# Kyowa Kirin R&D Day

December 10, 2020

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Kyowa Kirin Co., Ltd.

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# Agenda

- Introduction
- Topics
  - Projects aiming to launch products within 10-20 years

    Axcelead / InveniAI
  - Projects aiming to launch products within 10 years

    Drug discovery using bispecific antibody technology developed in-house / Collaboration-leveraged drug discovery
  - Projects aiming to launch products within several years

    ME-401 / KHK7791 / RTA 402
- Summary
- Q&A Session

# Initiatives for expanding the opportunities to create value unique to Kyowa Kirin

- **Initiatives and innovation through internal activities + collaborations**
  - Axcelead, InveniAI, SBI Biotech
  - Next generation antibody technology, Nucleic acid therapeutics, Small molecule drug discovery, Regenerative medicine
- **Foster next generation product candidates (global products, etc.)**
  - KHK4083, KW-6356, ME-401, RTA 402, KHK7791…

## Technology strategy

**Utilize next generation antibody technology and diverse modalities to build a platform that will support revolutionary new pharmaceuticals**

## Disease strategy

**Utilize the accumulated knowledge and technology to change the lives of patients by providing unique value for UMN**

# Projects aiming to launch products within 10-20 years

# Development of revolutionary small molecule drug discovery technology (collaboration with Axcelead)

## Kyowa Kirin

- ✓ **Analysis of potential target drugs**
  - Screening technology that imitates the pathology, and molecule design technology
- ✓ **Diverse drug discovery modality research**
  - Fusion with biopharmaceutical research
- ✓ **R&D experience in the priority categories**
  - Appropriately grasp the treatment needs

## Axcelead Drug Discovery Partners

- ✓ **Small molecule drug discovery infrastructure**
  - Leading capability in Japan
- ✓ **Vast experience in drug discovery**
  - Diverse expertise and know-how
- ✓ **Huge volume of drug discovery data**
  - Huge volume of data and analytical capabilities that enable efficient drug discovery

**Strengthen technology-driven drug discovery and strive to create innovative new pharmaceuticals**

# Promotion of data driven drug discovery (collaboration with InveniAI)

- **InveniAI:**
  - Possesses drug discovery technology that uses AI and machine learning and has experience working with multiple pharmaceutical companies
  - Started collaborating with InveniAI in 2018 aimed at maximizing the value of Kyowa Kirin's assets
- **Expand the collaboration with InveniAI, and initiate efforts to identify new indications and potential target drugs suited to the next generation antibody technology independently developed by Kyowa Kirin**


Diverse drug discovery modality research centered on antibody technology


Drug discovery technology that utilizes AI and machine learning

## Utilize the strengths of each company, and accelerate "data driven drug discovery" based on data science

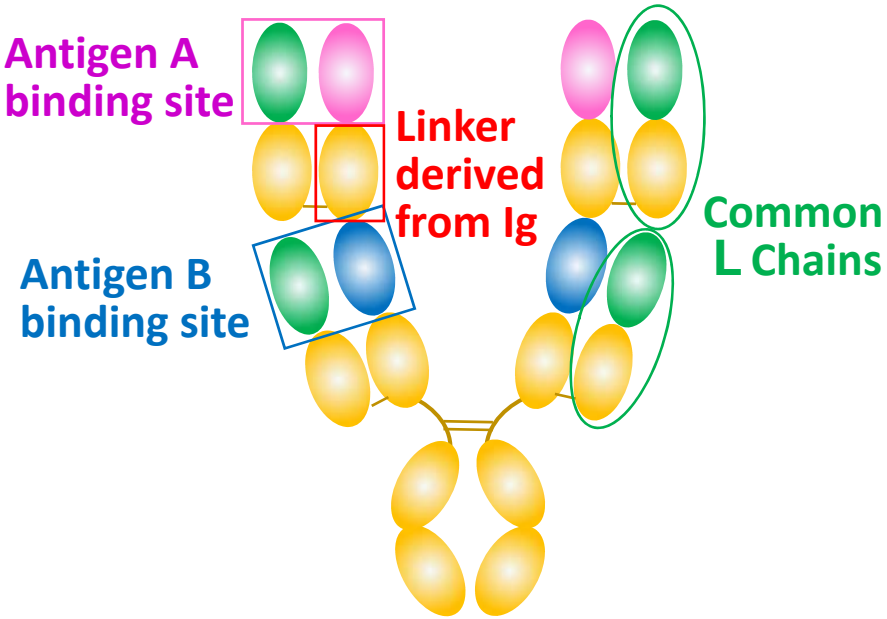
# Projects aiming to launch products within 10 years

# Drug discovery using in-house developed bispecific antibody technology

# In-House Development of Bispecific-Antibody Technology

**Key points**

- Apply Kyowa Kirin's unique bispecific-antibody technology for new therapeutic antibodies
- Pursue the development of "first in class" drugs by blending technology with biology




**An Example of Kyowa Kirin's unique bispecific-antibody technology**

- **Selection of linkers derived from Immunoglobulin (Ig) and the common sequence of L Chains**
  - Committed to the native sequences*
  - Application of human antibody producing animals*
- **Versatility equivalent to wild type IgG**
  - High productivity
  - High stability
  - Low antigenicity
- **Unique biology based on bivalent x bivalent binding**

* Kyowa Kirin's commitment to the native sequences derived from the research for POTELLIGENT®, COMPLEGENT®, and human antibody producing animals

# Flagship Project

**Ideas Based on Research in Biology** × **Unique Bispecific-Antibody Technologies** = **'First-in-Class' Drugs That Combine Efficacy and Safety**

If targeted by conventional antibodies…

**Safety Issues**

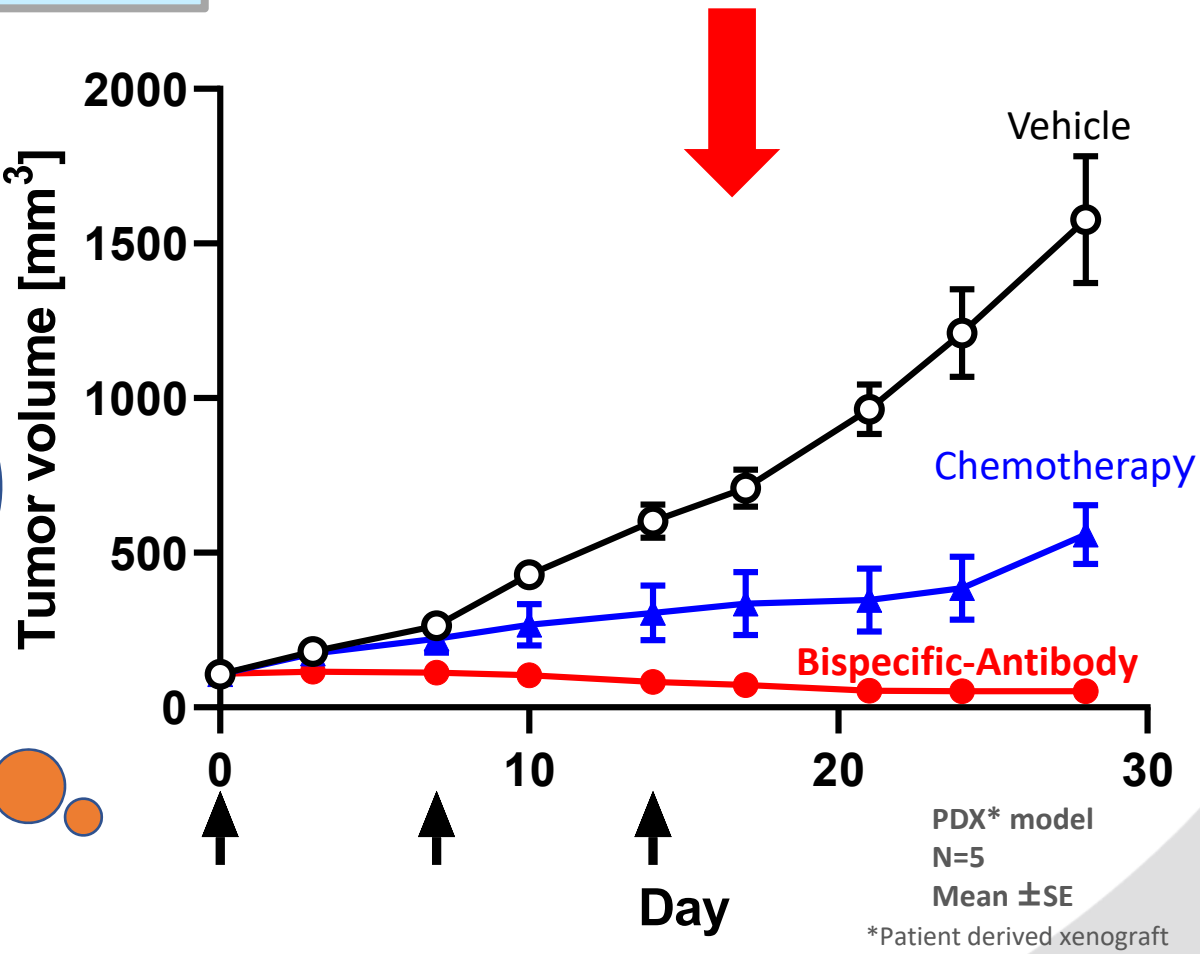
**Issues related to the limitations of conventional modalities**

- Ideal efficacy, if the issue of systemic side effects (safety) is resolved.
- Ideal efficacy, if there is tissue selectivity.
- Ideal pharmacological function, if there is cell selectivity.

