

# Financial Results

## FY2021 Q2

(January to June 2021)

**Carna Biosciences, Inc.**

July 2021












Stock Code: 4572

- Initiated dosing in a FIH Phase 1 study of BTK inhibitor AS-1763 in Europe. (April)
- Initiated dosing in a FIH Phase 1 study of CDC7 inhibitor AS-0141 in Japan. (June)
- Announced positive results for AS-0871 Phase 1 Single Ascending Dose study. (July)
- Completed dosing in Phase 1 Single Ascending Dose study of BTK inhibitor AS-1763. (July)
- Bought back and canceled Series 18<sup>th</sup> Subscription Rights to Shares. (July)
- Issued Series 19<sup>th</sup> Subscription Rights Shares. (July)







# Drug Discovery R&D (ddRD) Business

## <Oncology>

Compound	Target	Indication	Discovery/Preclinical	Clinical	Partner
AS-0141	CDC7/ASK	Cancer			
Small Molecule	Kinase	Immuno-Oncology			
AS-1763	BTK	Blood Cancer			
Small Molecule	ALK5	Immuno-Oncology			
Small Molecule	CDK1	Cancer			

\*Greater China only

## <Other Therapeutic Areas>

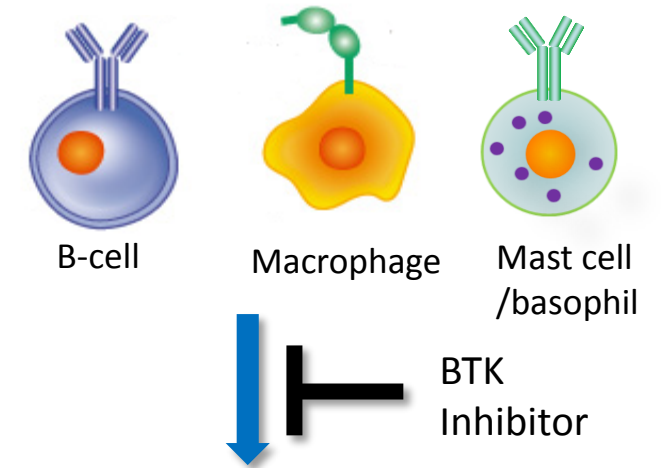
Compound	Target	Indication	Discovery/Preclinical	Clinical	Partner
Small Molecule	Kinase	Psychiatry & neurology			
AS-0871	BTK	Immune-inflammatory diseases			
Small Molecule	N/A	Malaria			
Small Molecule	STING	Immune-inflammatory diseases			

✓ We are actively pursuing early discovery programs to create next wave of pipeline.

# BTK Inhibitor Program

## Bruton's Tyrosine Kinase (BTK)

- ✓ BTK is one of the crucial kinases for the B-cell maturation and macrophage activation
- ✓ BTK has been recognized as a validated therapeutic target since the success of Ibrutinib, the first FDA approved BTK inhibitor
- ✓ The expected peak sales of Ibrutinib is > \$10 billion\*



## <Sales of BTK inhibitors in market>

Launch	Product	Company	Target	2020	2026 Est.
2013	Ibrutinib	AbbVie/J&J	Blood cancer	\$8.4B	\$10.7B*1
2017	Acalabrutinib	Astra Zeneca	Blood cancer	\$522M*2	

- In January 2019, Loxo Oncology, developing kinase inhibitors including non-covalent BTK inhibitor LOXO-305, was acquired by Eli Lilly for \$8.0 billion.
- In December 2019, ArQule, developing non-covalent BTK inhibitor ARQ 531, was acquired by Merck for \$2.7 billion.

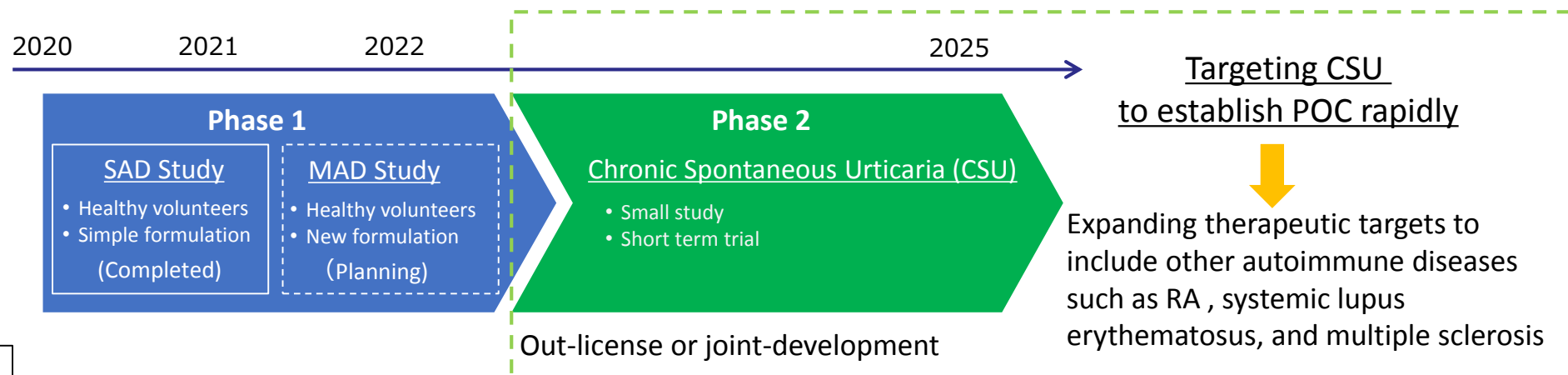


High potential of non-covalent BTK inhibitors for sizable license deals

## AS-0871 : Targeting Immune-inflammatory diseases

- Small molecule BTK inhibitor
- Non-covalent/reversible
- High kinase selectivity
- Orally available
- Demonstrated significant efficacies in arthritis models
- Showed efficacy in systemic lupus erythematosus model
- Find a partner to conduct further development after completing Phase 1 study

- ✓ Phase 1 Single Ascending Dose (SAD) study in healthy volunteers was initiated in H2 2020 in the Netherlands, finding AS-0871 was well-tolerated without any safety concerns at all dose levels.
- ✓ Multiple Ascending Dose (MAD) study using new drug formulation is planned in H2 2021.
- ✓ MAD study will include a skin prick test to see the potential of AS-0871 for the treatment of Chronic Spontaneous Urticaria (CSU), a disease with high unmet needs.
- ✓ Plan to find a partner for out-licensing or joint-development after completing the MAD study.
- ✓ Potential for autoimmune diseases in addition to CSU.



POC : Proof of Concept

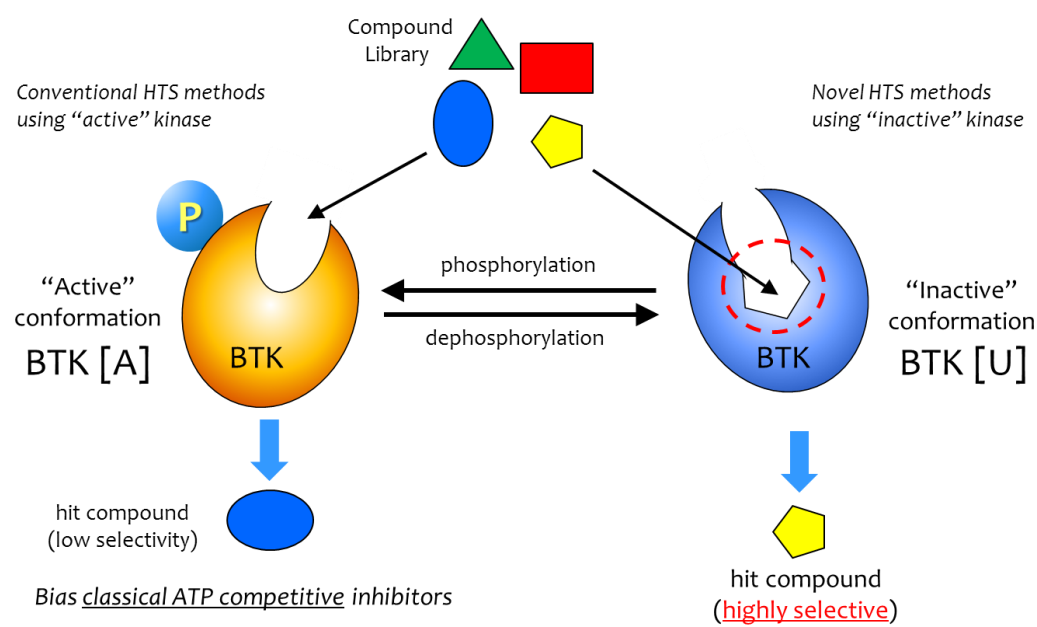
## ◆ Targeting Inactive Conformation of BTK

