



# Forward looking statements

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- This presentation material is a summary translation of the original published in Japanese. In case of any discrepancy, the Japanese original shall prevail.

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- 1. Financial results and future outlook**
2. Telomelysin
3. TelomeScan
4. OBP-AI-004
5. Zika vaccine





JPY in million

	Sales	OP	CP	NP
Forecast FY 2017	200	△1,400	△1,400	△1,400
Results FY 2016	178	△861	△864	△931

- Sales: License fee and sales of virus
- Loss: Investment in R&D and increase in patent-related costs (JPY 0.9bn)  
foreign currency fluctuation risk (1 USD=JPY112)

# First half of FY2017: earnings results



	Sales	OP	CP	JPY in million NP
FY2017 First Half	<b>19</b>	<b>△509</b>	<b>△517</b>	<b>△518</b>
FY2016 First Half	<b>44</b>	<b>△410</b>	<b>△416</b>	<b>△417</b>
(ref.) FY 2016 full year	178	△861	△864	△931

## Sales

1. License fee for TelomeScan from Wonik Cube
2. Sales of TelomeScan to Deciphera

## OP

1. Cost reduction efforts
2. Delay in R&D activities


**Cash and equivalents** JPY 3 bn (JPY 450 million increase yoy)

**R&D costs** JPY 208 million (JPY 80 million increase yoy)



# First half of FY2017: achievements/status




**Telomelysin**<sup>®</sup>  
 OBP-301  
*"Telomelysin*<sup>®</sup>*"*

## <R&D-related>

- |                            |      |  |
|----------------------------|------|--|
| 1. Melanoma                | P2   | FPI  |
| 2. Esophageal cancer       | P1   | FPI  |
| 3. HCC                     | P1/2 | Multiple administration (Cohort 5) started |
| 4. Solid tumors, with PD-1 | P1/2 | CTN submitted and a kick-off meeting held  |

## <Business-related>

- Hengrui's GMP facilities for virus production under plan
- Signed a revised strategic alliance agreement with Medigen


**TelomeScan**<sup>®</sup>  
*Cancer Diagnosis*

- PTC: PMDA consultation underway for gastric/pancreatic cancer application
- CTC: working on a project for process automatization while clinical testing services are temporary halted
- Juntendo University's paper on lung cancer published in journal
- 7 conference presentations

**OBP-801**  
*Epigenetic cancer treatment*

- Solid tumor Phase 1 Cohort 3 in progress
- Explorative study with Kyoto Prefectural University of Medicine extending the application into ophthalmologic field

**AI-004**  
*Novel HBV drug*

- Compound screening at Kagoshima University in progress

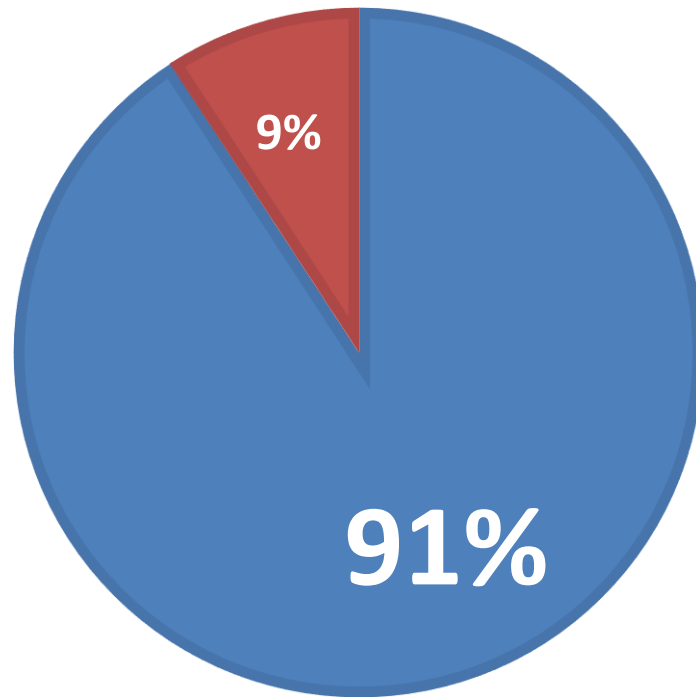
Others

- Strategic investment in Washington University biotech venture specialized in development of vaccines for Zika and other emerging infectious diseases
- Oncolys USA operations kicking-off

MSCB financing announced in December 2016 is almost complete.

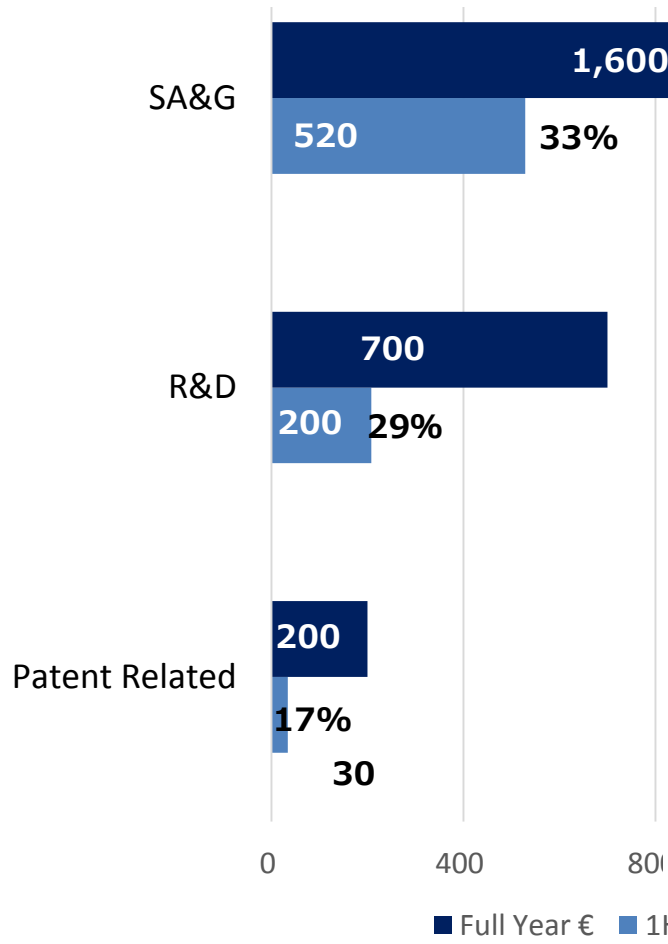
→ About 91% executed and the total amount raised is JPY 1.3 bn (as of 31 July 2017)

<MSCB execution status>





## <1H results vs. FY2017 full year forecasts>



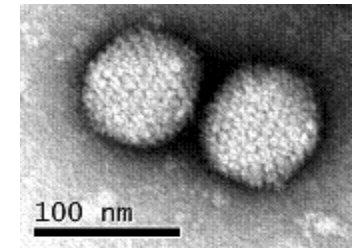
### <Main factors>

- Delayed Telomelysin GMP acceptance inspection
- Delayed melanoma trial due to additional documentations for NIH
- Reduced NG Telomelysin-related patent cost
- Postponed TelomeScan-related collaboration cost
- R&D/patent cost reduction as a result of revision of strategic alliance with Medigen