# Flagship Project

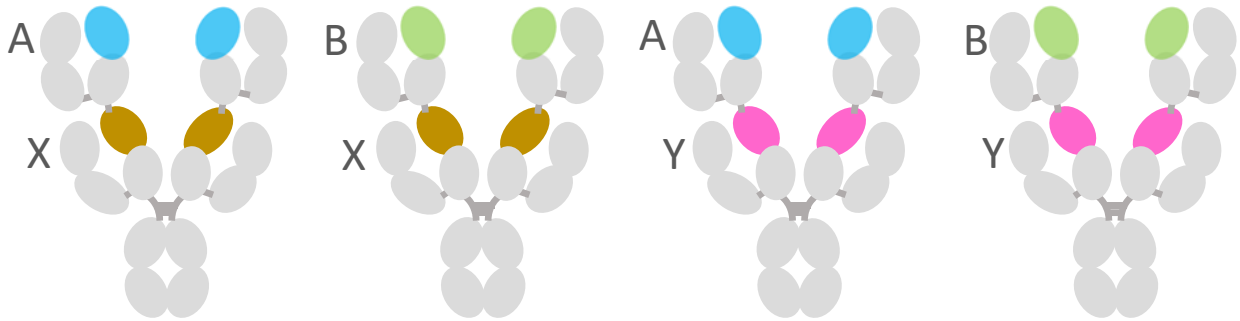
Ideas Based on Research in Biology × Unique Bispecific-Antibody Technology = 'First-in-Class' Drugs That Combine Efficacy and Safety

Realizing Ideal Efficacy with Safety Through Bispecific-Antibody Technologies

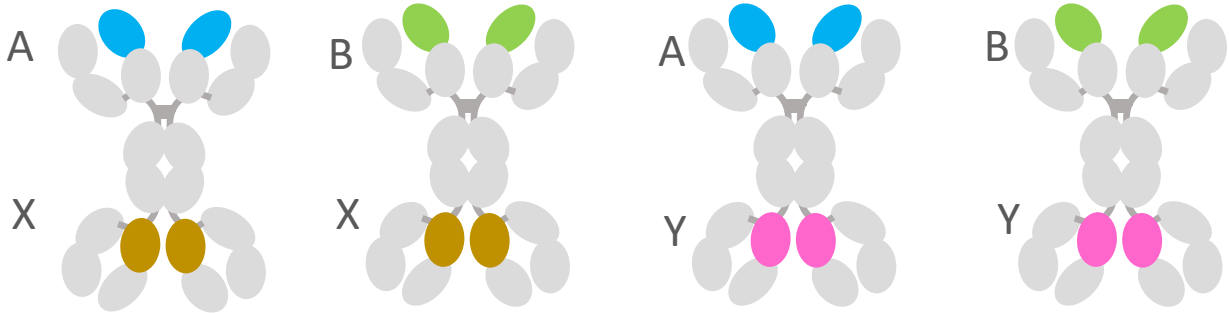


# Expansion of the Bispecific-Antibody Project

Type I




Type II




**Combinations of the targets**
(A,B… ) x (X, Y…)

×

**Selection of the types**
(Type I, II)

=

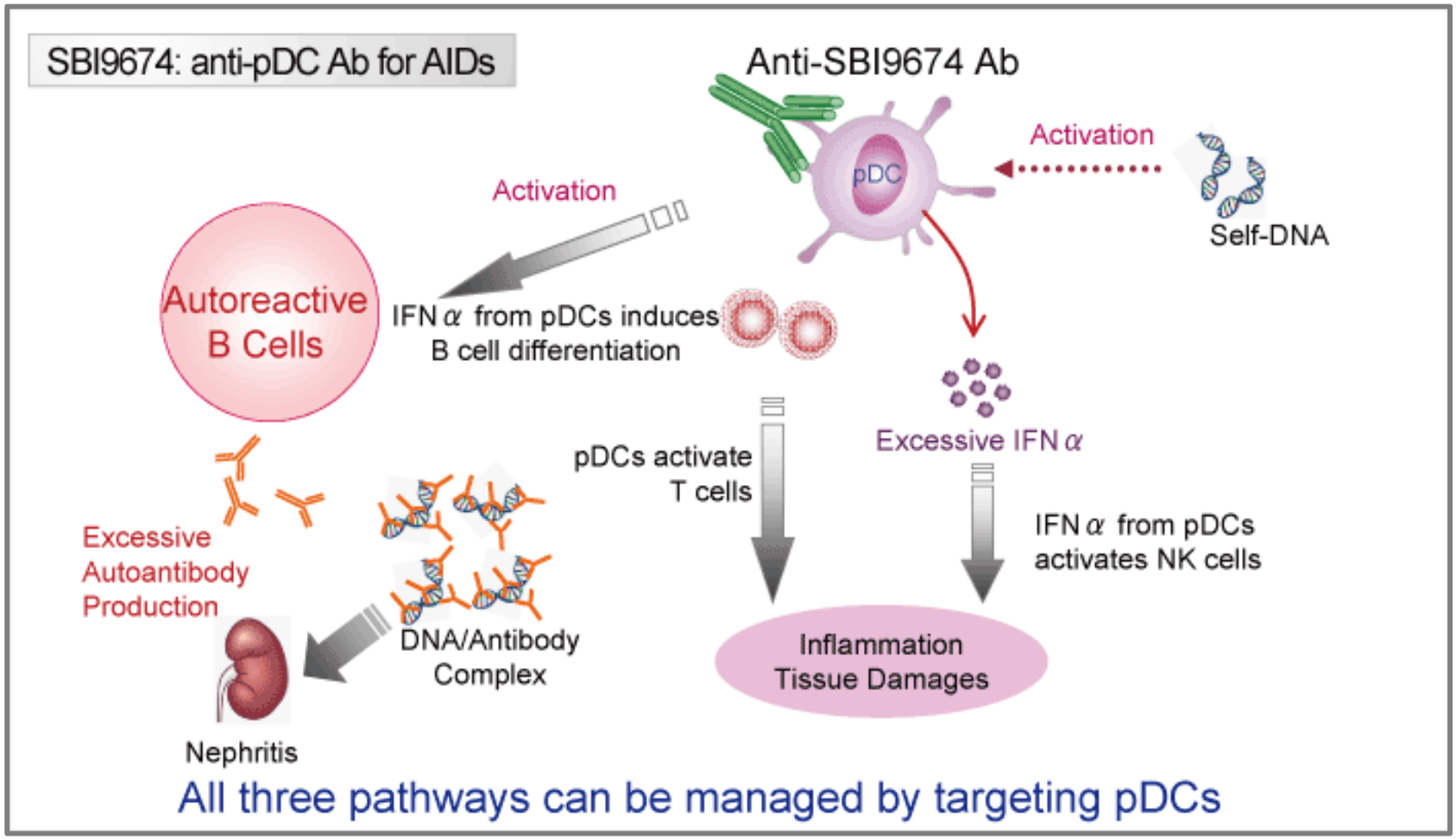
**Challenges exceeding the limitations of conventional modalities**

# Collaboration-leveraged drug discovery

# New antibody that targets pDCs (in-licensed from SBI Biotech)

**In 2016 Kyowa Kirin concluded an exclusive licensing agreement with SBI Biotech Co., Ltd. covering development, manufacturing and sales worldwide for SBI-9674, an antibody drug for autoimmune diseases**