Contents lists available at ScienceDirect  
**Biorganic & Medicinal Chemistry Letters**  
 ELSEVIER  
 journal homepage: www.elsevier.com/locate/bmcl

Journal of  
**Medicinal Chemistry**  
 Article  
 S. Ch. The. J. Med. Chem. 2016, 41, 8917–8933  
 pubsci.elsevier.com

**TR-FRET binding assay targeting unactivated form of Bruton's tyrosine kinase**  
 Tokiko Asami<sup>a</sup>, Wataru Kawahata, Masaaki Sawa  
 Carma Biosciences, Inc., BMA 3F, 1-5-5 Minatogima-Minamimachi, Chuo-ku, Kobe 650-0047, Japan

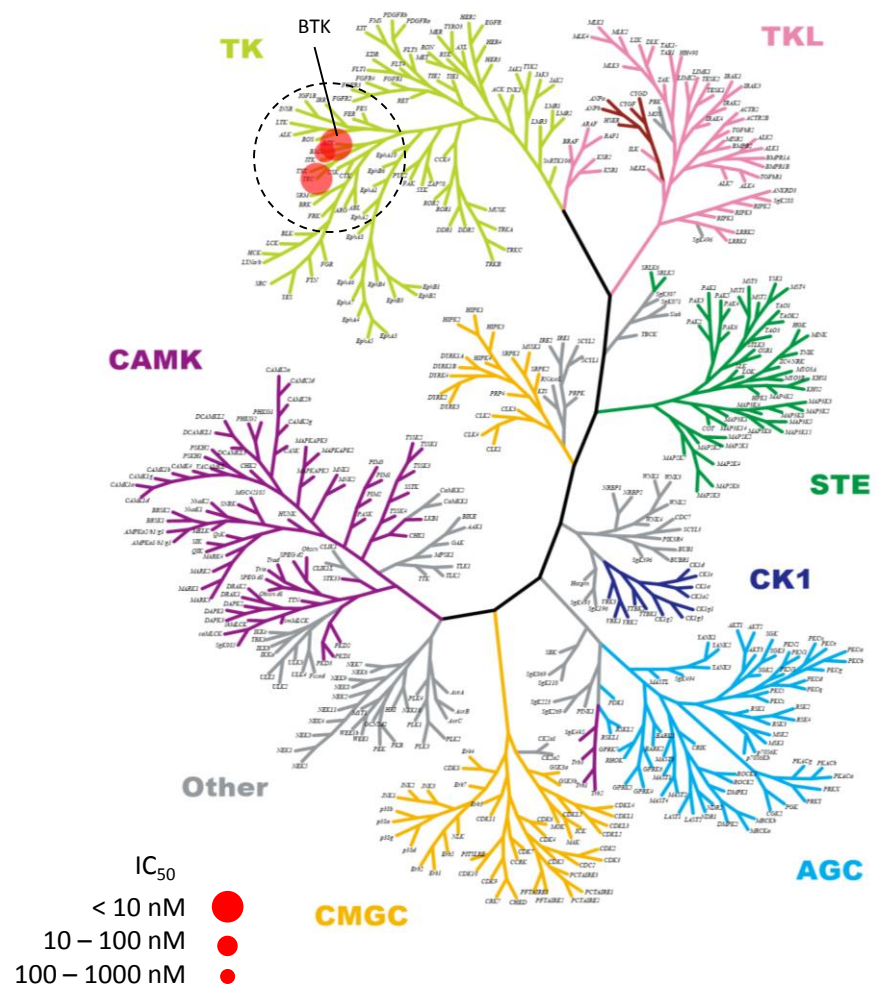
**Design and Synthesis of Novel Amino-triazine Analogues as Selective Bruton's Tyrosine Kinase Inhibitors for Treatment of Rheumatoid Arthritis**  
 Wataru Kawahata,<sup>a</sup> Tokiko Asami, Takao Kiyoi, Takayuki Irie, Haruka Taniguchi, Yuko Asamitsu, Tomoko Inoue, Takahiro Miyake, and Masaaki Sawa<sup>a</sup>  
 Research and Development, Carma Biosciences, Inc., 3rd Floor, BMA, 1-5-5 Minatogima-Minamimachi, Chuo-ku, Kobe 650-0047, Japan



	BTK IC <sub>50</sub> (nM)	
	BTK [A]	BTK [U]
AS-0871	3.4	0.3

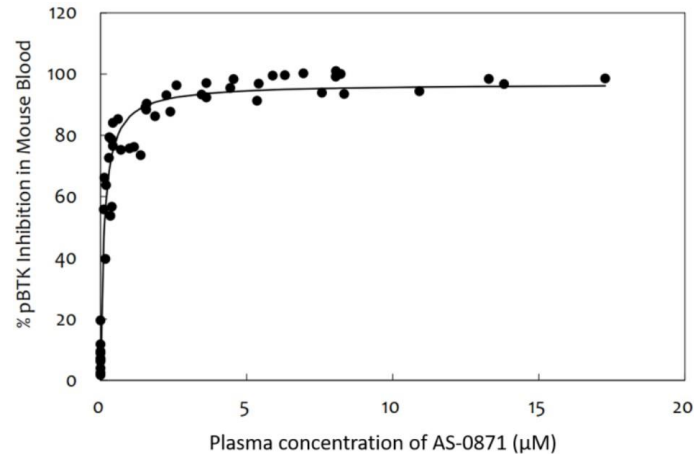
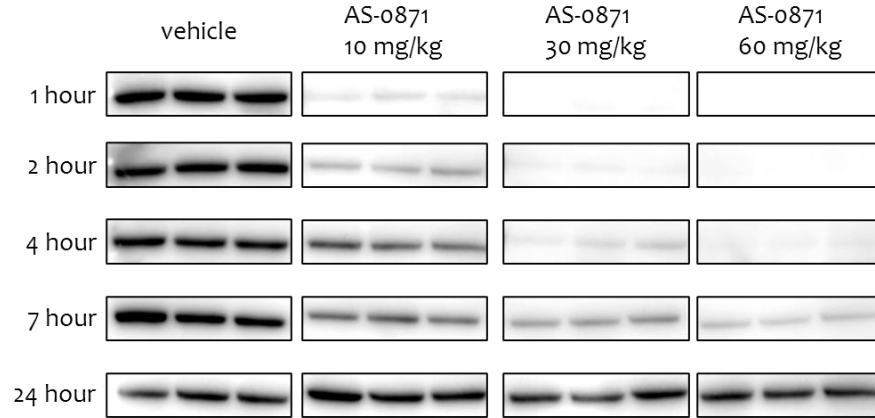
## ◆ Kinase Selectivity Profiling

Only inhibited 2 other kinases in a total of 312 kinases tested at 0.3 μM concentration.

