

October 30, 2023

To whom it may concern,

Company Name: Nippon Kayaku Co., Ltd.  
Representative: Atsuhiko Wakumoto, President  
and Representative Director  
Code Number: 4272 TSE, Prime  
Contact: Noriko Kiyoyanagi, General Manager,  
Corporate Communications Division  
(Phone: +81-3-6731-5237)

### **Execution of Licensing Agreement for a New Drug Candidate**

Nippon Kayaku Co., Ltd. (Headquarters: Tokyo, Japan; President and CEO: Atsuhiko Wakumoto; hereinafter "Nippon Kayaku") and AnHeart Therapeutics Inc. (Headquarters: New York, NY, USA; CEO: Junyuan Jerry Wang; hereinafter "AnHeart") announce that the two companies have entered into a licensing agreement (hereinafter "the Agreement"). Under the Agreement, Nippon Kayaku obtains the exclusive rights to market and distribute Taletrectinib (Development code: AB-106/DS-6051b; hereinafter "the Product"), a novel, next-generation, brain-penetrant, selective ROS1 inhibitor currently under development by AnHeart, for the territory of Japan.

#### 1. Outline of the Agreement

Nippon Kayaku obtains from AnHeart the exclusive rights to market the Product in Japan. AnHeart shall continue to conduct global Phase II clinical trials for the development of the Product, and Nippon Kayaku shall be responsible for the regulatory application for approval, packaging, labeling, distribution, sales, promotion, etc. of the Product in Japan. Nippon Kayaku is to make an upfront payment of \$40 million USD to AnHeart upon the signing of the Agreement, and make further milestone payments in the event of future regulatory approval, domestic sales exceeding certain amounts, and royalties based on domestic net sales.

#### 2. Outline of AnHeart Therapeutics Inc.

- (1) Name: AnHeart Therapeutics Inc.
- (2) Headquarters: 777 Third Avenue, Suite 1704, New York, NY 10017
- (3) Representative and CEO: Junyuan Jerry Wang
- (4) Established: 2018
- (5) Fiscal Year End: December

- (6) Main Business: Discovery, research and development, sales, imports/exports, etc. of pharmaceutical products
- (7) Number of employees (including affiliates): 106 (as of September 30, 2023)
- (8) Past relationship with Nippon Kayaku: Capital, personal and business relationships have not previously occurred.

### 3. About AnHeart

AnHeart is a global clinical-stage biopharmaceutical company developing novel precision therapies for people with cancer. Its lead investigational therapy, Taletrectinib, is a next-generation ROS1-inhibitor currently in pivotal Phase 2 trials for ROS1-positive non-small cell lung cancer (“NSCLC”). Taletrectinib has been granted Breakthrough Therapy Designation by both the U.S. Food and Drug Administration and the China National Medical Products Administration. AnHeart’s second investigational therapy, Safusidenib, is a mIDH1-inhibitor being evaluated in a Phase 2 trial for IDH1-mutant glioma.

Its mission is to improve the lives of people with cancer. They are supported by leading life sciences investors and have built an organization with deep oncology drug discovery and development expertise, with offices in New York and Shanghai.

### 4. About Taletrectinib

ROS1 is an enzyme protein called tyrosine kinase that is involved in cell growth. The ROS1 fusion gene is a potent oncogene found in a variety of cancers and in approximately 1-2% of advanced non-small cell lung cancers. Taletrectinib drug is being developed to suppress ROS1 gene function in ROS1 fusion gene-positive non-small cell lung cancer (“ROS1-positive NSCLC”).

The results of a Phase II study (TRUST-I study, NCT04395677) conducted in China were presented at the European Lung Cancer Congress 2023. A global Phase II study (TRUST-II study, NCT04919811) is currently underway in multiple countries, including the United States, Japan, Korea, Europe, Canada, and China, to evaluate the efficacy and safety of the Product in ROS1-positive NSCLC patients; both those who have and have not been previously treated with a ROS1 tyrosine kinase inhibitor.

Interim data from the TRUST-II study presented at the European Society of Medical Oncology Congress 2023 showed that 92% of advanced ROS1-positive NSCLC patients who had not received prior ROS1 tyrosine kinase inhibitor therapy, and 57% of patients who had, achieved tumor shrinkage (confirmed objective response rate: cORR as assessed by an independent review committee). For more information on this data,

please visit the AnHeart Therapeutics Inc. website

(<https://www.anhearttherapeutics.com/news/press-releases/102123/>).

#### 5. History

(1) Internal approval date: October 24, 2023

(2) Date of contract signing: October 27, 2023

#### 6. Future outlook

The impact of the payments related to the Agreement on our business performance for the fiscal year ending March 31, 2024 has been factored into the announcement regarding the revision of business forecasts of October 30, 2023. We believe that this transaction will contribute to improving our business performance and corporate value in the medium to long term.

[Contact]

Corporate Communications Division

TEL: 03-6731-5237