### <Action>

Assigning key personnel in Oncolys USA

1. Realizing oncolytic virotherapy
2. Developing treatments for intractable diseases



## For “Good” medicine



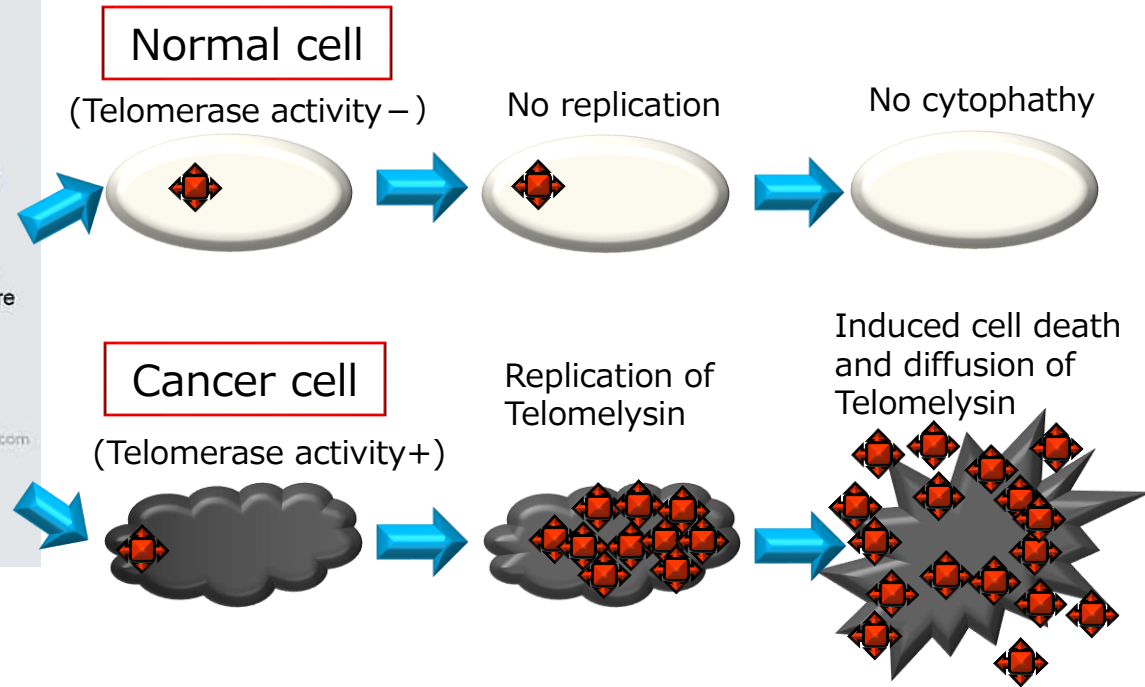
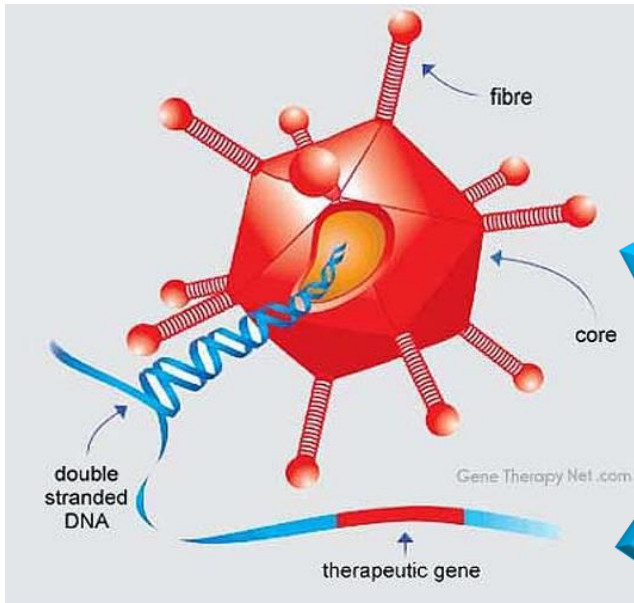
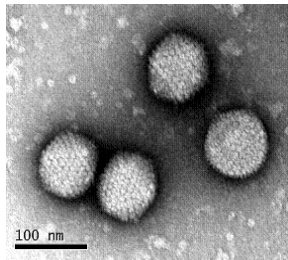


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# Telomelysin : oncolytic virotherapy



Ref.) *The Lancet Oncology* Vol. 3 Jan. 2002

Colorectal cancer

(15 days after administration)

Control group

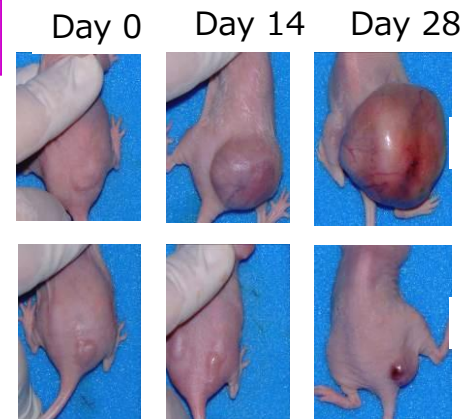


Telomelysin



Ref) *Curr. Cancer Drug Targets*, 7: 191-201, 2007

Lung cancer



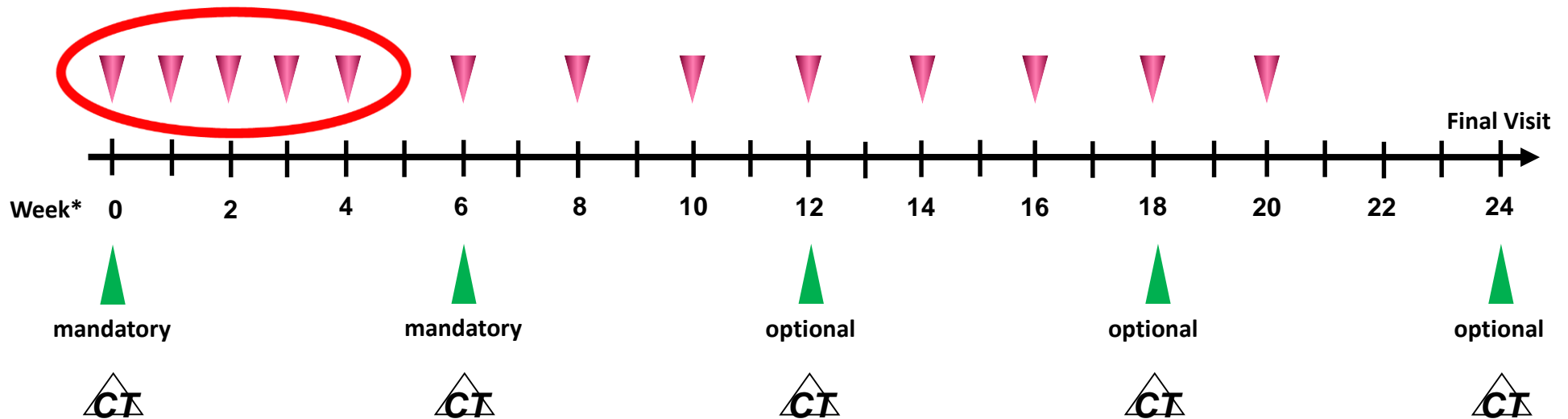




# Clinical trials updates



- FPI achieved in Atlantic Cancer Center on 28 July
- Oncolys pushing ahead to speed up the enrollment of patients in 5 sites

