(Translation)

August 3, 2022

To: Shareholders,

Company Name: Renascience Inc.
Name of Representative: Koji Naito, President & CEO
(Code: 4889 TSE Growth)
Inquiries: Hiroyasu Ishimaru, Executive Officer in charge of Administration and Corporate Planning

Announcement of Initiation of Phase III Trials for Chronic Myeloid Leukemia

The Company today announced that the first subject has been dosed and the clinical trial has started in a phase III study of the PAI-1 inhibitor RS5614 for chronic myeloid leukemia (CML).

This phase III study is a multicenter, placebo-controlled, double-blind (*1) study to evaluate the efficacy of RS5614 in combination with tyrosine kinase inhibitors (TKIs) in the patients with chronic phase CML. Sixty patients with chronic phase CML who have been on TKIs treatment for at least 3 years will be included in the study. The study will verify that the combination of the investigational agent RS5614 with TKIs significantly increases the DMR maintenance rate (*2) for more than two years compared to the TKIs alone.

This study was selected by the Japan Agency for Medical Research and Development (AMED) as a project in the “Practical Research of Innovative Cancer Control” program in FY 2022 and is being conducted under the support of AMED (representative organization: Tohoku University; the Company is a sharing organization).

(*1) Double-blind: A clinical trial method in which patients are randomly assigned into two groups, one to receive the investigational drug (RS5614 in this case) and the other to receive a control drug (placebo with no effect in this case), and both groups receive the drugs simultaneously under the condition that neither physicians nor patients know which drug will be administered. This is a clinical trial method to avoid the possibility of deliberate actions such as administering the investigational drug to patients who are expected to respond to the drug, or the possibility of preconceptions that the drug should be effective being reflected in the evaluation. The results of each group are compared and evaluated to determine if the investigational drug is effective.

(*2) DMR maintenance rate: Current treatment of chronic phase CML requires lifelong use of expensive TKIs, but it has recently been shown that some patients who achieve the deepest therapeutic effect, DMR, and maintain it for a certain period do not relapse even after discontinuing TKIs (maintenance of treatment-free remission). The cumulative DMR achievement rate published to date for existing TKIs

over one year (48 weeks) is 8-12% (historical control), but in the late phase II study, the cumulative DMR achievement rate for one year of combination therapy with RS5614 and TKIs was as high as 33%. In a late phase II study, confirming the efficacy of RS5614. DMR maintenance is defined as the continuation of the status of DMR for a certain period of time.

There is no particular impact of this matter on the Company's business performance at this time.

(Reference)

About AMED Adopted Projects

Name of Program: Practical Research of Innovative Cancer Control in FY2022

Research Area: 3-2 Investigator-initiated Clinical Trial for the Development and Regulatory Approval of Innovative Cancer Medicine (Pharmaceuticals)

Name of Project: Phase III Study to Evaluate the Safety and Efficacy of TM5614 (RS5614) in Long-term Combination with TKI in Chronic Myeloid Leukemia

(Principal Investigator: Professor Hideo Harigae, Tohoku University)

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