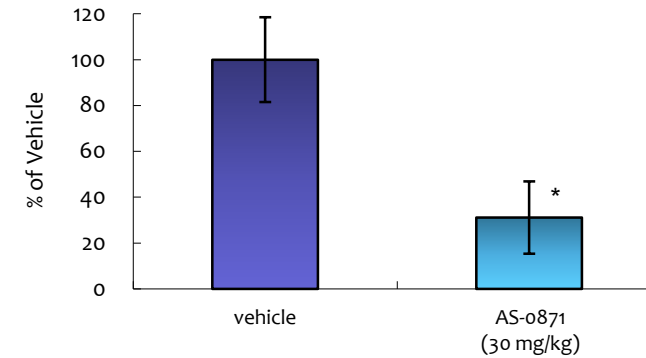


## ◆ PK/PD Study

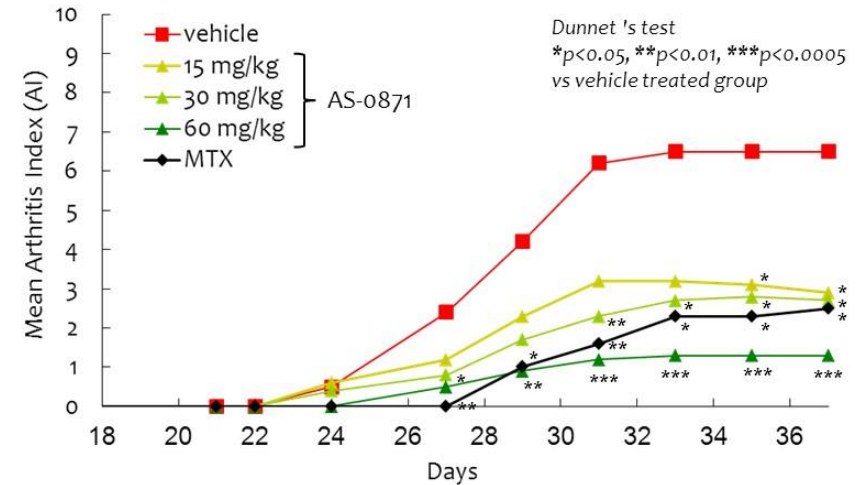
Auto-phosphorylation status of BTK was measured following oral single administration of AS-0871



## ◆ Passive cutaneous anaphylaxis (PCA) mouse model



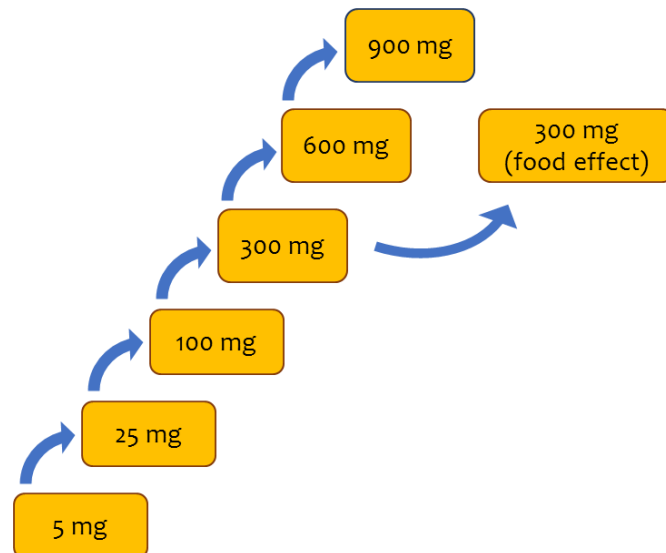
## ◆ Collagen-induced arthritis (CIA) mouse model





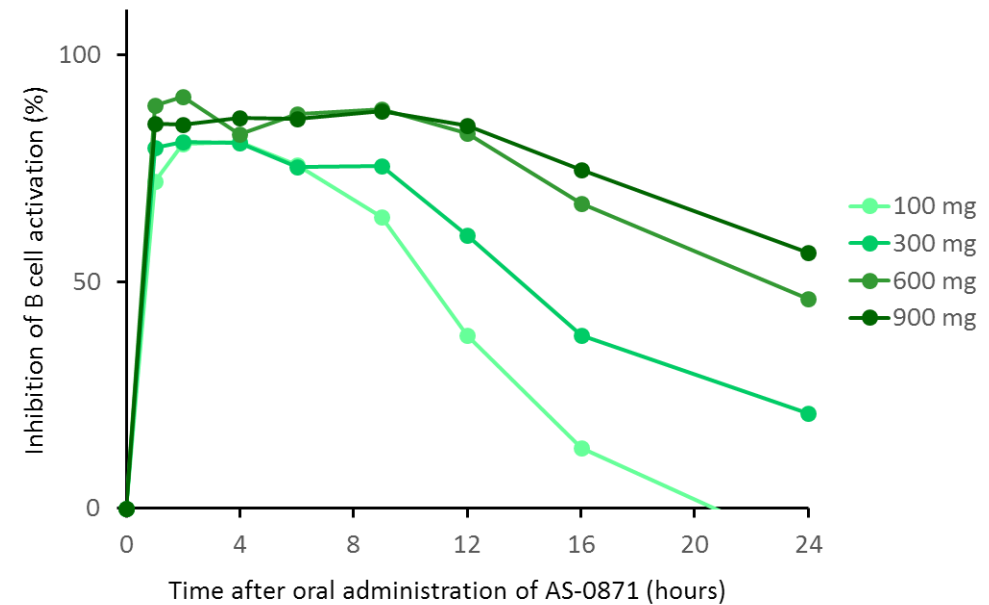
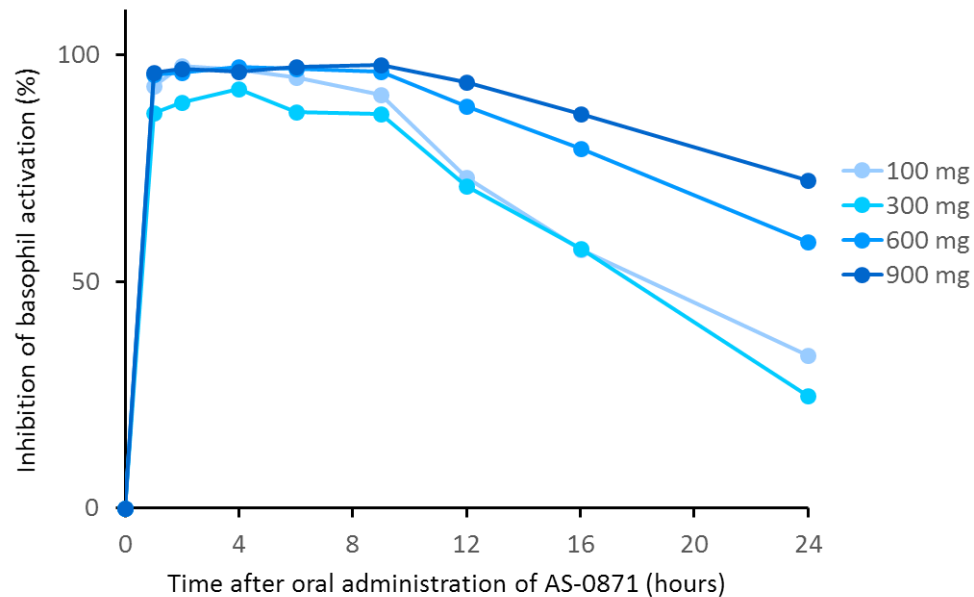
## SAD Part (Completed)

Step 1 Single Ascending Dose Study (SAD)	Step 2
<ul style="list-style-type: none"><li>• 6 dose levels (8 subjects/cohort)</li><li>• Placebo controlled (6 active / 2 placebo)</li><li>• Safety and tolerability</li><li>• Pharmacokinetics and pharmacodynamics</li></ul>	<ul style="list-style-type: none"><li>• Food effect</li></ul>



- ✓ AS-0871 is well-tolerated without any safety concerns.
- ✓ Favorable pharmacokinetic profile.
- ✓ Blood samples to assess PD effects were analyzed for evaluation of the B-cell and basophil responses. Administration of AS-0871 at 100mg or above resulted in strong inhibition of B-cell and basophil activation.
- ✓ Dose selection for the MAD study will be based on the results obtained from the completed SAD study.
- ✓ Switching to a new formulation in the MAD study.