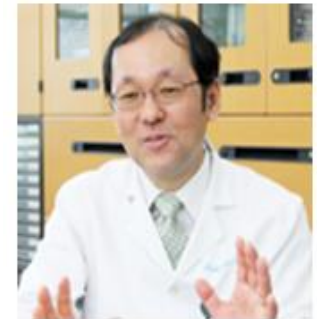
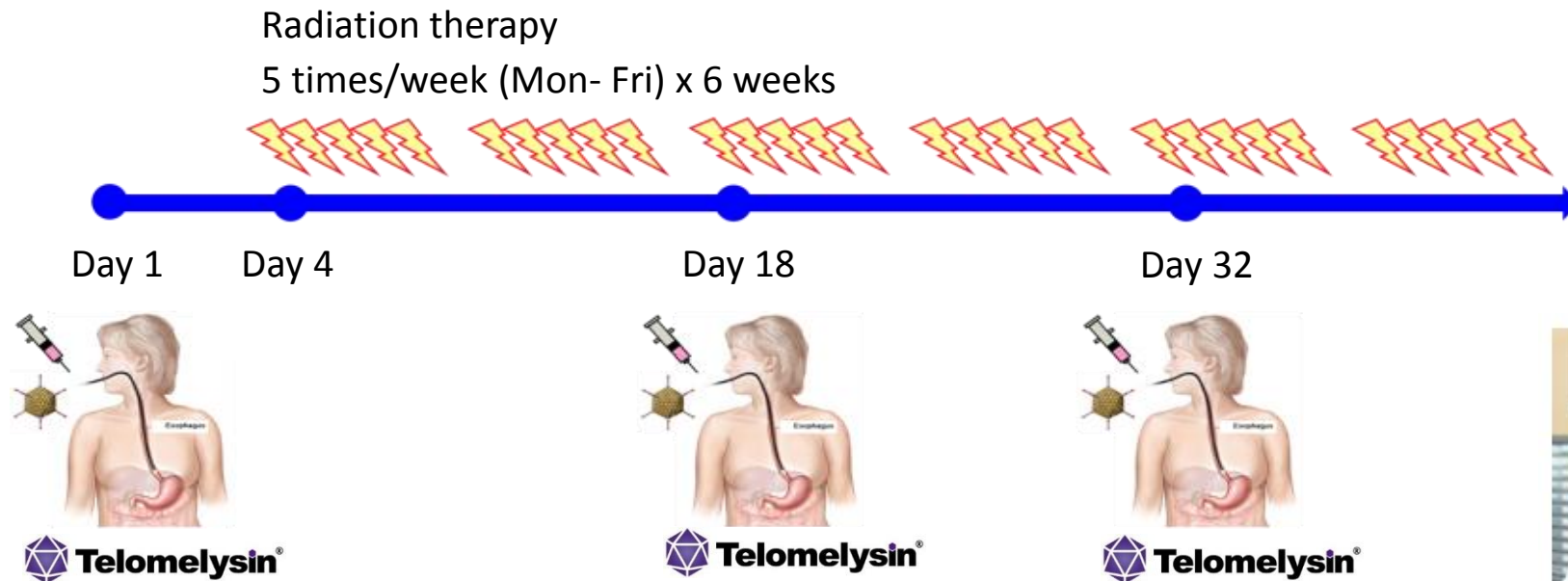


Investigators	Clinical trial sites
Dr. Eric Whitman	Atlantic Health Systems
Dr. Robert Andtbacka	Huntsman Cancer Institute
Dr. Mohammed Milhem	University of Iowa
Dr. Sanjiv Agarwala	St. Luke's University Health Network Inc.
Dr. Sunil Reddy	Stanford University





6 CR in 10 cases: interim data presented at JSGCT 2017 and JSMO 2017



**Toshiyoshi Fujiwara, M.D., Ph.D.**  
Professor & Chairman  
Department of Gastroenterological  
Surgery, Okayama University Graduate  
School of Medicine, Dentistry, and  
Pharmaceutical Sciences

JSGCT: Japan Society of Gene and Cell Therapy  
JSMO: Japanese Society of Medical Oncology

1. FPI in Okayama University Hospital (7 July)
2. Kick-off meeting with key investigators (15 July)

Interim data from clinical research by Okayama University

Dose	Case	Age	Stage	Response
Level 1 1x10 <sup>10</sup> vp	001	82	cStage I	CR
	002	85	cStage I	CR
	003	92	cStage II	PR
	004	68	cStage Iva	SD
	005*	79	cStage III	PD
	006	88	cStage I	CR
	007	53	cStage II	CR
Level 2 1x10 <sup>11</sup> vp	001	89	cStage I	PR
	002	75	cStage II	CR
	003	85	cStage I	CR

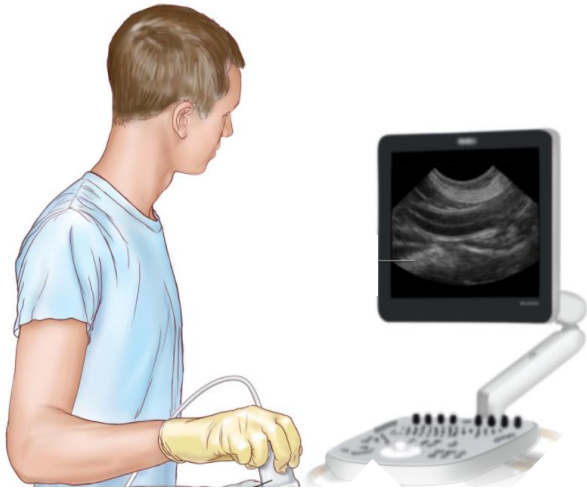


(\* Level 1 005 dropped out as the enrollment was cancelled

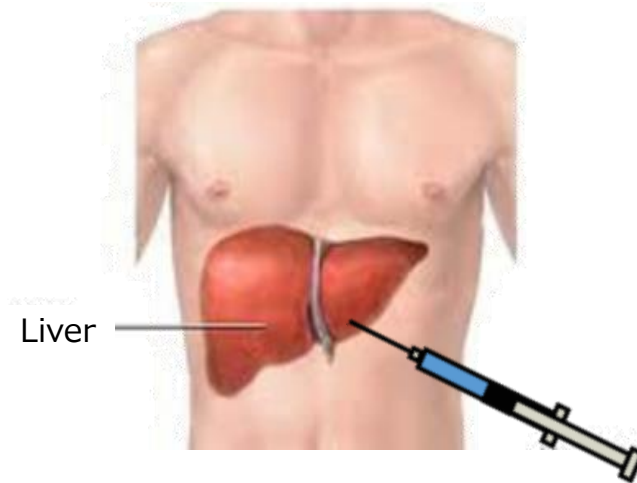
Ref.): presentation materials by Okayama University and the Company, etc.

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1. Cohort 4 administration completed
2. Cohort 5 multiple administration( $2 \times 10^{12}$ vp x 3) started

