseus Proteomics Inc.
Established	February 2001
Office	HQ/Laboratory: 4-7-6 Komaba, Meguro-ku, Tokyo, Japan Nagoya Laboratory: 2-22-8 Chikusa-ku, Nagoya-shi, Aichi, Japan
Capital	1,939 million yen*
Employee	24 (R&D, Business Development: 19, Administration: 5) *

*as of Mar. 31, 2023



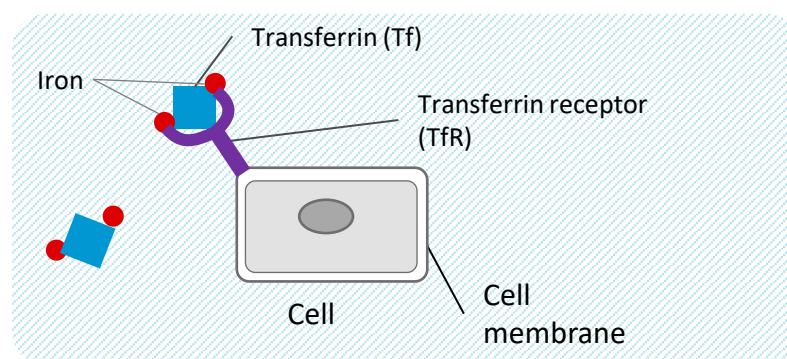
PPMX-T003:

First-in-class anti-cancer drug candidate targeting transferrin receptor

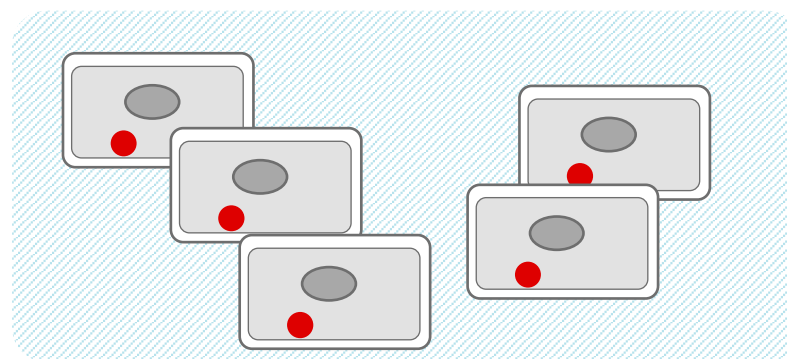
Transferrin receptor (TfR):

- Strong target molecule for anti-cancer drug
- Expressed on cell membrane. Binds to transferrin (Tf) carrying iron for cellular iron uptake

1 TfR binds to Tf



2 Cell proliferation



[Cells where TfR is highly expressed]

- Erythroblast (normal cell, RBC producing cell)
- Cancer cell (especially acute cancer which is actively proliferating)

Well-known concept

Blocking iron
⇒ **Death or inhibition of cell proliferation**

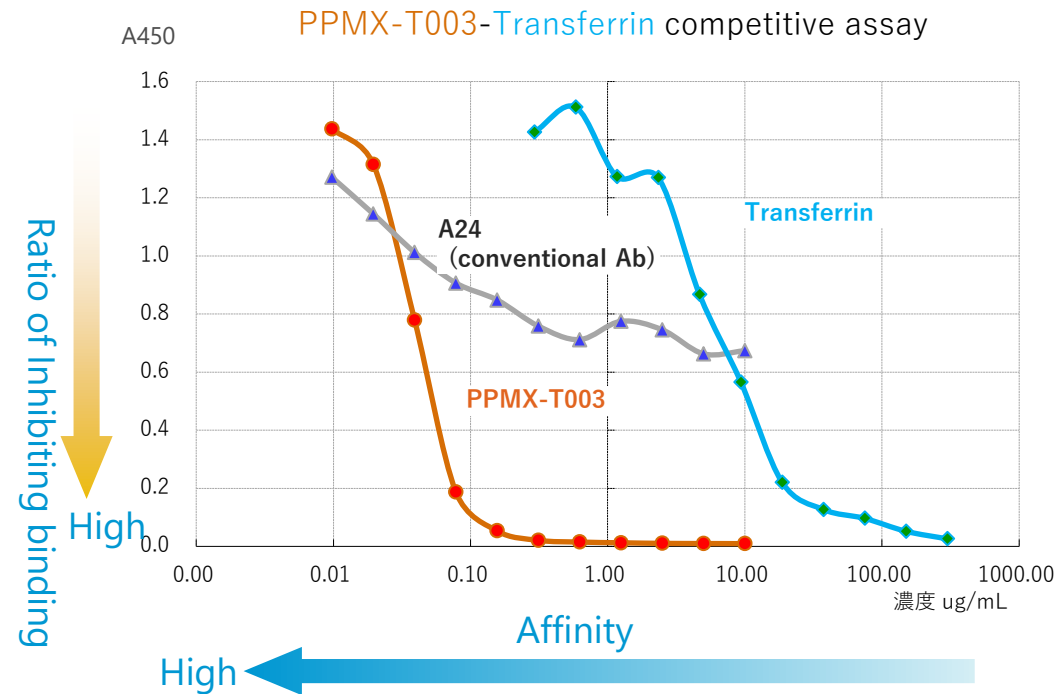
Inhibiting cellular iron uptake leads to death/proliferation inhibition of cancer cells

PPMX-T003:

Highly functional Ab obtained by our phage display technology

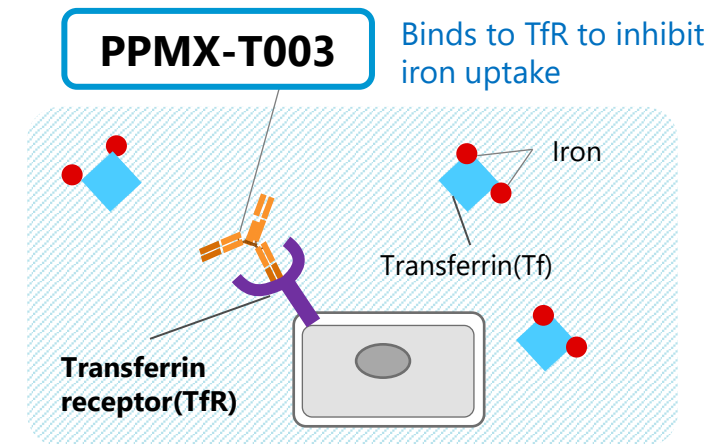
Shows unprecedented result in inhibiting ratio of binding Tf to TfR

Inhibits iron uptake into **erythroblast** and **cancer cells** and leads to cell death/proliferation inhibition

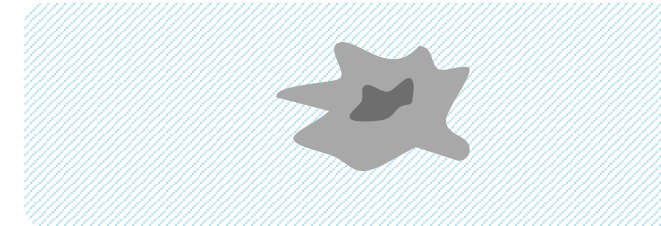


Inhibition of iron uptake has been difficult, however, PPMX-T003 is expected to bring it to reality as the first therapeutic drug for cancer and PV.

1 PPMX-T003 binds to TfR more tightly than Tf



2 Iron uptake inhibited. Cell death or proliferation inhibition of cells



Anti-Transferrin receptor Ab with incomparable function of inhibiting binding

PPMX-T003:

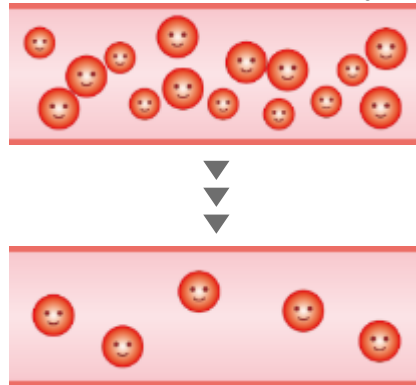
Indication: Polycythemia vera (PV)

- RBC increases to an abnormal level.
- Thrombosis is easily formed due to thick and slow blood flow. Various organs are affected by thrombosis.
- 2 out of 100,000 people develop this disease. Number of patients in Japan: 30,000 (estimated by PPMX. Average life expectancy: 16 yrs)

Current therapeutics

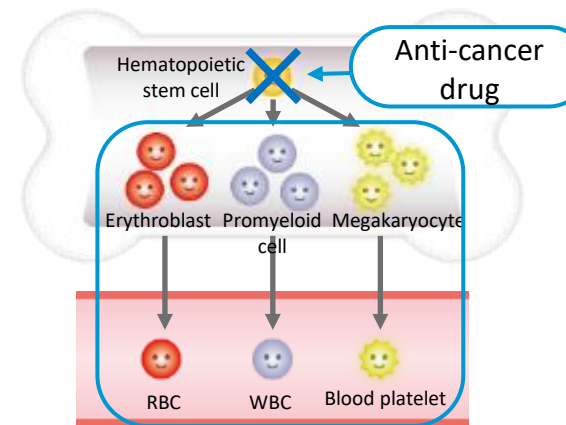
Therapeutic phlebotomy

Half of patients are treated by therapeutic phlebotomy only.



- Anemia
- Lassitude
- Depression
- Restless hands and legs
- Other diseases by iron deficiency

Anti-cancer drug, etc.

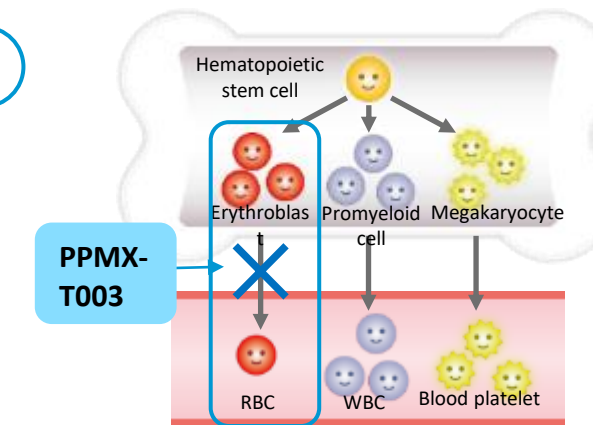


- Entire hematopoietic stem cell affected
- Secondary cancer risk
- Many side effects

New candidate

PPMX

PPMX – T003



- Acts only on erythroblast
- **Few side effects**
- **Safe to use**

PPMX-T003: effects on inhibiting abnormal proliferation of RBC expected



[Inquiry]

Email: ir@ppmx.com

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