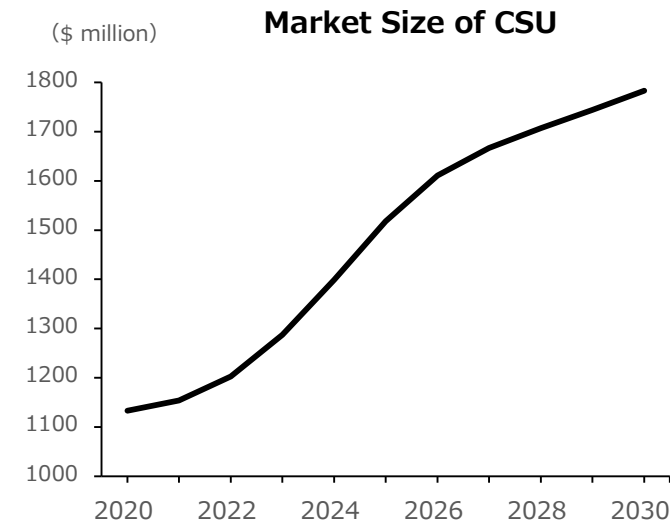
- ✓ Pharmacodynamic study demonstrated that subjects who received AS-0871 showed dose proportional inhibitions in basophil and B-cell activations, and significant and sustained inhibitory effects were observed at 100 mg and above.
- ✓ Oral administration of AS-0871 achieved therapeutic plasma levels needed to inhibit B cells and basophils activation, suggesting that AS-0871 has a potential to become a new treatment option for inflammatory diseases.



- ◆ Fenebrutinib is the only non-covalent BTK inhibitor under development targeting autoimmune diseases.
- ◆ No non-covalent BTK inhibitors under development targeting Chronic Spontaneous Urticaria.

Compound	Company	Development Phase
Fenebrutinib (GDC-0853)	Roche / Genentech	P3 Multiple Sclerosis

- ✓ Chronic Spontaneous Urticaria (CSU) is one of most frequent skin diseases with unmet medical needs since curative treatment is not available.
- ✓ CSU is a distressing skin disorder that characterized by itching and hives lasting for more than 6 weeks, which has major detrimental effects on quality of life with sleep deprivation and other conditions.
- ✓ An underlying cause is rarely detected and symptoms can be exacerbated by infectious diseases or stress.
- ✓ The lack of efficacy of approved standard therapy (antihistamines) in many patients is another major problems.
- ✓ Omalizumab, humanized anti-IgE anti IgE antibodies, has been approved as the third-line therapy, but the drug is very expensive (\$1874 per 4 weeks on average).
- ✓ The market size of CSU in 2020 was estimated as \$1,133 million in major seven countries. The market size excluding antihistamines was \$1,062 million.
- ✓ The market size of CSU is expected to become \$1,783 million in 2030 with launch of several humanized anti-IgE anti IgE antibodies competing with omalizumab.
- ✓ There are no approved BTK inhibitors targeting CSU.



Source: DelevelInsight

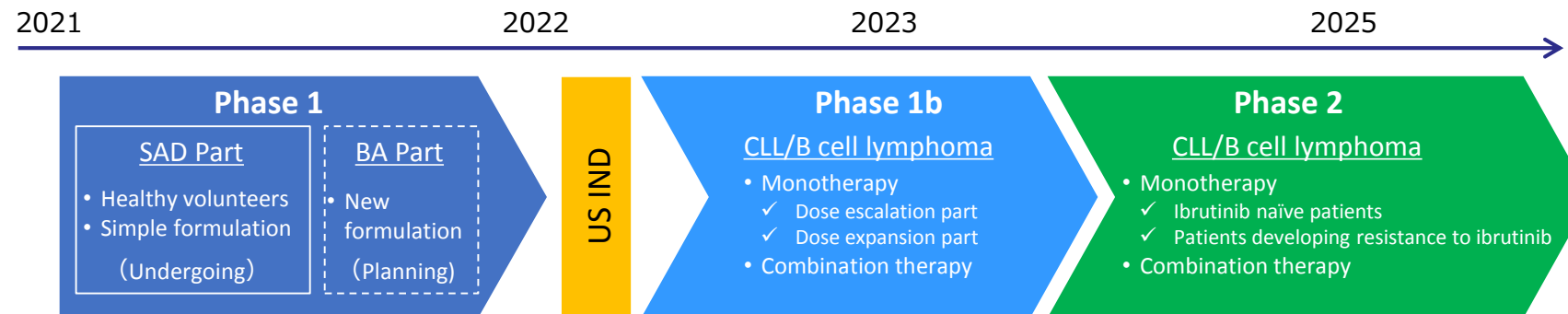
\*1 Market size of CSU is estimated by DelevelInsight.

\*2 Major seven countries include US, Germany, France, Italy, Spain and Japan.

## AS-1763 : Targeting Blood Cancer

- Small molecule BTK inhibitor
- Non-covalent/reversible
- High kinase selectivity
- Inhibits both BTK wild type and ibrutinib resistant BTK C481S mutants
- Orally available
- Displayed strong anti-tumor effects in lymphoma model with both wild type and C481S mutant BTK
- Displayed efficacy in immuno-oncology model
- Potential applications for autoimmune diseases
- Plan to accelerate the clinical studies utilizing the clinical data of BioNova, the licensee in Greater China

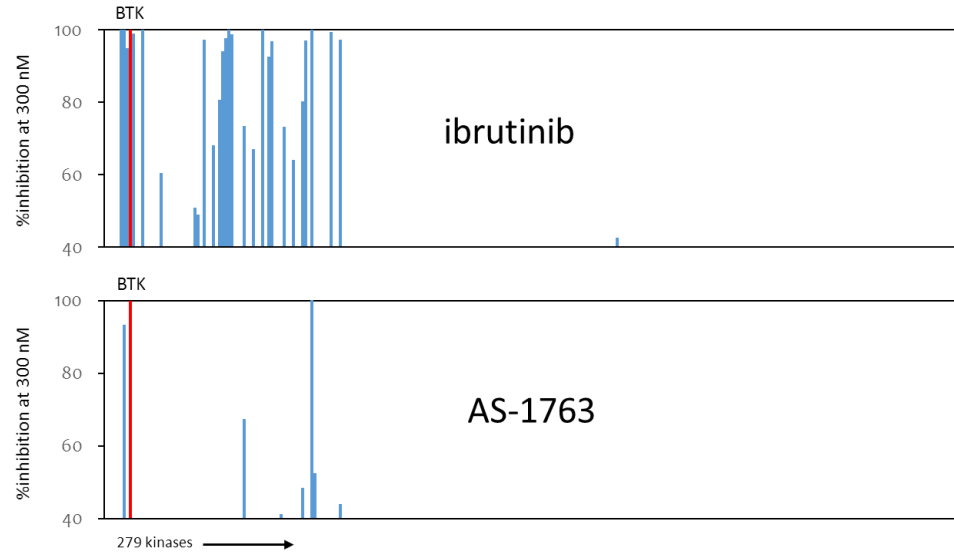
- ✓ Phase 1 single ascending dose (SAD) study in healthy volunteers was initiated in the Netherlands in April 2021. Dosing in the SAD part has been completed.
- ✓ Plan to initiate Phase 1b study in patients with chronic lymphocytic leukemia (CLL)/B cell lymphoma in the U.S. after the completion of the SAD study.
- ✓ Aim to conduct clinical studies efficiently, collaborating with BioNova.