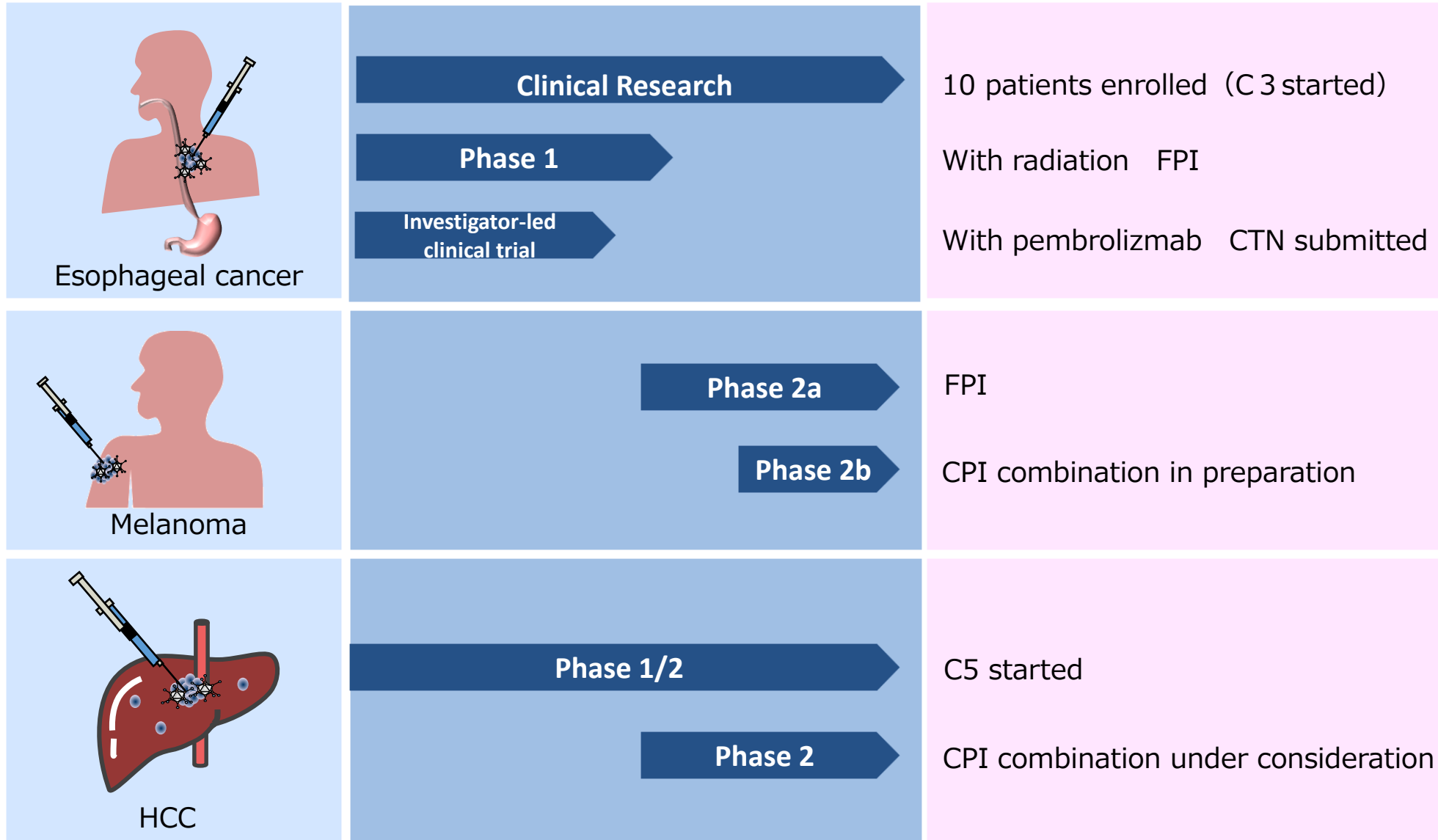


Areas for injection are monitored by use of sonogram.



Directly injected to cancer cells





- GMP tech-transfer of Telomelysin in progress
- GMP facilities for virus production under plan



**CFDA to ease rules: acceptance of clinical trial data collected overseas is on the table**

## Jiangsu Hengrui Medicine (江蘇恒瑞医药股份有限公司)

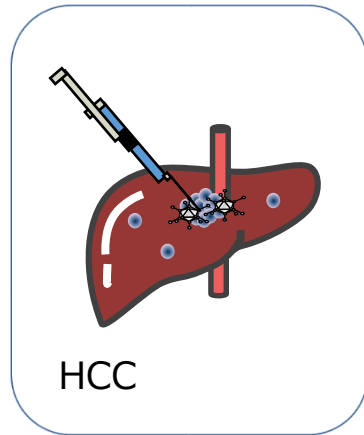
Sales: approx. JPY180 Bn Employees: approx. 13,000 (as of 2016)



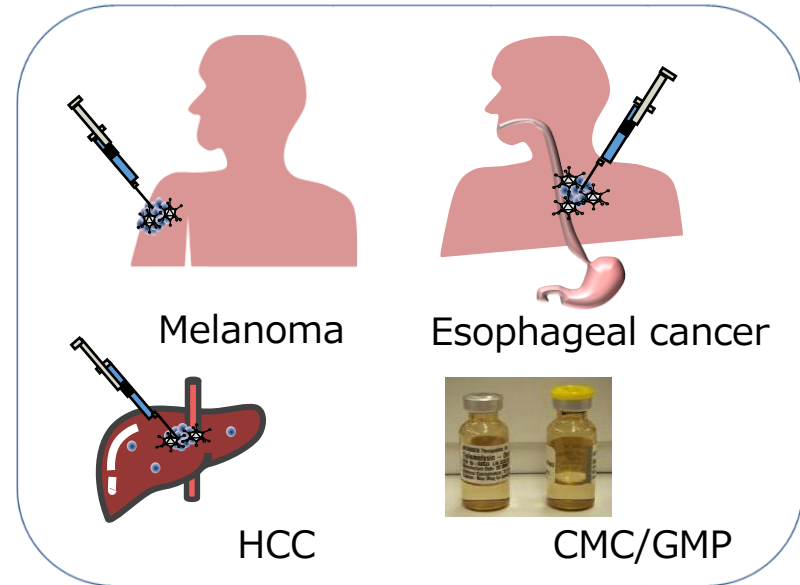
Major pipelines related to cancer treatment		indications	Development Stage*
YN-968-D1 (Apatinib)	VEGFR2 inhibitor	Gastric cancer	Launched
SHR-1210	Anti-PD-1 antibody	Lung cancer, esophageal cancer, NPC	Phase 3
SHR-1258 (Pyrotinib)	RTK inhibitor	HER2 +ve metastatic breast cancer	Phase 3
SHR-1020 (Famitinib)	RTK inhibitor	CRC, lung cancer	Phase 3
HTI-1403	RTK inhibitor	RTK +ve cancer	IND
HTI-1316	Anti-PD-L1 antibody	PD-L1 +ve advanced tumor	IND

\*The most advanced development stage regardless of therapy type (mono, combination etc.) for each drug candidate is shown in this table.

Ref.) ClinicalTrials.gov and other public data as of July 2017



Expanded cost-split agreement



**Constant cost saving on  
Telomelysin-related R&D expenses**



Listed on Taiwan Stock Exchange (3176)  
HQ: Taipei, Taiwan  
Representative: Stanley Chang, CEO





## Telomelysin: what's next?



- Number of patients: approx. 31,000 in 2014
- Estimated incidence: approx. 22,000 between 2015 - 2019  
(Incidence worldwide: approx. 456,000 in 2012)

Stage I · II · III · IV



+

Post-operative CPI

Operation applicable  
Stage I · II · III

**Application for Sakigake  
Designation Scheme**

Operation/chemotherapy  
inapplicable patients  
Stage I · II

 + Radiation

 +  
Pre-operative  
chemotherapy/radiation



Ref.) PMDA 2014 Patient Report (2014), NCC Center for Cancer Control and Information Services, Cancer today IARC website.