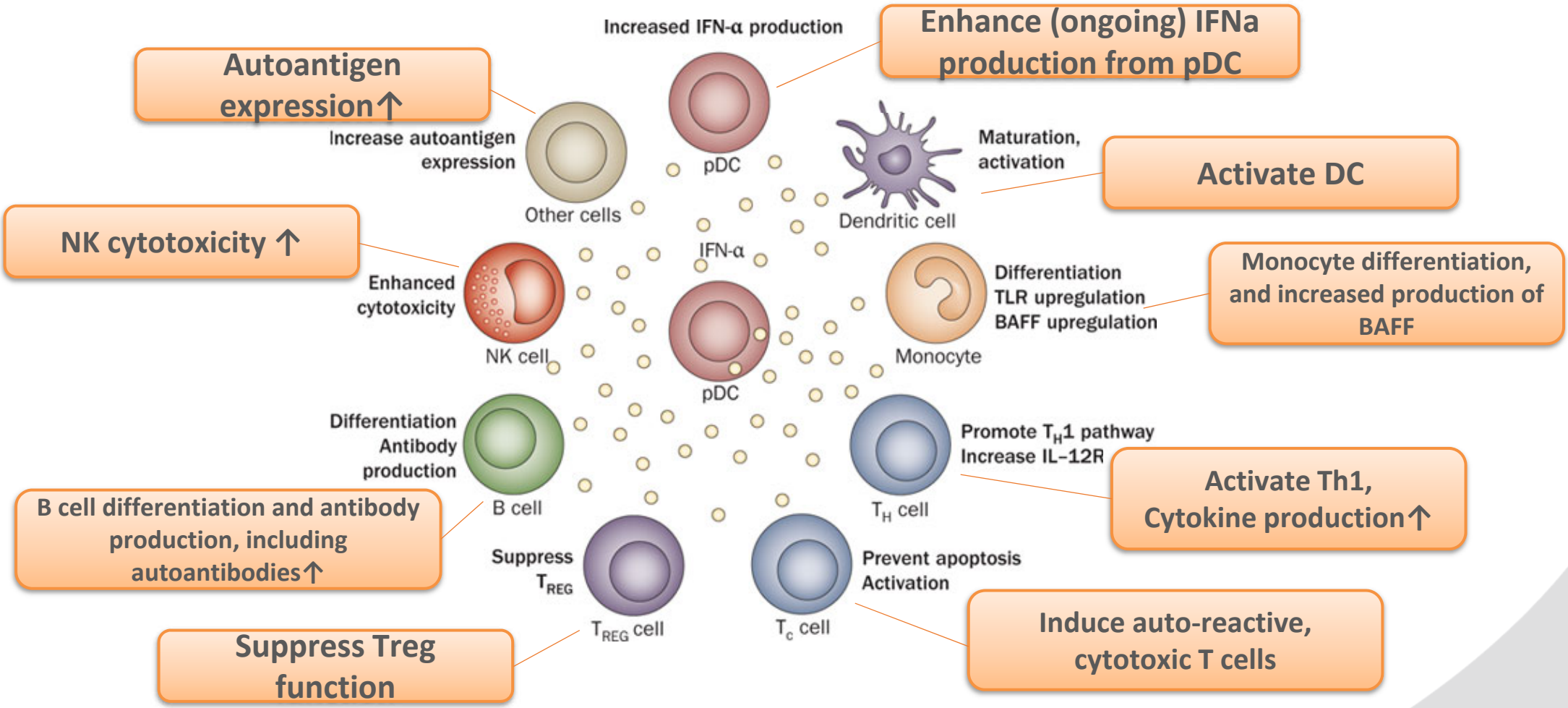
*** pDC : Plasmacytoid dendritic cell**




Source: SBI Biotech homepage （https://www.sbibiotech.jp/english/pipeline/sbi9674.html）

# New antibody that targets pDCs (in-licensed from SBI Biotech)

- **pDCs are known to be the main source of type 1 interferons (Type 1 IFN), which are the cause of various autoimmune diseases**
- **Type 1 IFN produced from pDCs coordinate immune functions through a variety of mechanisms (see the illustration below)**




Source: Nat Rev Rheumatol. 2010

# New antibody that targets pDCs (in-licensed from SBI Biotech)

- **At this year's ACR (American College of Rheumatology) convergence, the results of the Phase 2 study of the developed compound that targets pDCs (Anti-BDCA2 mAb) in patients with SLE/CLE were reported**

**ABSTRACT NUMBER: 0935 • ACR Convergence 2020**

**Efficacy and Safety Results from a Phase 2, Randomized, Double-Blind Trial of BIIB059, an Anti-Blood Dendritic Cell Antigen 2 Antibody, in SLE**

**Richard Furie**[1], Ronald van Vollenhoven[2], Kenneth Kalunian[3], Sandra Navarra[4], Juanita Romero-Díaz[5], Victoria Werth[6], Xiaobi Huang[7], Hua Carroll[8], Adam Meyers[7], Cristina Musselli[7], Catherine Barbey[9] and Nathalie Franchimont[7], [1]Zucker School of Medicine at Hofstra/Northwell, Great Neck, NY, [2]Department of Rheumatology, Amsterdam Rheumatology and Immunology Center, Amsterdam, Netherlands, [3]University of California San Diego, La Jolla, CA, [4]University of Santo Tomas, Manila, Philippines, [5]Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran, Mexico City, Mexico, [6]University of Pennsylvania and the Michael J. Crescenz VA Medical Center, Philadelphia, PA, [7]Biogen, Cambridge, MA, [8]Biogen, Cambridge, [9]Biogen, Baar, Switzerland

Background/Purpose: Type I interferons (IFN-I), inflammatory mediators principally produced by plasmacytoid dendritic cells (pDCs), components of the innate immune system, have been implicated in the...

**ABSTRACT NUMBER: 0986 • ACR Convergence 2020**

**BIIB059, a Humanized Monoclonal Antibody Targeting Blood Dendritic Cell Antigen 2 on Plasmacytoid Dendritic Cells, Shows Dose-Related Efficacy in a Phase 2 Study in Participants with Active Cutaneous Lupus Erythematosus**

**Victoria Werth**[1], Richard Furie[2], Juanita Romero-Díaz[3], Sandra Navarra[4], Kenneth Kalunian[5], Ronald van Vollenhoven[6], Filippa Nyberg[7], Benjamin Kaffenberger[8], Saira Sheikh[9], Goran Radunovic[10], Xiaobi Huang[11], Hua Carroll[12], Francois Gaudreault[12], Adam Meyers[11], Catherine Barbey[13], Cristina Musselli[11] and Nathalie Franchimont[11], [1]University of Pennsylvania and the Michael J. Crescenz VA Medical Center, Philadelphia, PA, [2]Zucker School of Medicine at Hofstra/Northwell, Great Neck, NY, [3]Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran, Mexico City, Mexico, [4]University of Santo Tomas, Manila, Philippines, [5]University of California San Diego, La Jolla, CA, [6]Department of Rheumatology, Amsterdam Rheumatology and Immunology Center, Amsterdam, Netherlands, [7]Karolinska University Hospital, Stockholm, Sweden, [8]Ohio State University, Columbus, OH, [9]Division of Rheumatology, Allergy and Immunology, University of North Carolina, Chapel Hill, NC, [10]Institute of Rheumatology, University of Belgrade, Belgrade, Serbia, [11]Biogen, Cambridge, MA, [12]Biogen, Cambridge, [13]Biogen, Baar, Switzerland

Background/Purpose: No approved targeted therapies have been developed for cutaneous lupus erythematosus (CLE), a disfiguring autoimmune disease that severely impairs quality of life.1 BIIB059 is...

Source: ACR convergence 2020 Abstract

- ✓ pDCs are involved in the pathology of autoimmune diseases incl. SLE/CLE
- ✓ Expectations are increasing for a therapeutic agent that targets pDCs

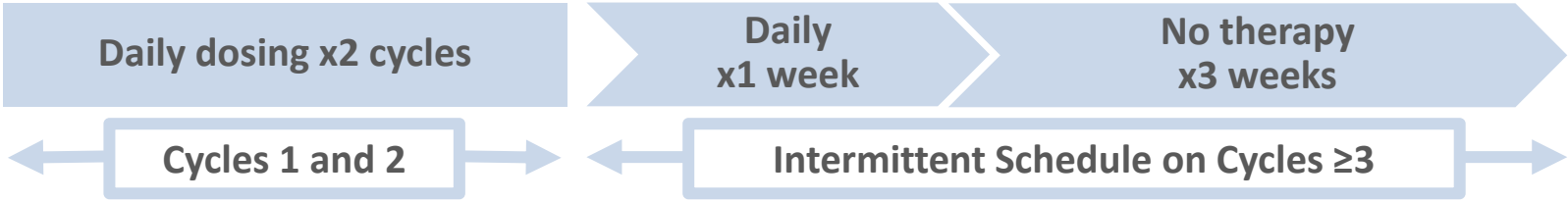
# Projects aiming to launch products within several years

# ME-401

# ME-401: Results of a Phase 1b Study in B-cell Malignancies

ASCO 2020
ClinicalTrials.gov Identifier: NCT02914938

## Treatment: ME-401 monotherapy or in combination with rituximab administered in IS




## Overall Response Rate (ORR) and Adverse Events of Special Interest (AESI)

| Diagnosis | Evaluable Patients | ORR n (%) |
|---|---|---|
| **FL** | **36** | **30 (83%)** |
| By treatment group | | |
| ME-401 monotherapy | 17 | 13 (76%) |
| ME-401 + rituximab | 19 | 17 (89%) |
| **CLL/SLL** | **9** | **8 (89%)** |
| By treatment group | | |
| ME-401 monotherapy | 3 | 3 (100%) |
| ME-401 + rituximab | 6 | 5 (83%) |

| Adverse Event of Special Interest (AESI) | Grade ≥ 3 |
|---|---|
| Diarrhea or colitis | |
| Diarrhea | 2 (3.5%) |
| Colitis | 2 (3.5%) |
| Rash, all types | 1 (1.8%) |
| ALT/AST elevation | 1 (1.8%) |
| Stomatitis | 0 |
| Pneumonia/Infectious pneumonitis | 0* |
| Non-Infectious pneumonitis | 1 (1.8%) |