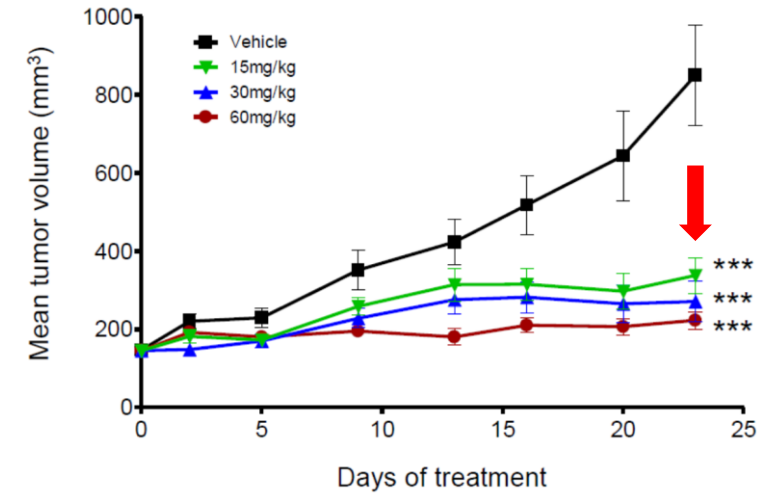
BA: Bioavailability  
IND: Initial New Drug application

# AS-1763: Strong Efficacy against C481S BTK mutant

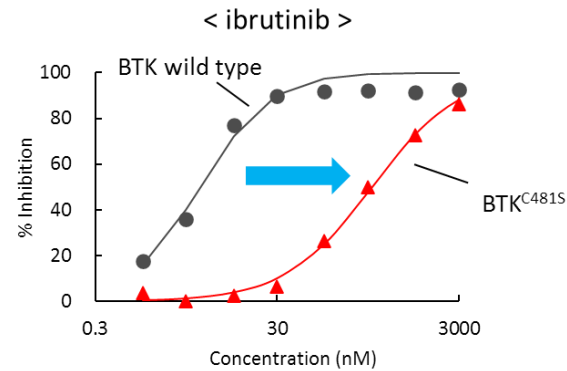
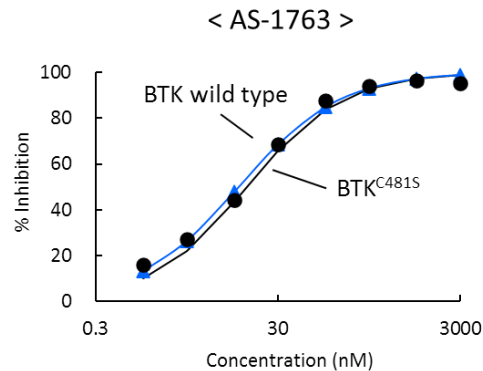
## ◆ High kinase selectivity



## ◆ AS-1763 significantly inhibits tumor growth in a B-cell lymphoma mouse model



## ◆ AS-1763 inhibits both WT and C481S mutant BTK enzymes



- First generation covalent BTK inhibitors
  - ✓ First generation covalent BTK inhibitors including ibrutinib are key therapeutic options for patients with B cell malignancies including chronic lymphocytic leukemia (CLL).
  - ✓ Sales of the first generation BTK inhibitors, ibrutinib, acalabrutinib, and zanubrutinib, totaled over \$9 billion in 2020. Sales of ibrutinib is expected to be over \$10 billion according to an estimate by Evaluate Pharma.
  - ✓ However, patients are reported to develop resistance during the treatment as more first generation BTK inhibitors are prescribed.

<Sales of first generation BTK inhibitors>

(\$million)	Development/ Marketing	2019	2020	2026Est.
Ibrutinib	AbbVie + J&J	7,291	8,433	10,722
Acalabrutinib	AstraZeneca	164	522	n.a.
Zanubrutinib	BeiGene	1	41	n.a.

Source: Financial report of the companies for historical data. Estimate for 2026 is based on EvaluatePharma.

- A high unmet medical need for new therapeutic approaches to overcome the BTK C481S-mediated resistance
- ✓ Patients treated with ibrutinib are reported to develop resistance during the treatment due to substitution of cysteine residue at 481 position with serine (C481S mutation) in BTK, which prevents the covalent binding of the first generation irreversible BTK inhibitors.
- ✓ AS-1763 significantly abrogates cell proliferation in both wild type and C481S mutant BTK lymphoma cells, strongly suggesting that AS-1763 will be a new therapeutic option for treating patients with B cell malignancies both having wild type and C481S mutation in BTK.
- ✓ Inhibitors for BTK C481S-mediated resistance have not been launched, therefore there is a high unmet medical need for new therapeutic options.
- ✓ Two non-covalent BTK inhibitors to treat patients with BTK C481S mutation are currently under development. ArQule and Loxo that originally developed the programs were acquired by big pharma.

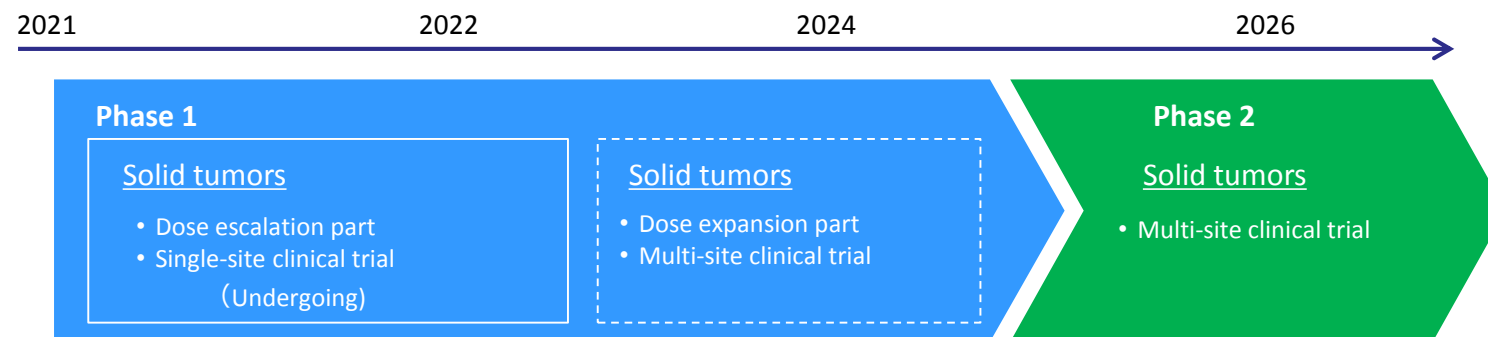
Compound	Company	Development Phase
ARQ531	Merck (ArQule)	P2
LOXO-305	Loxo / Lilly	P3



## AS-0141 : Targeting Cancer

- Small molecule CDC7 inhibitor
- High kinase selectivity
- Potential First-in-class drug
- Orally available
- Potent anti-proliferative activity against various cancer cell lines
- Demonstrated strong anti-tumor activity in several human tumor xenograft models
- Conducting Phase 1 study in Japan targeting solid tumors.