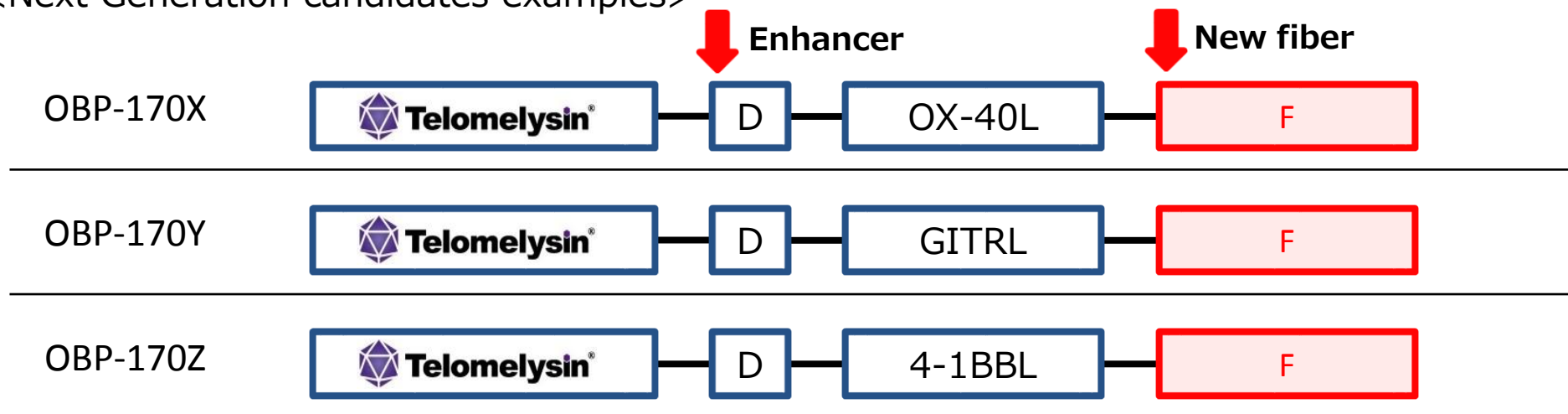


- ✓ Regionally administrable/ abscopal effect
- ✓ Good tolerability
- ✓ Established GMP/QC



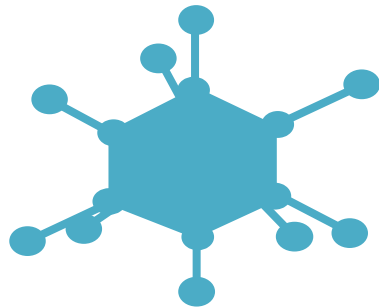
- ✓ Further immunity enhancing effect
- ✓ Intravenously injectable
- ✓ Stable at 4°C

<Next Generation candidates examples>

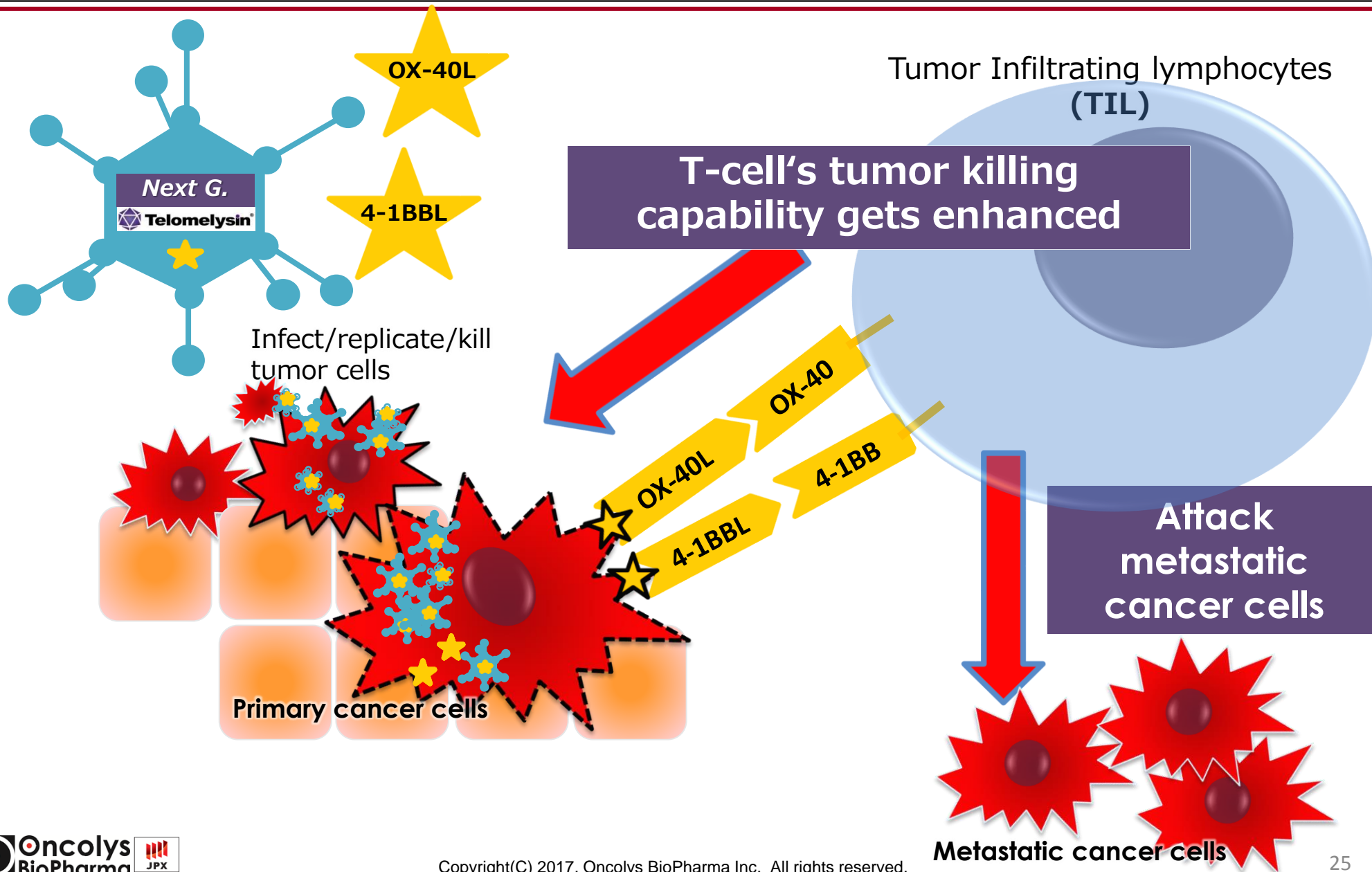


## Next Generation Telomelysin: concept (2)

1. A specific gene inserted in NG Telomelysin is delivered to a tumor cell.
2. Target molecule is expressed on the tumor cell surface.
3. Replication of NG Telomelysin and an adjunctively used tumor antibody induce stronger anti-tumor activities.



Targets	
OX40	GSK Pfizer AZ Roche Incyte etc.
GITR	Novartis AZ MSD Incyte etc.



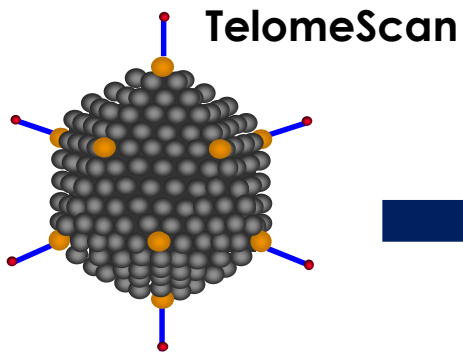
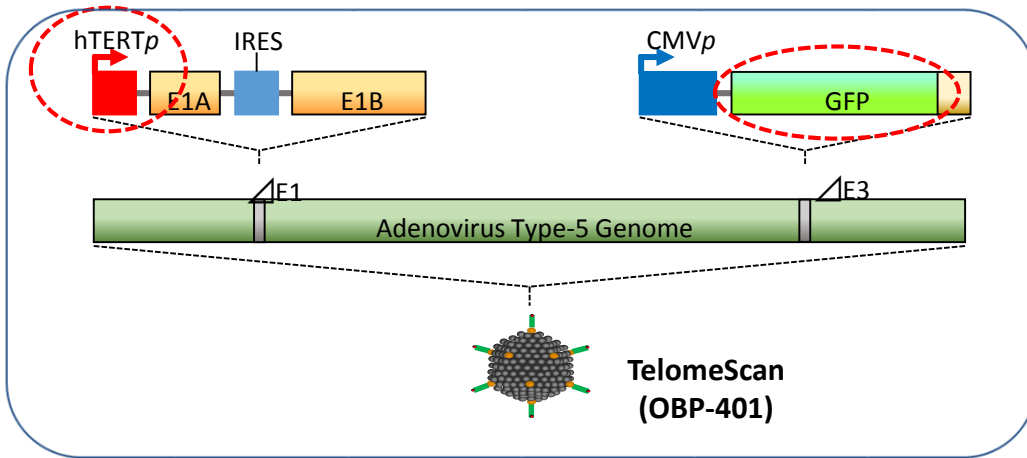
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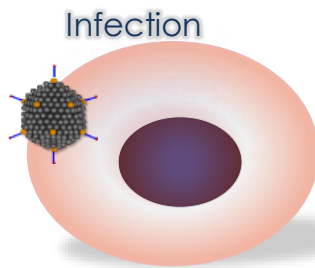