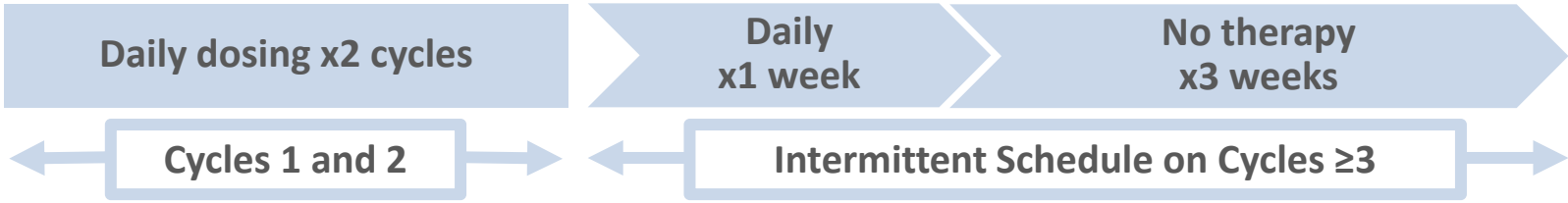
**ME-401 administered on an intermittent schedule showed a high response rate and was generally well tolerated in r/r FL and CLL/SLL**

* A patient with grade 5 COVID-19 pneumonia in Cycle 15
IS: Intermittent schedule, 1 cycle: 28 days, ORR: Overall response rate, FL: Follicular Lymphoma, CLL/SLL: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, r/r: Relapsed/Refractory

# ME-401: Global Phase 2 TIDAL* Study in r/r Follicular Lymphoma or Marginal Zone Lymphoma

ClinicalTrials.gov Identifier: NCT03768505

- Subjects: Patients with r/r FL after failure of at least two systemic therapies
- Treatment: ME-401 monotherapy administered on an intermittent schedule



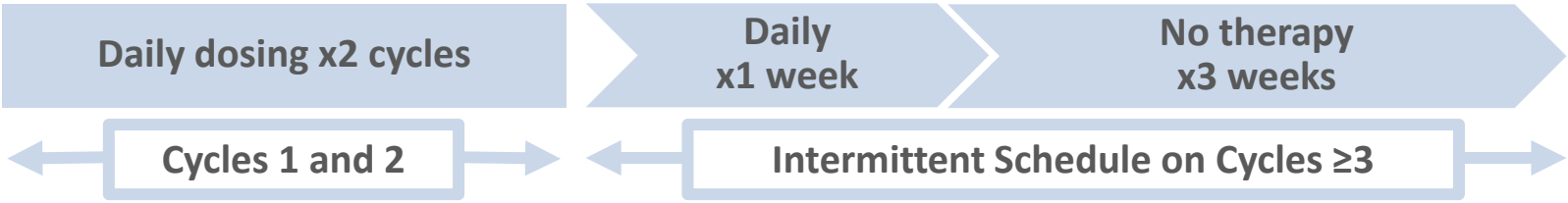

- Target number of patients: 180
- Study location: US, Europe, Oceania, South Korea, Taiwan
- Primary endpoint: Overall response rate
- The results of TIDAL are intended to be submitted to the U.S. Food and Drug Administration (FDA) to support accelerated approval of the marketing application

* TIDAL: **Tri**als of PI3K **D**elt**A** in Non-Hodgkin's **L**ymphoma

# ME-401: Japanese Phase 2 K02 Study in r/r Indolent B-cell NHL

ClinicalTrials.gov Identifier: NCT04533581

- **Subjects: Patients with r/r indolent B-cell NHL* after failure of at least two systemic therapies**
- **Treatment: ME-401 monotherapy administered on an intermittent schedule**

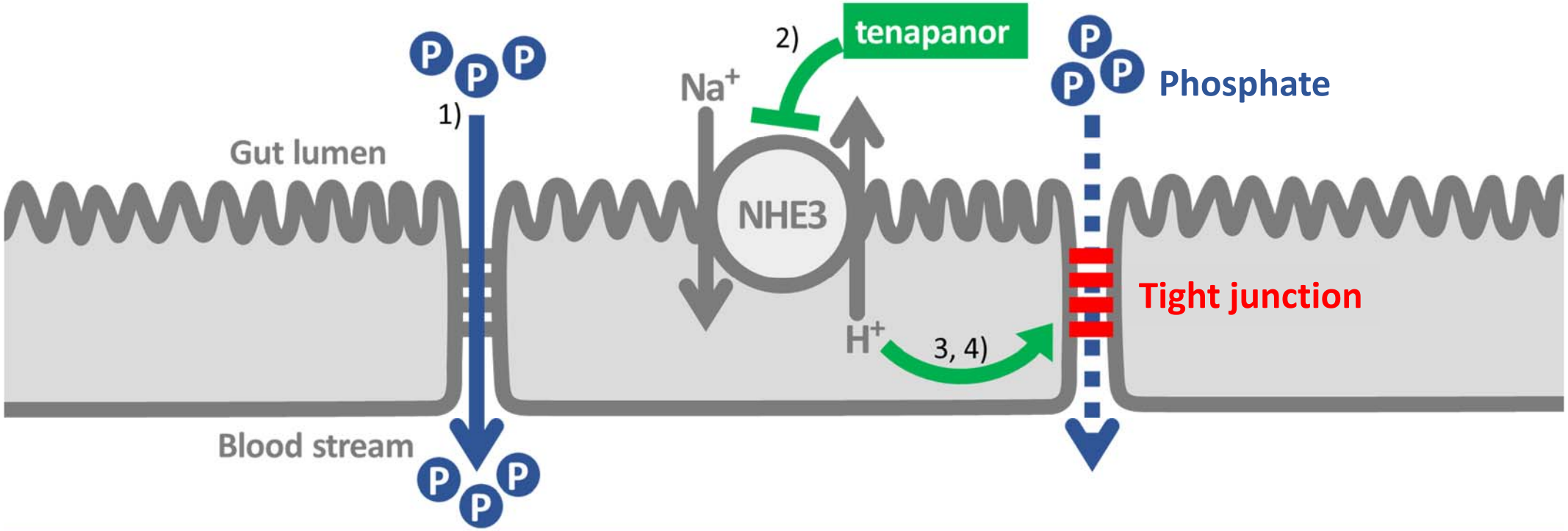



- **Target number of patients: 60**
- **Study location: Japan**
- **Primary endpoint: Overall response rate**
- **Plan to consider submission of the marketing application to the Japanese authorities after completion of the K02 study**

* Excluding Small lymphocytic lymphoma (SLL), lymphoplasmacytic lymphoma (LPL), and Waldenström's macroglobulinemia (WM)

# KHK7791

# KHK7791 / tenapanor




## Mechanism of action

- ✓ The primary uptake route of phosphorous is passive transport between cell membranes
- ✓ Tenapanor inhibits NHE3 and thereby inhibits the uptake of sodium ($Na^+$)
- ✓ At the same time, the concentration of protons ($H^+$) in the cells increases
- ✓ The increased intracellular proton concentration tightens the epithelial cell junctions, which regulates the uptake of phosphorous in the digestive tract, and thereby inhibits the uptake of phosphorous

## Features

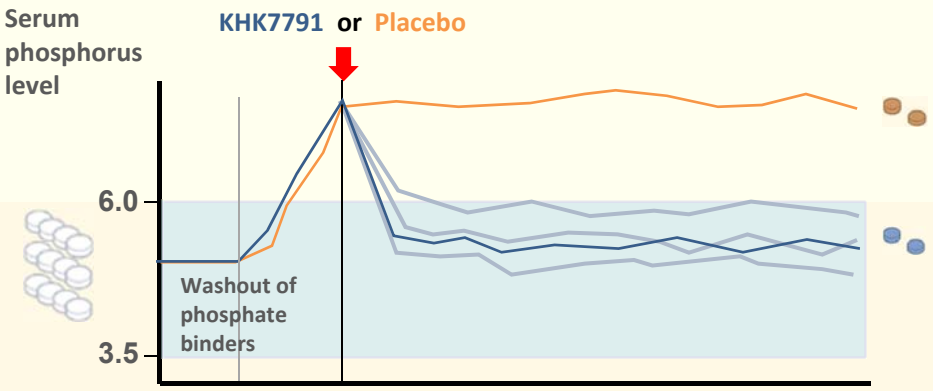
- ✓ Unlike existing phosphorous binders, the novel mechanism of action makes it a first-in-class phosphorous absorption inhibitor