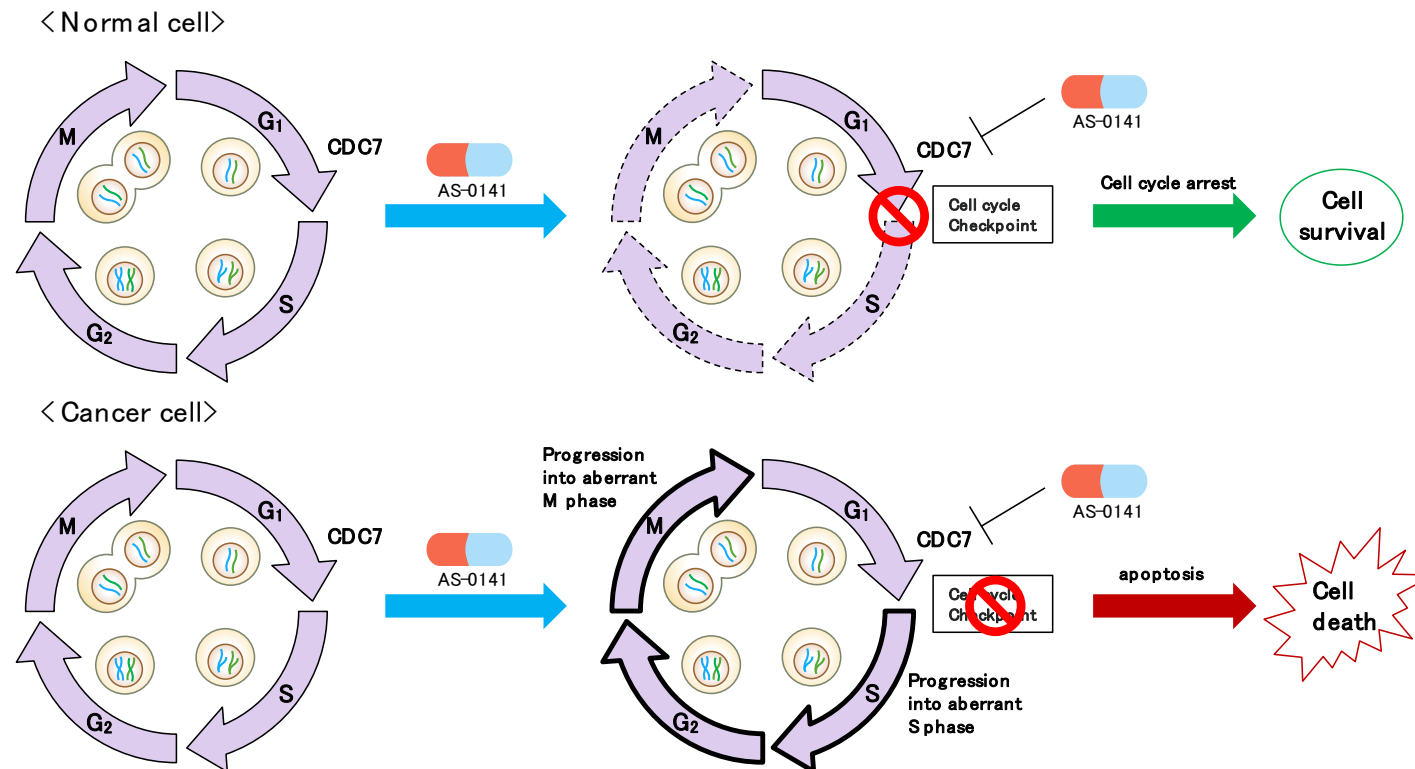
- ✓ In H1 2021, Carna initiated Phase 1 study in Japan in patients with unresectable, advanced, recurrent, or metastatic solid tumors.
- ✓ The study consists of two parts, a dose escalation and an expansion.
- ✓ The Phase 1 clinical study of AS-0141 is designed to assess the safety and tolerability of AS-0141 in advanced solid tumors, as well as to identify the recommended Phase 2 dose.



# AS-0141: Highly Selective CDC7 Inhibitor

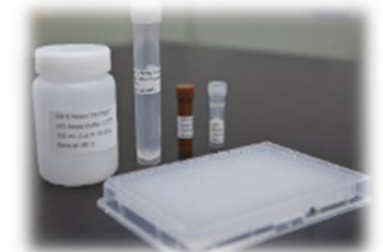
## ■ CDC7 kinase inhibitor

CDC7 (cell division cycle 7) is a serine-threonine kinase that plays a critical role in DNA synthesis and is required for the activation of DNA replication origins throughout the S phase of the cell cycle. Inhibition of CDC7 in cancer cells causes lethal S phase or M phase progression, whereas normal cells survive, most likely through induction of cell cycle arrest at the DNA replication checkpoint. It has been reported in the literature that CDC7 is overexpressed in many cancers. Therefore, CDC7 is an attractive target for cancer drug development.



# Drug Discovery Support (ddSP) Business

- Sales at the Drug Discovery Support business in Q2 was JPY430 million, down 18.4% yoy.
  - ✓ In North America, sales to Gilead contributed.
  - ✓ In Japan, profiling service and agent business (cell-based assay and X-ray crystallography) were weaker than expected in Q2.
- Robust start for the new service
  - ✓ Launched a full-panel assay service (192 kinds of kinases) for cell-based assay service using NanoBRET™ technology developed by Promega.
- Expanding lineup of kinase proteins and profiling service
  - ✓ 6 products, including high-demand mutant kinase biotinylated kinases, have been newly added to the line-up and 4 EGFR mutant targets were added to the profiling service.
  - ✓ Proposing project-based service to collaborate with clients, leveraging Carna's drug discovery technology.



# FY2021 Q2 Results

# FY2021 Q2 Consolidated Financial Results



(JPY million)	FY2020 Q2 Actual	FY2021 Q2 Actual	YoY Change	FY2021 Plan	
Sales	579	<b>430</b>	-149 -25.8%	923	-In line with the FY sales plan. -Received an upfront payment from licensing in Q1 FY2020.
Operating Profit/Loss	(375)	<b>(777)</b>	-402	(1,811)	
Ordinary Profit/Loss	(380)	<b>(774)</b>	-393	(1,816)	
Net Profit/Loss	(397)	<b>(776)</b>	-378	(1,825)	
R&D Cost	615	<b>877</b>	+262 +42.6%	1,981	-Investment in clinical studies.

Note 1: Rounded down to the nearest million yen.

Note 2: YoY change % for Operating Profit/Loss, Ordinary Profit/Loss, and Net Profit/Loss are not presented since losses were recorded.

Note 3: FY2021 plan was disclosed on February 12, 2021.

# FY2021 Q2 Results by Business Segment



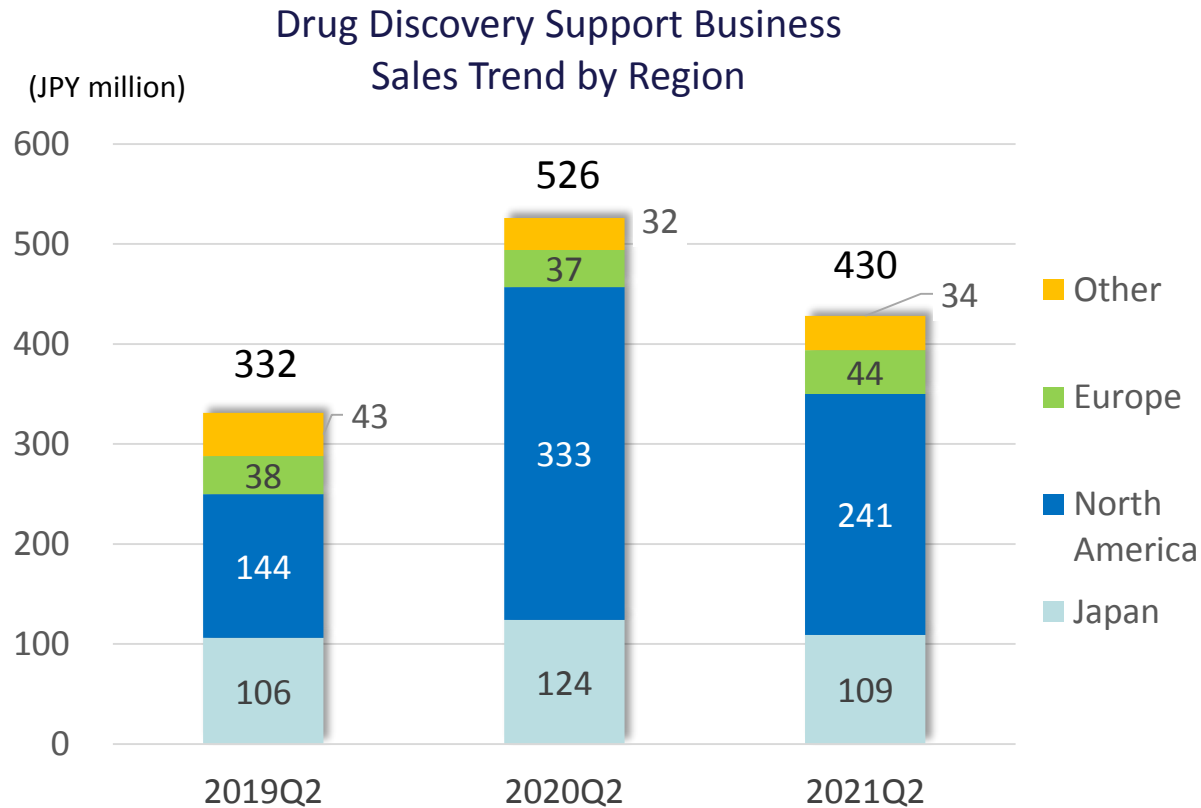
(JPY million)	FY2020 Q2 Actual	FY2021 Q2 Actual	YoY Change	FY2021 Plan	vs. FY Plan	
Total Sales	579	<b>430</b>	-149 -25.8%	923	46.6%	
ddSP business	526	<b>430</b>	-96 -18.4%	923	46.6%	In line with the FY sales plan.
ddRD business	53	—	-53	—	—	Received an upfront payment from licensing in Q1 2020.
Total Operating Profit/Loss	(375)	<b>(777)</b>	-402	(1,811)	—	
ddSP business	237	<b>145</b>	-92 -39.0%	207	69.7%	On track vs. FY plan.
ddRD business	(613)	<b>(922)</b>	-309	(2,019)	—	Investment in clinical studies.