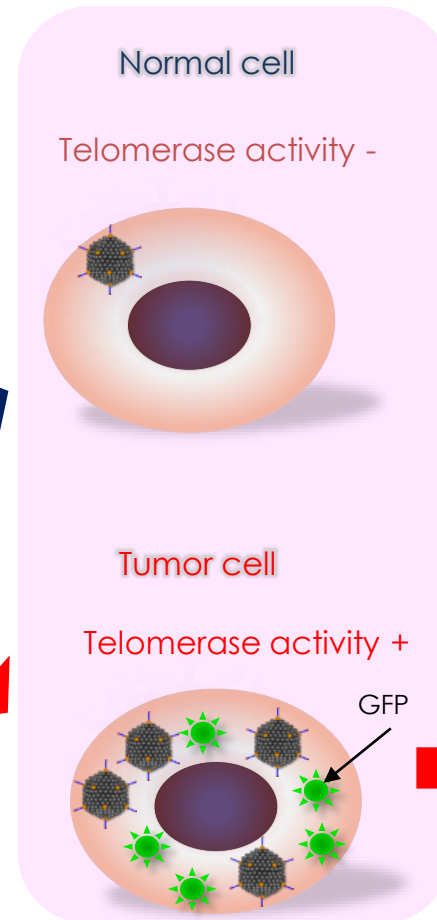
TelomeScan is a gene-modified adenovirus which replicates and express GFP when infected to telomerase activity-positive tumor cells.



TelomeScan

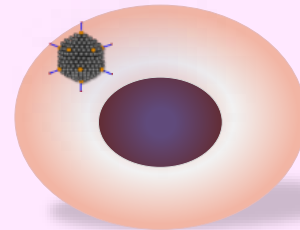


Infection



Normal cell

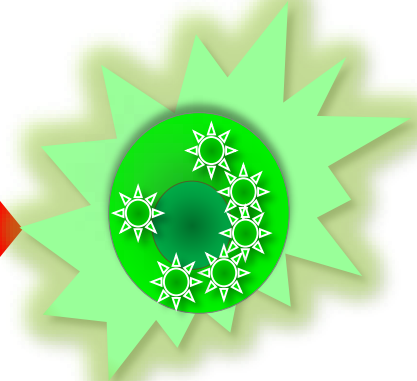
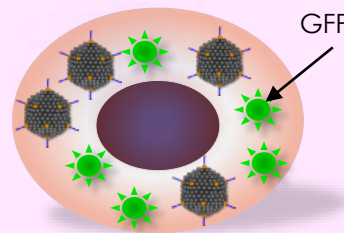
Telomerase activity -