# Summary of the Phase 2 studies (Dose-finding, Add-on, Switching)

Presented at ASN

Presented at EDTA

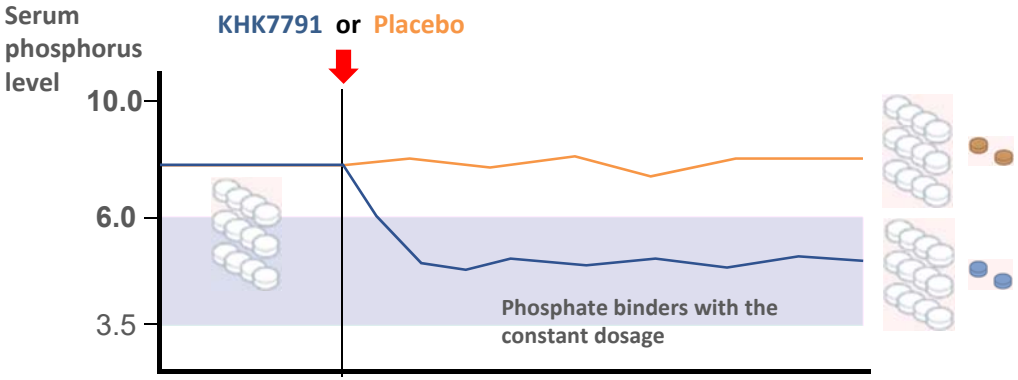
## Dose-finding




***Objectives***

- ✓ Explain that hyperphosphatemia can be treated with a single agent, KHK7791
- ✓ Explain the validity of using KHK7791 for patients who are starting treatment for hyperphosphatemia

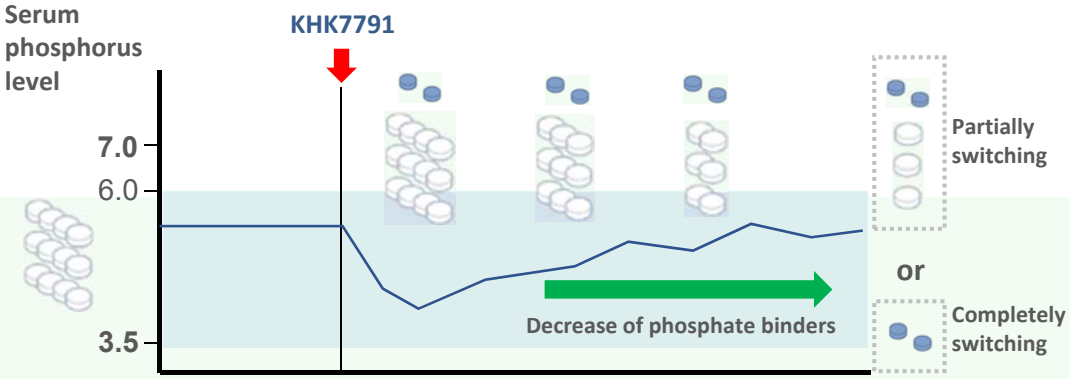
## Add-on




***Objectives***

- ✓ Satisfy the unmet needs that cannot be controlled with existing phosphate binders
- ✓ Confirm the efficacy by coadministration of KHK7791 with phosphate binders

## Switching




***Objectives***

- ✓ Explain the benefit of switching from existing phosphate binders, taking advantage of the small pill size and quantity
- ✓ Quantitatively confirm the reduction in phosphate binder pill burden

# KHK7791: PB switching study design

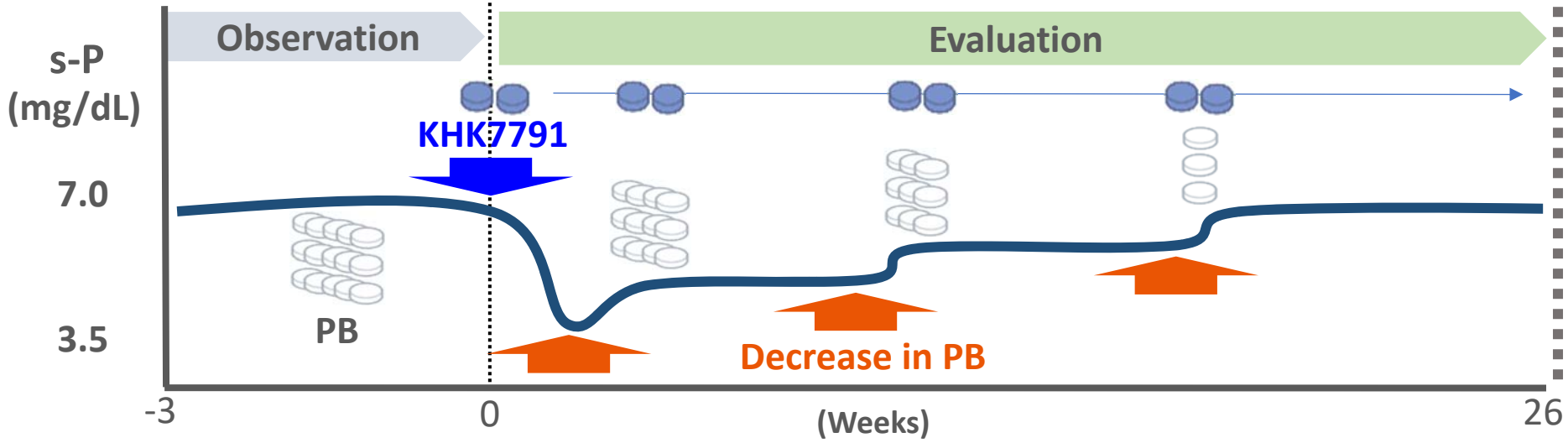
ClinicalTrials.gov Identifier: NCT03831607

- Open-label, single-arm, phosphate binder (PB) switch study for hyperphosphatemia patients on hemodialysis

Screening 92 subjects → Pre-enrollment 83 subjects → Enrollment 67 subjects → Phosphate binder (PB) + KHK7791

Enrollment criteria
Serum phosphorus level (s-P) : 3.5-7.0 mg/dL

Observation period (3 weeks) → Evaluation period (26 weeks)




- Primary endpoint : Achievement of 30% decrease in the mean total tablet number (PB+KHK7791) compared to baseline PB

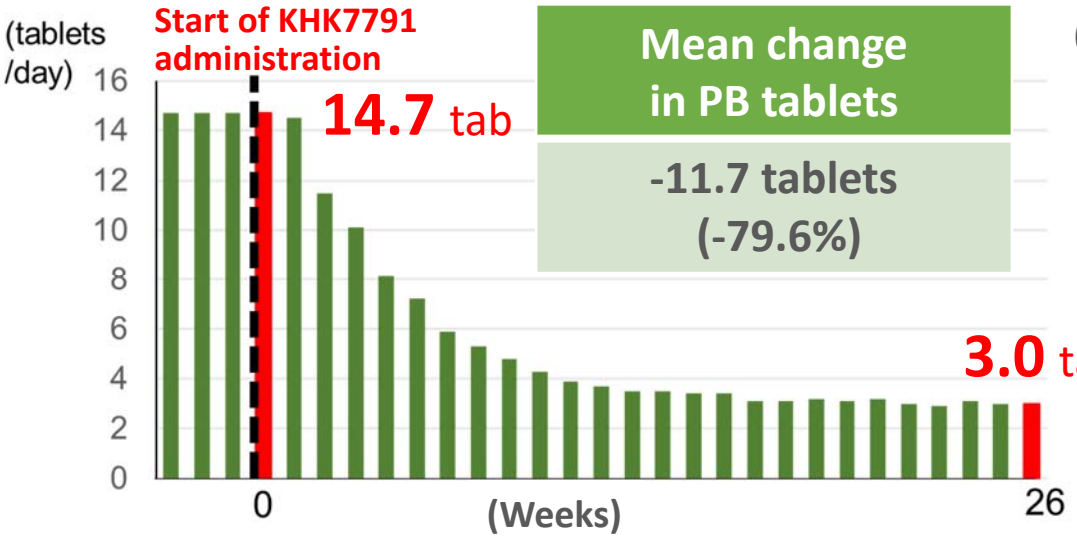
# KHK7791: PB switching study results

## ■ Primary endpoint

| | Achievement ratio | *P* value [95%CI] |
|---|---|---|
| 30% decrease | 71.6% (48/67) | <0.001 [59.3, 82.0] |

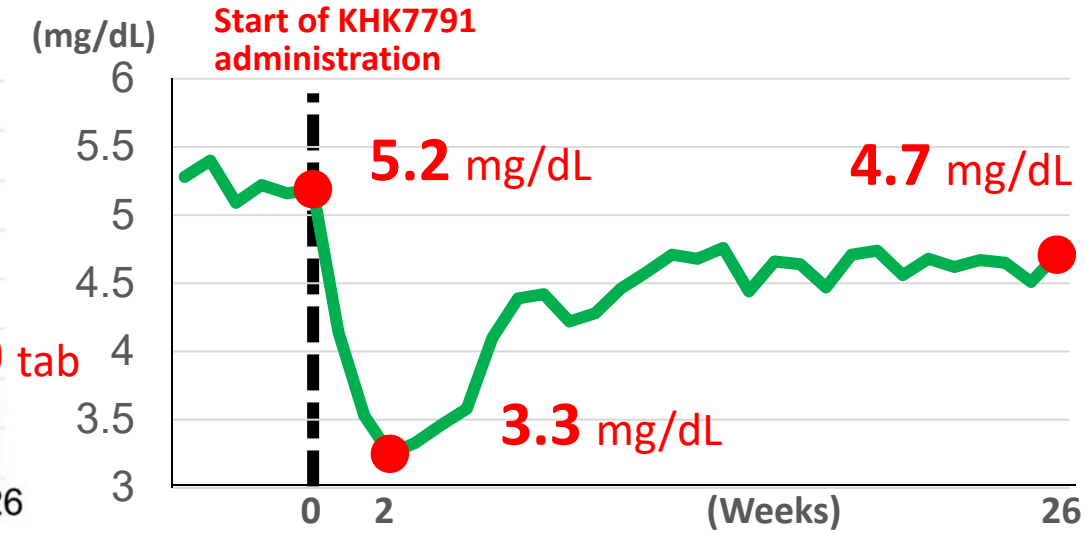
*CI* confidence interval.