Note 1: Rounded down to the nearest million yen.

Note 2: YoY change % for consolidated operating profit/loss and ddRD operating profit/loss are not presented since losses were recorded.

Note 3: FY2021 plan was disclosed on February 12, 2021.

Note 4: ddRD: Drug Discovery R&D business, ddSP: Drug Discovery Support Business



- **Japan:** Decreased 12.4% YoY  
Sales of kinase proteins were robust. Profiling service and agent business (cell-based assay service and X-ray crystallography) were weak.
- **North America:** Decreased 27.4% YoY  
Sales decreased compared to an upbeat sales in Q2 FY2020, but on track vs. plan. Sales to Gilead contributed.
- **Europe:** Increased 20.5% YoY  
Kinase proteins, profiling service and NanoBRET assay service were robust.
- **Other:** Increased 7.0% YoY  
Sales in China continued show a recovery.

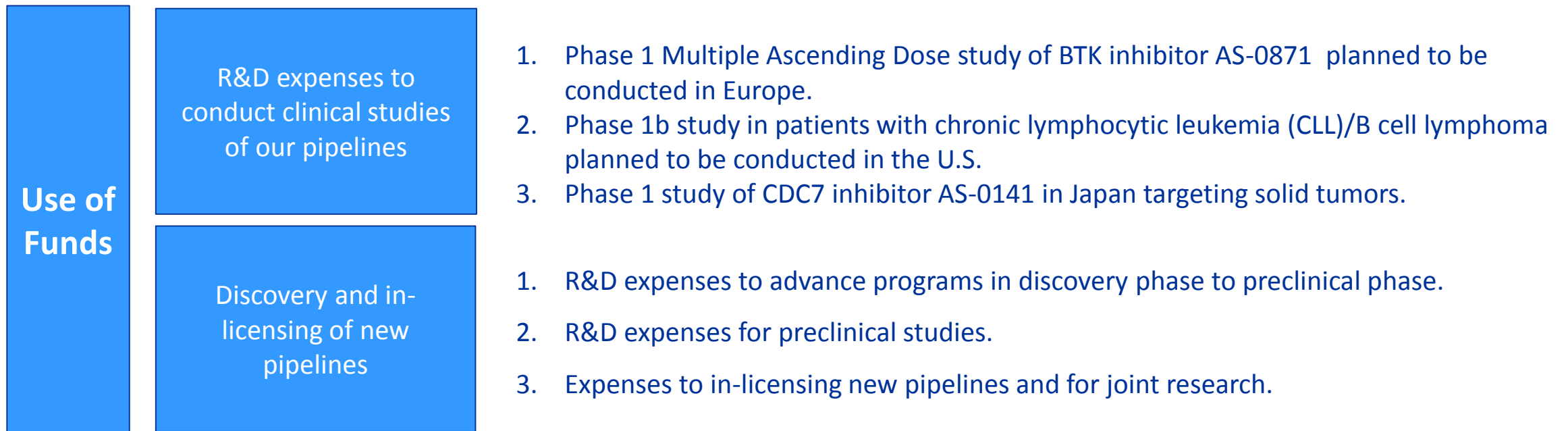
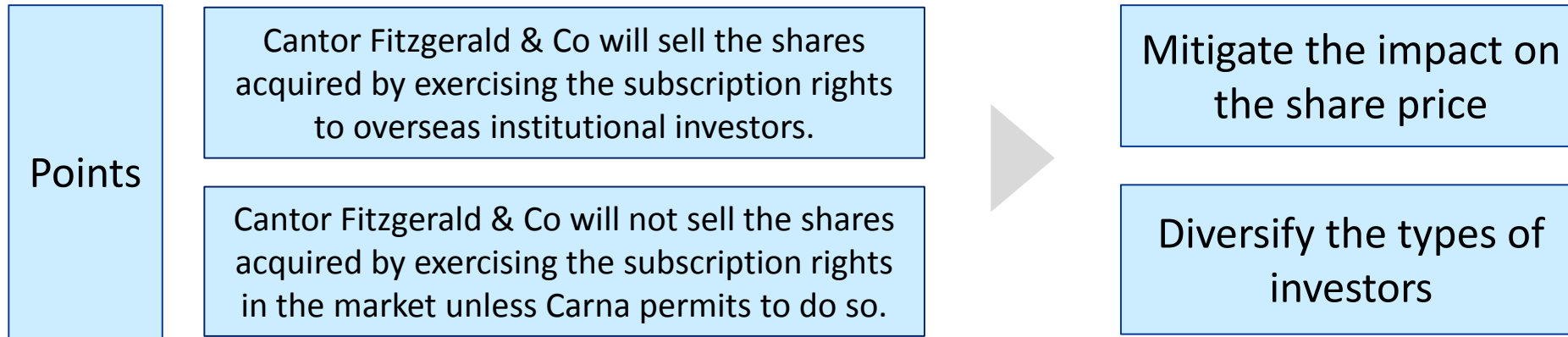


# Balance Sheet

(JPY million)	As of Dec. 31, 2020	As of Jun. 30, 2021	Change	Reason for changes
Current assets	4,708	3,522	-1,185	
Cash and deposits	4,299	3,213	-1,086	
Non-current Assets	127	140	+13	
Total assets	4,835	3,662	-1,172	
Current liabilities	727	370	-356	
Non-current liabilities	284	195	-89	Long term loans payable -70 Bonds payable -14
Total liabilities	1,011	565	-445	
Total net assets	3,824	3,096	-727	Retained earnings -776
Total liabilities and net assets	4,835	3,662	-1,172	

Shareholders' equity ratio	79.0%	84.5%
BPS	308.0 yen	248.8 yen
PBR	3.9x	5.5x
Share price of Carna	1,212 yen	1,367 yen

Note: Share price is the closing price of the term end.



# Appendix

(JPY million)	FY2020 Actual	FY2021 Plan	Outlook for 2022 - 2025
Total Sales	1,133	<b>923</b>	
ddSP business	1,080	<b>923</b>	Maintain stable sales.
ddRD business	53	-	Revenue from milestone payments and upfront payments.
Total Operating Loss	(1,057)	<b>(1,811)</b>	
ddSP business	458	<b>207</b>	Maintain stable profit while investing in product developments.
ddRD business	(1,515)	<b>(2,019)</b>	Continue to invest in R&D. Deliver profits depending on the size of milestone payments and upfront payments.
Ordinary Loss	(1,077)	<b>(1,816)</b>	
Net Loss	(1,111)	<b>(1,825)</b>	

(JPY million)	FY2020 Actual	FY2021 Plan	Outlook for 2022 – 2025
R&D Cost	1,474	<b>1,981</b>	Invest in R&D (JPY1 bn to 2.5 bn) for the future growth.
Capex	68	<b>21</b>	Invest in equipment for R&D and IT system (JPY20 mn to 100 mn.)