Fluorescent emission by GFP

Tumor cell

Telomerase activity +



**PTC \***  
**gastric &  
pancreatic cancer**

\*PTC ; Peritoneal Tumor Cell



**Osaka University**  
**Okayama University**



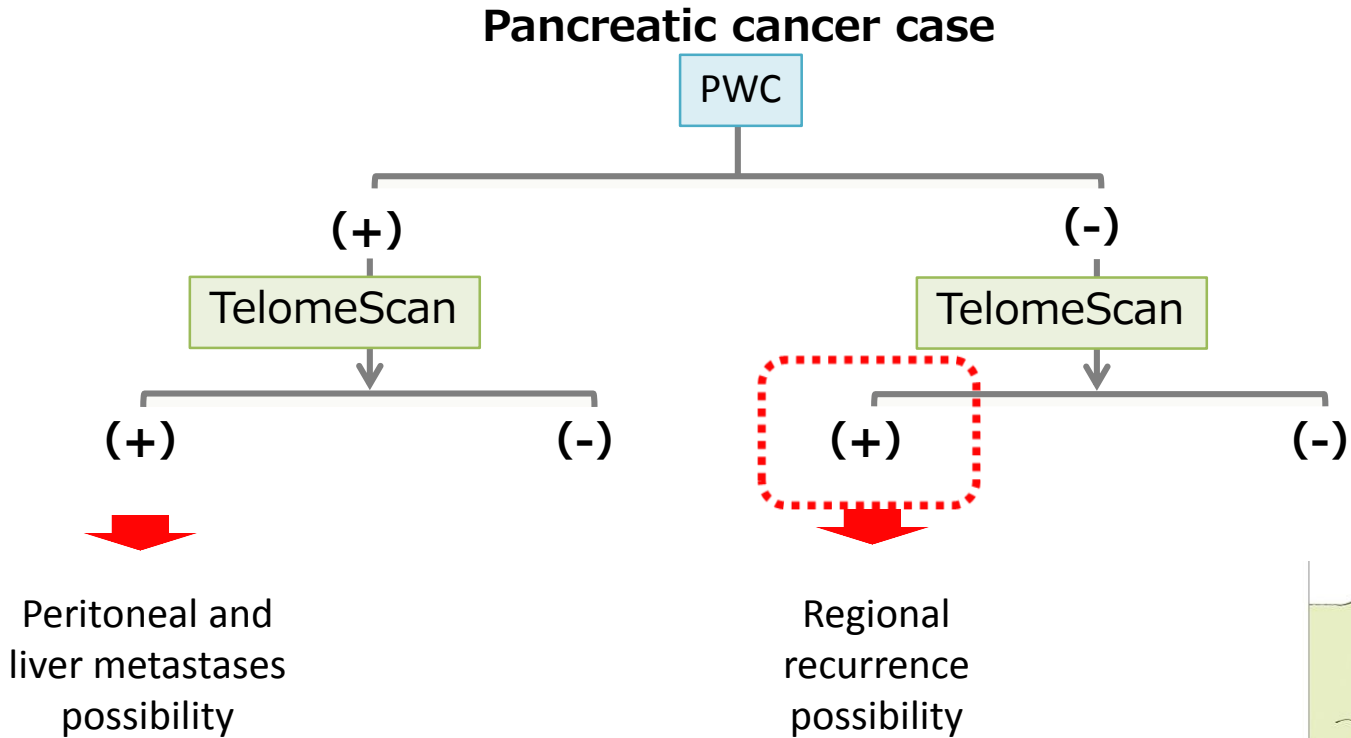
**CTC**  
**Lung &  
prostate cancer**



**Juntendo University**

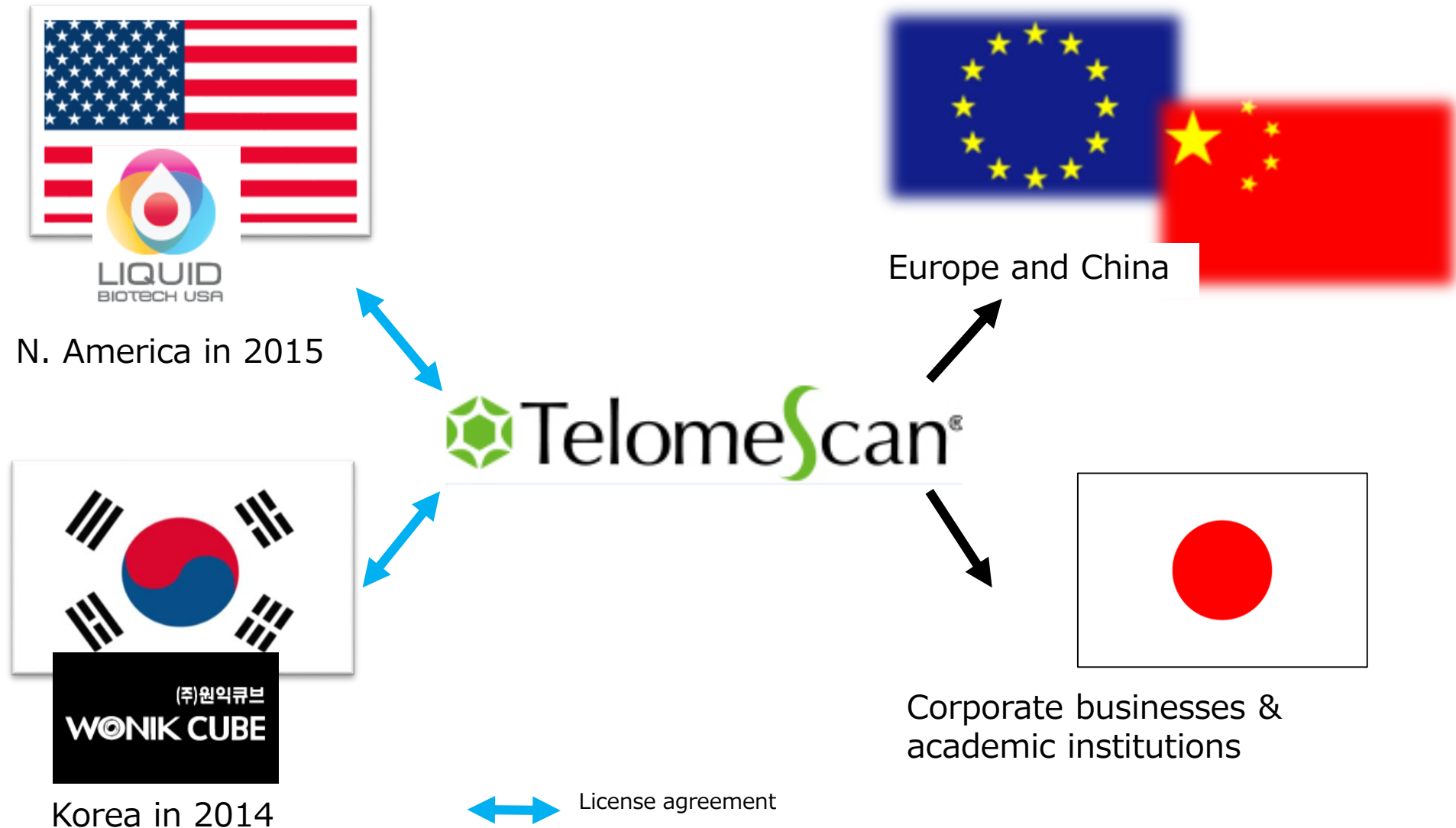
Application for companion diagnostics

**Pancreatic cancer**  
peritoneal washing cytology (PWC)



**⇒ Intraperitoneal chemotherapy**





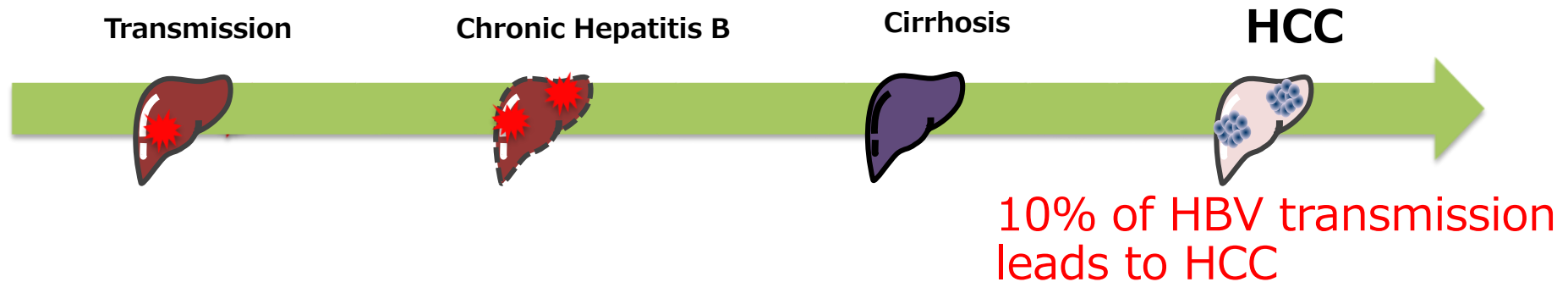
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# Hepatitis B (HBV)

- HBV is a member of the small DNA virus.
- Its DNA considered to activate tumor DNA within infected liver cells



In the world, 350 million patients have persistent HBV infection

- Of which 70% are in Asia Pacific region
- 1.5 million patients in Japan

Ref.) Articles on "Nikkei Biotech", Nikkei BP,17032014, etc.

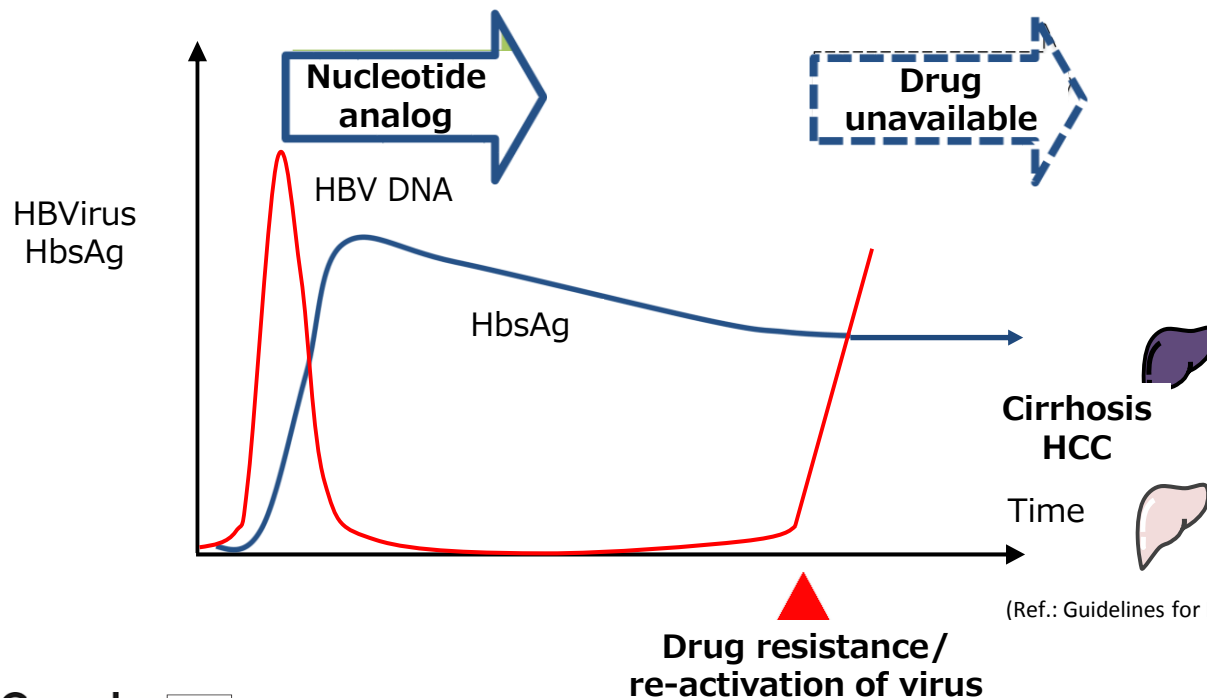


# Long-term goal of HBV treatment: HBsAg elimination

The Japan Society of Hepatology's official guidelines for Hepatitis B treatment sets the elimination of HBs antigen (HBsAg) as a long-term goal.