## ■ Mean change in total PB tablets over time




| Mean change in PB tablets |
|---|
| -11.7 tablets (-79.6%) |

## ■ Mean change in s-P over time

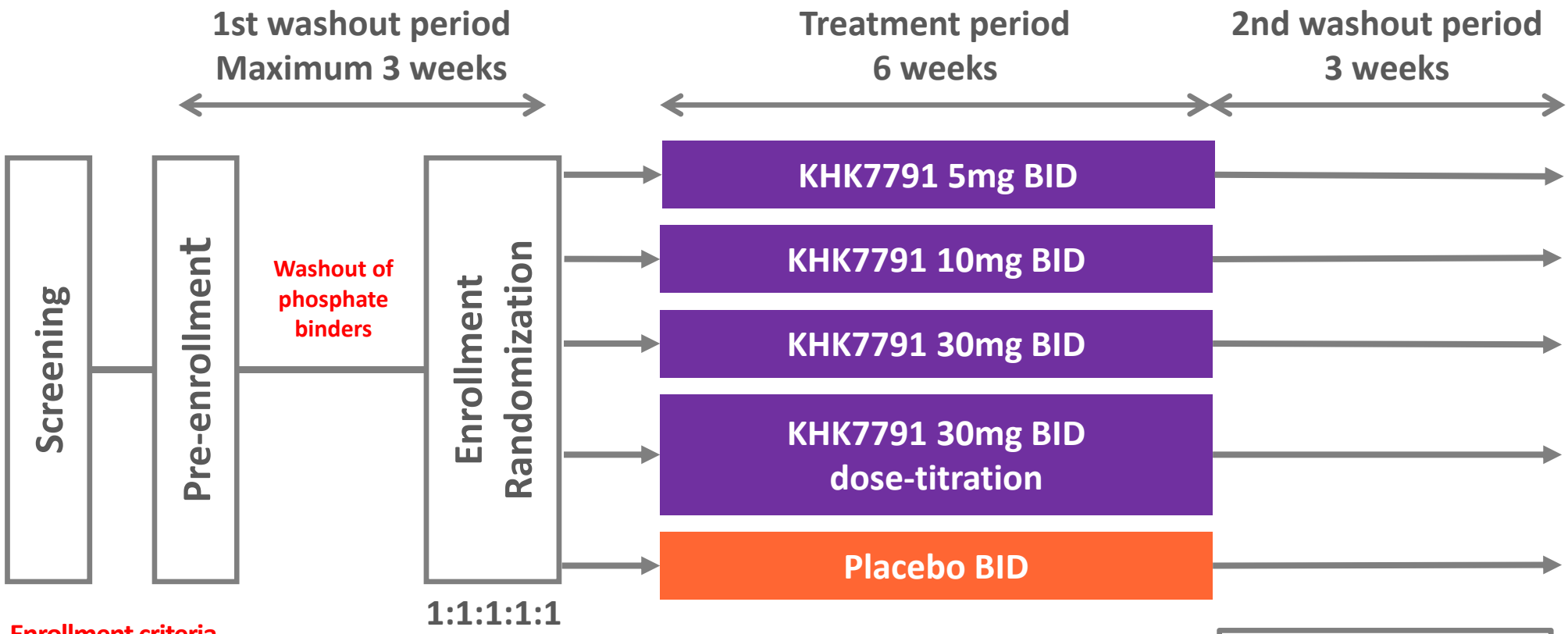



**More than 70% patients achieved a 30% decrease in the total number of PB tablets compared to the baseline.**

# KHK7791: Dose-finding study design

ClinicalTrials.gov Identifier: NCT03864458

- A phase 2, randomized, double-blind, placebo-controlled, dose-finding study of KHK7791 in hyperphosphatemia patients on hemodialysis




- Primary endpoint: Changes in serum phosphorus levels from baseline values at Week 6

# KHK7791: Dose-finding study results

## ■ Primary endpoint

| | | Placebo N=41 | KHK7791 5 mg N=42 | KHK7791 10 mg N=41 | KHK7791 30 mg N=42 | KHK7791 30 mg dose-titration N=41 |
|---|---|---|---|---|---|---|
| Week 6 Serum phosphorus level (mg/dL) | Mean±SD | 0.6±1.6 | -0.9±1.7 | -1.4±1.5 | -1.9±1.2 | -2.0±1.1 |
| | Median | 0.4 | -1.0 | -1.5 | -2.1 | -2.0 |
| | Difference | - | -1.6 | -2.0 | -2.6 | -2.6 |
| | 95% CI | - | [-2.3,-0.9] | [-2.7,-1.3] | [-3.2,-2.0] | [-3.2,-2.0] |
| | p-value | - | <0.001 | <0.001 | <0.001 | <0.001 |

## ■ Drug-related TEAEs, discontinued

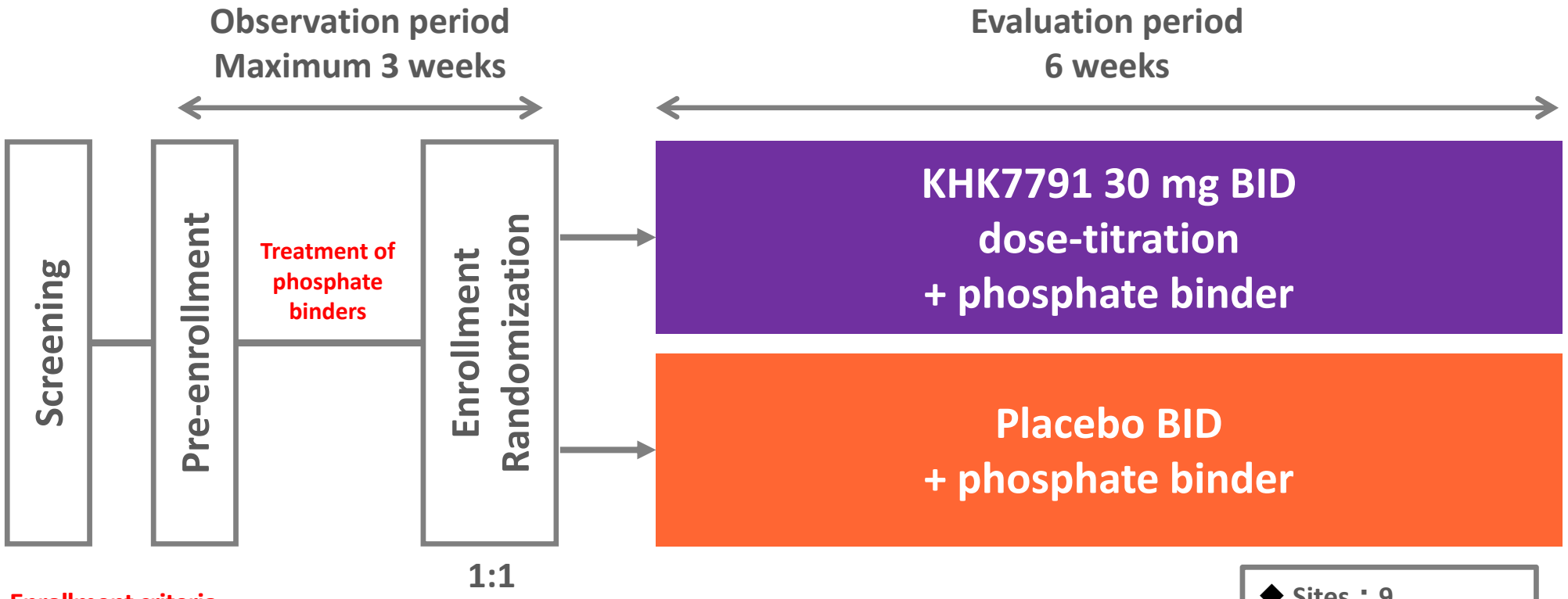
| | | Placebo N=41 | | KHK7791 5 mg N=42 | | KHK7791 10 mg N=41 | | KHK7791 30 mg N=42 | | KHK7791 30 mg dose-titration N=41 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | N | % | N | % | N | % | N | % | N | % |
| Drug-related TEAEs | | 7 | (17.1) | 22 | (52.4) | 28 | (68.3) | 32 | (76.2) | 28 | (68.3) |
| [Gastrointestinal disorders] | | 5 | (12.2) | 22 | (52.4) | 28 | (68.3) | 32 | (76.2) | 28 | (68.3) |
| **Diarrhea** | | **4** | **(9.8)** | **21** | **(50.0)** | **27** | **(65.9)** | **32** | **(76.2)** | **27** | **(65.9)** |
| Severity of diarrhea | Mild | 4 | | 21 | | 25 | | 28 | | 24 | |
| | Moderate | 0 | | 0 | | 2 | | 4 | | 3 | |
| | Severe | 0 | | 0 | | 0 | | 0 | | 0 | |