\* Business plan for FY2021 does not include milestone payments and upfront payments related to license agreements as the timing or the amounts are difficult to predict. Numerical targets for 2022-2025 are not disclosed for the same reason.

ddRD: Drug Discovery R&D business  
ddSP: Drug Discovery Support Business

# Key Milestones



Business		Milestones		
		2020	2021	2022 and after
ddRD	AS-0871	✓ Initiate Ph1 (Achieved in Aug. 2020)	❑ Initiate Ph1 MAD study (H2 2021)	❑ Start partnering activity (2022)
	AS-1763	✓ IND submission (CTA submitted in Jan. 2021)	✓ Initiate Ph1 (Achieved in Apr. 2021)	❑ Initiate Ph1b (2022)
	AS-0141		✓ Initiate Ph1 (Achieved in Jun. 2021)	❑ Initiate Ph1 expansion part (2022)
	Research program	❑ Bring one or more programs in preclinical stage	❑ Bring one or more programs in preclinical stage	
ddSP		<ul style="list-style-type: none"> <li>✓ Achieve sales target of JPY1,030 mn (Sales of JPY1,080 mn achieved)</li> <li>✓ Launch new products (27 new products launched)</li> <li>✓ Expand NanoBRET service (Sales more than doubled)</li> </ul>	<ul style="list-style-type: none"> <li>❑ Achieve sales target of JPY920 mn</li> <li>❑ Launch new products</li> <li>❑ Expand NanoBRET service</li> <li>❑ Propose project-based service to collaborate with clients, leveraging Carna's drug discovery technology.</li> </ul>	<ul style="list-style-type: none"> <li>❑ Expand kinase protein offering further</li> <li>❑ Grow assay services by adding targets</li> </ul>

ddRD: Drug Discovery R&D business  
 ddSP: Drug Discovery Support Business  
 IND: Initial New Drug application in the U.S.  
 CTA: Clinical Trial Application in Europe

✓ Achieved  
 ❑ Plan or to be achieved

➤ *Advance clinical trials of our innovative pipelines to maximize corporate value*

Started internal drug discovery activity	Demonstrated strong capabilities in drug discovery	Maximize the value of pipelines	Continue delivering profits
2010-2015	2016-2020	2021-2025 (Plan)	2026-2030 (Plan)
<ul style="list-style-type: none"> <li>Established in-house research capability</li> <li>Established pipeline</li> </ul>	<ul style="list-style-type: none"> <li>Out-licensed multiple programs</li> <li>Initiated clinical trials</li> </ul>	<ul style="list-style-type: none"> <li>Advance clinical trials of AS-0871, AS-1763, and AS-0141</li> <li>Milestone payments from the out-licensed programs and deliver profits</li> <li>Initiate pre-clinical and clinical studies of new pipelines</li> </ul>	<ul style="list-style-type: none"> <li>Milestone payments and royalty income from the out-licensed programs and expand profits</li> <li>Potential revenue from new license deals</li> <li>Initiate pre-clinical and clinical studies of new pipelines</li> </ul>



<ddRD>

- ✓ Advance clinical trials of AS-0871, AS-1763, and AS-0141
- ✓ Create next wave of pipeline
- ✓ Milestone payments and royalty income from out-licensed programs



<ddSP>

- Expand sales of in-house developed products and services in North America and Asia
- Sustainable sales growth by launching new products and services and reaching new customers
- Generate cash to invest in ddRD

ddRD: Drug Discovery R&D business  
ddSP: Drug Discovery Support Business

# Potential Revenue from Out-licensed Programs



- Carna is in license agreements with the pharmaceutical companies listed below and eligible to receive milestone payments upon achievement of certain development and commercial milestones. Carna will also receive royalties on future net sales.

## < License/joint research agreements with pharmaceutical companies >

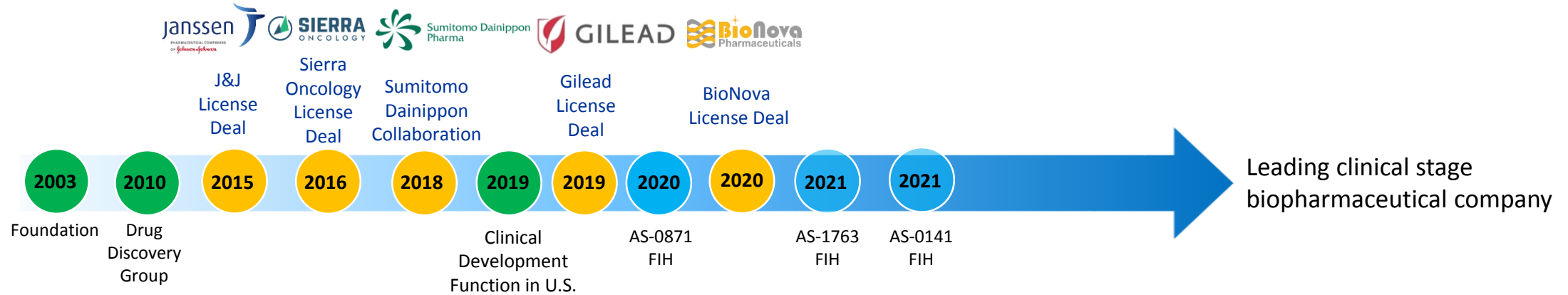
Partner	Compound (Target)	Upfront payment	Total milestone payments expected	Royalty	Region	Contract date
Sumitomo Dainippon Pharma (Joint research)	Kinase inhibitor (Psychiatric and neurological disorders)	JPY80M (including research milestone)	JPY10.6B	Undisclosed	Worldwide	Mar. 2018
Gilead Sciences (Out-license)	Kinase inhibitor (Immuno- oncology)	\$20M	\$450M	Undisclosed	Worldwide	Jun. 2019
BioNova Pharmaceuticals (Out-license)	AS-1763	Undisclosed	\$205M	Up to two digits %	Greater China	Mar. 2020

\* The amount and timing of milestone payments as well as royalty rates are not disclosed due to the agreements with the partners.

# Building Long-Term Value



*Our goal is to deliver innovative therapies for patients suffering from serious diseases*



2003 - 2020	2021 Plan	Long term plan
<ul style="list-style-type: none"> <li>● Founding members who had expertise in kinase drug discovery technology spun out from Nippon Organon and established Carna.</li> <li>● Started offering kinase proteins and screening services to pharmaceutical companies for kinase inhibitor drug discovery.</li> <li>● In 2010, Drug Discovery Group was established to conduct internal drug discovery.</li> <li>● Entered into four license agreements and one joint-development agreement with pharmaceutical companies.</li> <li>● Initiated FIH study of BTK inhibitor AS-0871.</li> </ul>	<ul style="list-style-type: none"> <li>● Conducting Phase 1 studies of BTK inhibitor AS-0871, AS-1763, and CDC7 inhibitor AS-0141.</li> <li>● Strengthening global clinical development capability.</li> <li>● Advance research programs and initiate preclinical development</li> </ul>	<ul style="list-style-type: none"> <li>● Advance clinical studies of AS-0871, AS-1763, and AS-0141 and earn upfront payments and milestone payments from out-licensing the pipelines.</li> <li>● Receive milestone payments and royalties from licensees and strengthen financial position.</li> <li>● Create next wave of pipeline.</li> </ul>

FIH: First in Human





“Carna” is a goddess of Roman mythology who takes care of human health, protecting the human heart and other organs as well as everyday life, and is said to be the root for the word “cardiac.”

The word “biosciences” is derived from the words 'biology' and 'life sciences.'

Carna Biosciences has created contemporary Carna goddess with protein kinase.

## Carna Biosciences, Inc.

Corporate Planning

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Investors should aware that the actual performance of the company could be materially different from our current forecasts.

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