- Chronic hepatic failure has a obvious risk factor associated with HCC incidence.
  - Persistent HBV infection
- HBV treatment may eliminate the risk factor therefore reduce the cancer risk.

**No treatment available for recurring HBV after the existing drug administration**



**HBsAg implied as  
HBV risks factor**

(Ref.: Guidelines for Hepatitis B Treatment, Ver. 2.2., The Japan Society of Hepatology; PMDA HP)



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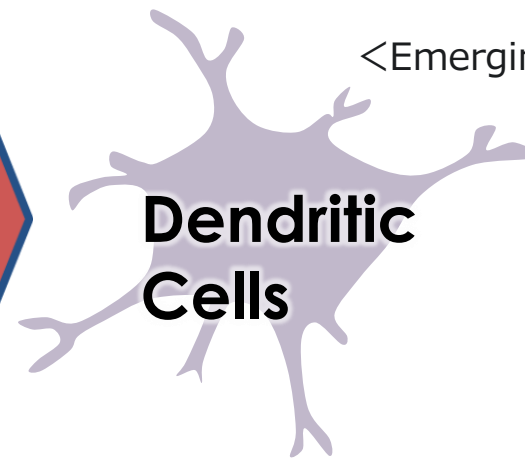
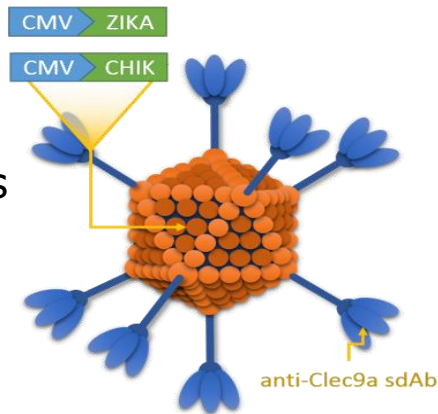
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# Investment in Washington University biotech venture

Investment agreement with Precision Virologics signed in March 2017, to enhance OBP's infectious disease pipeline and for broader business opportunity.

- ① Modified adenovirus
- ② Camelid antibodies
- ③ Zika DNA



<Emerging infectious diseases>

**Dendritic Cells**

**Zika**  
Chikungunya  
Dengue  
West Nile  
Ebola  
TB



First Refusal Right  
in Asia

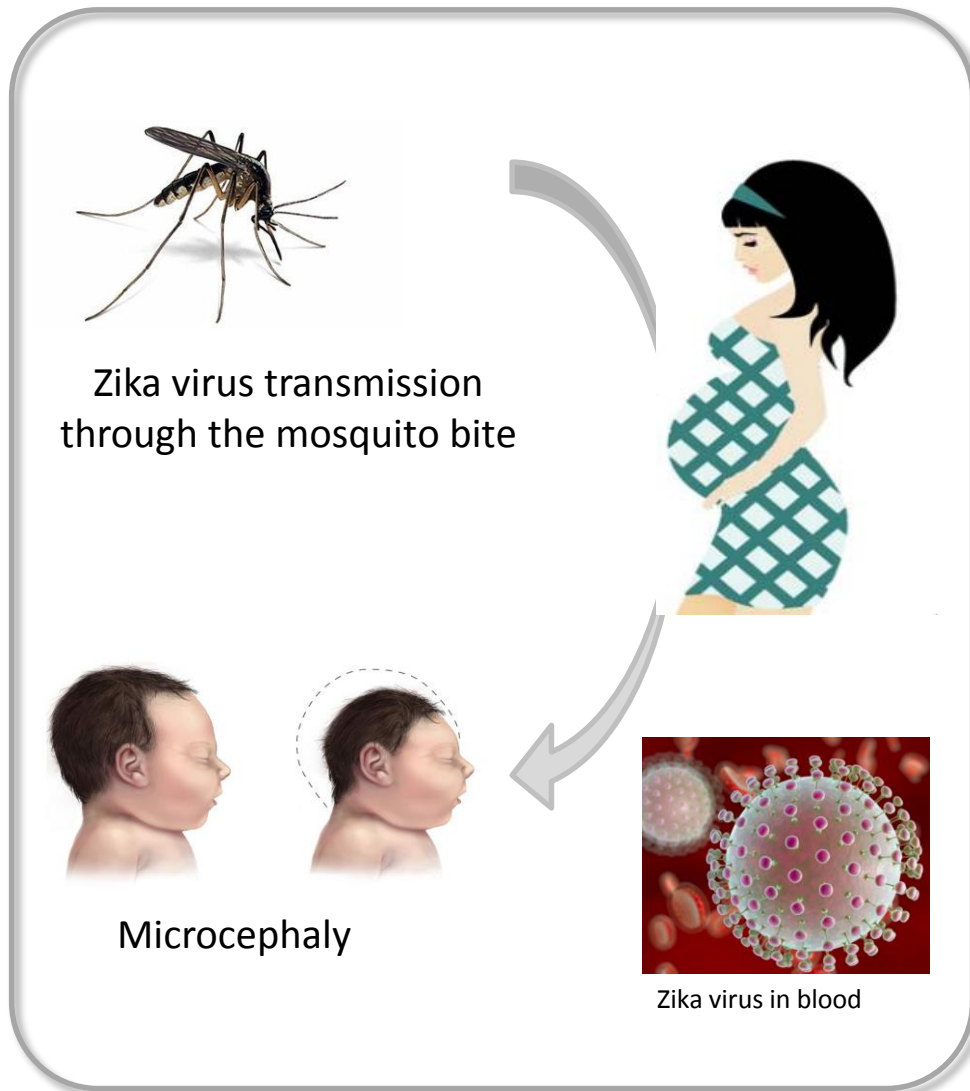


Board member  
USD 500,000



Dr. David T. Curiel  
Founder & CSO

# Potential Market for Zika Virus Vaccines

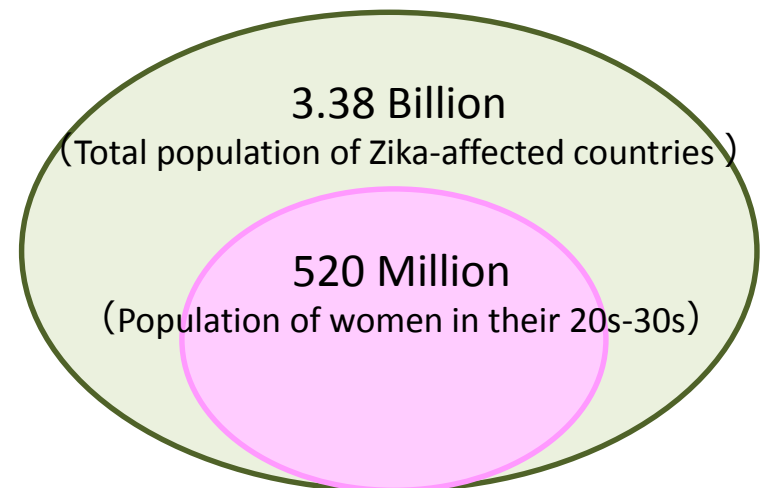


Zika transmission has been identified in 84 countries and regions in total so far.\*1



\*1 World Health Organization

Women of reproductive age needs vaccination



Ref) Yellow fever vaccine price: JPY10,000 (Japan), JPY2,500 (Thailand)



**Thank you!**