**KHK7791 significantly decreased serum phosphorus levels from baseline compared with the placebo and decreased serum phosphorus levels in a dose-dependent manner.**

# KHK7791: Add-on study design

ClinicalTrials.gov Identifier: NCT03864445

- A phase 2, randomized, double-blind, placebo-controlled, phosphate binder-combination study of KHK7791 in hyperphosphatemia patients on hemodialysis




Enrollment criteria
(Pre-enrollment, Enrollment) Serum phosphorus level : 6.1-9.9 mg/dL

- Primary endpoint: Changes in serum phosphorus levels from baseline values at Week 6

# KHK7791: Add-on study results

## Primary endpoint and target achievement ratio of serum phosphorus level (3.5～6.0 mg/dL)

| | | Placebo N=24 | KHK7791 N=23 |
|---|---|---|---|
| Week 6 Serum phosphorus level (mg/dL) | Mean±SD | 0.1±1.5 | -2.0±1.2 |
| | Median | -0.2 | -2.1 |
| | Difference | - | -2.1 |
| | 95% CI | - | [-2.9,-1.3] |
| | p-value | - | <0.001 |
| Week 6 Target achievement proportion | % (n/N) | 37.5 (9/24) | 87.0 (20/23) |

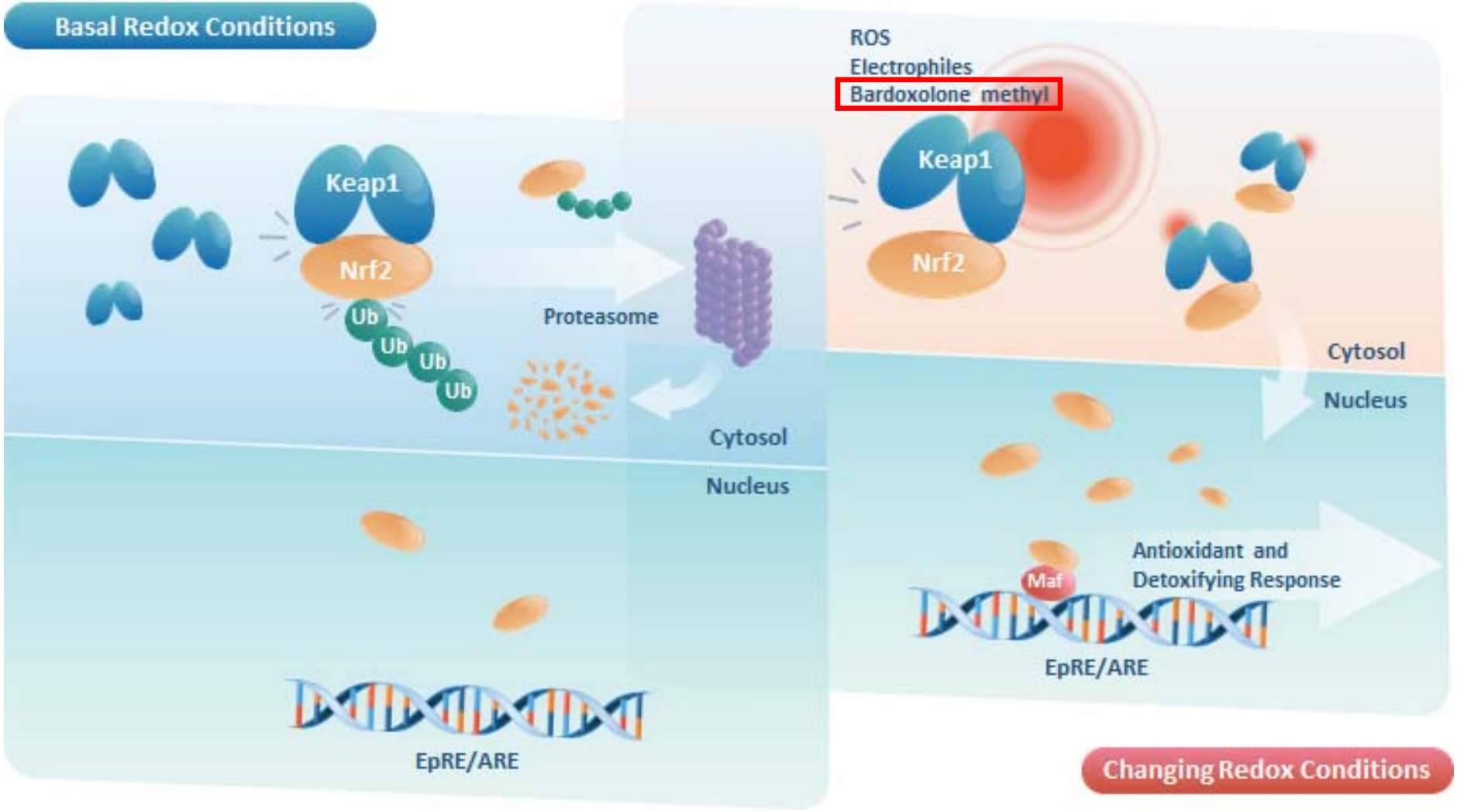
## Drug-related TEAEs, discontinued

| | | Placebo N=24 | | KHK7791 N=23 | |
|---|---|---|---|---|---|
| | | N | % | N | % |
| Drug-related TEAEs | | 2 | (8.3) | 16 | (69.6) |
| [Gastrointestinal disorders] | | 2 | (8.3) | 16 | (69.6) |
| **Diarrhea** | | **2** | **(8.3)** | **15** | **(65.2)** |
| Severity of diarrhea | Mild | 2 | | 8 | |
| | Moderate | 0 | | 7 | |
| | Severe | 0 | | 0 | |

**Adding on KHK7791 resulted in a significant decrease in serum phosphorus levels compared with the placebo.**

# RTA 402

# RTA 402 / Bardoxolone methyl




Kanda H and Yamawaki K, Clinical and Experimental Nephrology 24:857–864, 2020

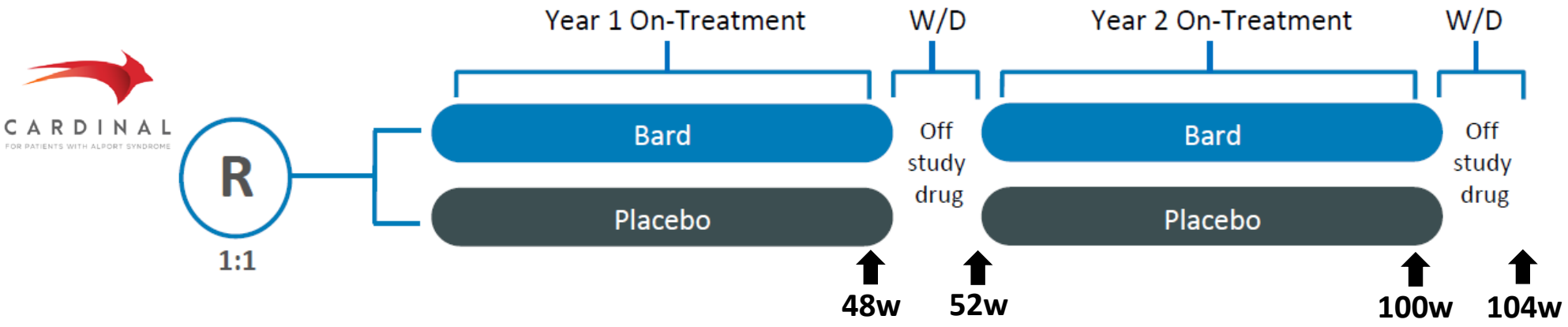
**RTA 402 (Bardoxolone methyl) activates the Keap1-Nrf2 pathway, which is an oxidative stress response system.**

# RTA 402: CARDINAL Phase 3 for Alport Syndrome patients

**What is Alport Syndrome?**

**Alport Syndrome is a kidney disease caused by genetic mutations in either the type IV collagen α3, α4 or α5 chain. In Japan, Alport Syndrome is certified as designated intractable diseases and specific pediatric chronic diseases. Severe cases have been reported to progress to end-stage kidney disease in the late teens and early 20s. Currently there is no approved treatment for Alport Syndrome as an indication.**

- Number of subjects : 157 (Placebo: 80, RTA 402: 77)
- Subjects : 12-70 years, eGFR: 30-90 mL/min/1.73m$^2$
- Primary efficacy endpoint : Change in eGFR from baseline at Week 48 and Week 100
- Key secondary endpoint : Change in eGFR from baseline at Week 52 and Week 104 (4 weeks after withdrawal of drug)
- Region : US, JP, EU, AU

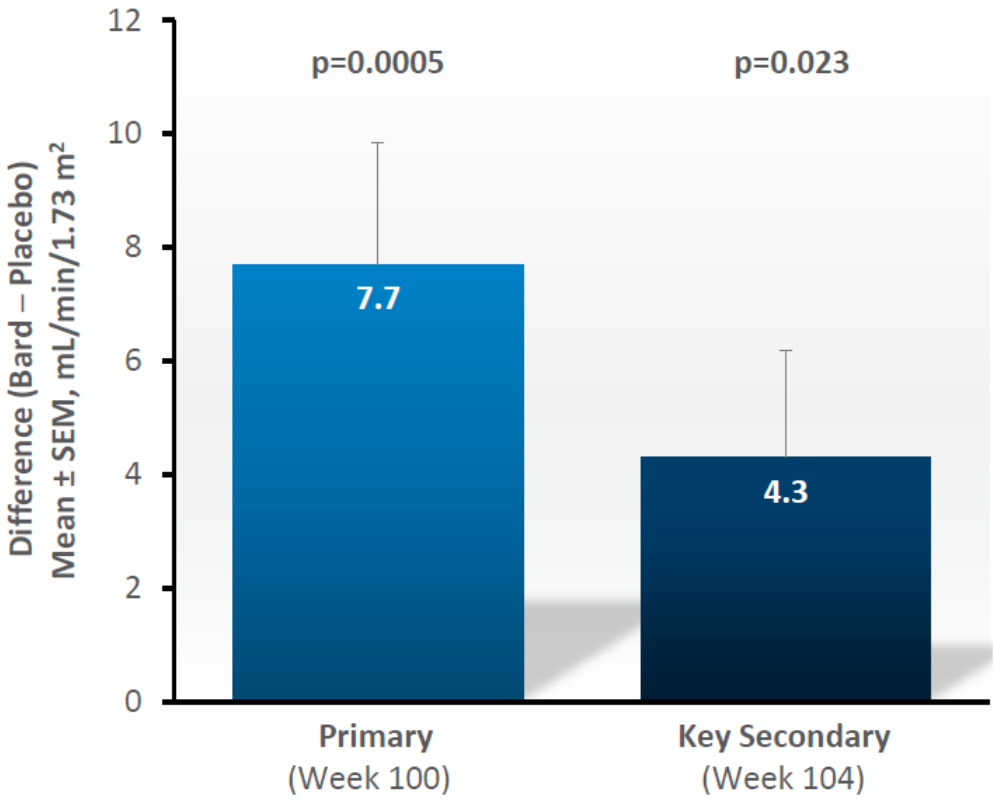



**The 2-year study period was completed, and Reata announced the year 2 results on Nov 9th.**

https://clinicaltrials.gov/ct2/show/NCT03019185
https://www.reatapharma.com/wp-content/uploads/2019/11/20191112_RETA_YEAR_ONE_TOPLINE_RESULTS_FROM_PIVOTAL_CARDINAL_STUDY_Mgmt_Call.pdf
https://www.reatapharma.com/wp-content/uploads/2020/11/Reata_Third_Quarter_2020_Earnings_Call_Deck.pdf

1-year results were published in Reata's 3Q financial results presentation last November. Both primary/key secondary endpoints have been met.

# RTA 402: CARDINAL Phase 3 for Alport Syndrome patients




Mean ± SEM eGFR Change (mL/min/1.73 m²)

| Endpoint | Placebo | Bard | Difference (Bard — Placebo) |
|---|---|---|---|
| Primary (ITT) | -8.5 ± 1.5 | -0.8 ± 1.6 | **7.7 ± 2.1 (p=0.0005)** |
| Primary (mITT) | -9.6 ± 1.5 | 1.7 ± 1.6 | **11.3 ± 2.2 (p<0.0001)** |
| Key Secondary (ITT) | -8.8 ± 1.4 | -4.5 ± 1.4 | **4.3 ± 1.9 (p=0.023)** |

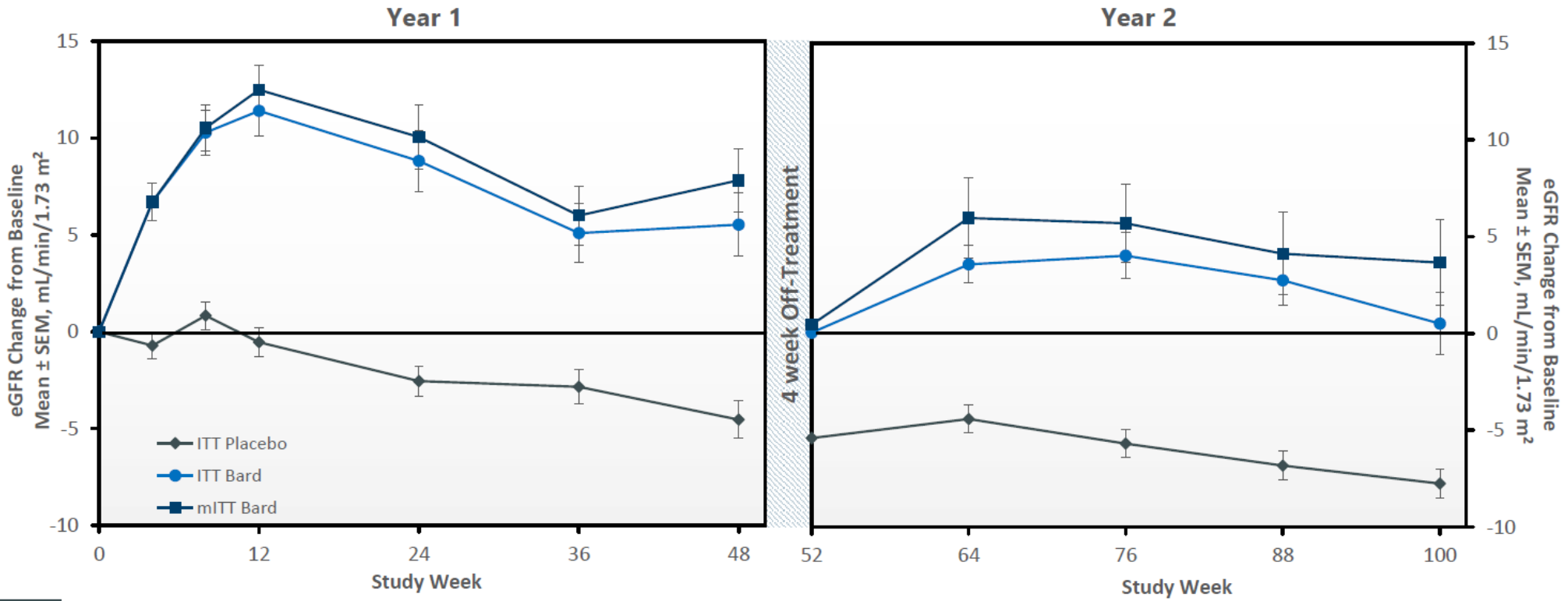
ITT: Intent to treat

mITT: modified-ITT, analysis assesses the effect of receiving treatment by excluding values after patients discontinued treatment

**Both primary/key secondary endpoints were met.**
**The results also show a favorable safety profile.**

https://www.reatapharma.com/wp-content/uploads/2020/11/Reata_Third_Quarter_2020_Earnings_Call_Deck.pdf

# RTA 402: CARDINAL Phase 3 for Alport Syndrome patients




| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Placebo ITT (n) | 80 | 80 | 79 | 75 | 71 | 68 | 70 | 71 | 72 | 73 |
| Bard ITT (n) | 77 | 74 | 69 | 65 | 66 | 66 | 63 | 61 | 62 | 65 |
| Bard mITT (n) | 77 | 69 | 62 | 60 | 57 | 57 | 56 | 53 | 51 | 48 |

**Effect for eGFR was observed over the study period in the RTA 402 group.**

**Based on the current results, KKC also plans to submit a marketing approval application for the indication of Alport Syndrome in Japan.**

https://www.reatapharma.com/wp-content/uploads/2020/11/Reata_Third_Quarter_2020_Earnings_Call_Deck.pdf

# Summary

## Summary (1): Challenging the creation of new value in R&D

# Initiatives for expanding the opportunities to create value unique to Kyowa Kirin

- **Initiatives and innovation through internal activities + collaborations**
  - **Axcelead, InveniAI, SBI Biotech**
  - **Next generation antibody technology**, Nucleic acid therapeutics, Small molecule drug discovery, Regenerative medicine
- **Foster next generation product candidates (global products, etc.)**
  - KHK4083, KW-6356, **ME-401**, **RTA 402**, **KHK7791**…

### Technology strategy

**Utilize next generation antibody technology and diverse modalities to build a platform that will support revolutionary new pharmaceuticals**

### Disease strategy

**Utilize the accumulated knowledge and technology to change the lives of patients by providing unique value for UMN**

# Summary (2): Challenging the creation of new value in R&D

## R&D spirits

# Q&A Session

# Thank you.

Kyowa Kirin Co., Ltd.


KYOWA KIRIN