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RaQualia Pharma Inc.
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Syros Pharmaceuticals Announced the Results of Phase 3 Clinical Trial for Myelodysplastic Syndrome and Future Plans

Nagoya, Japan, November 13, 2024 – RaQualia Pharma Inc. (headquartered in Nagoya; President & CEO: Hirobumi Takeuchi, “RaQualia”) announces today that Syros Pharmaceuticals Inc. (headquarters: Massachusetts, U.S.A., “Syros”), a licensee of TMRC Co., Ltd. (“TMRC”) that is a consolidated subsidiary of RaQualia, has announced the results of Phase III clinical trial in myelodysplastic syndrome (MDS) patients.

Tamibarotene is a selective agonist of the alpha subtype of retinoic acid receptors (RAR alpha or RARA). Syros has been conducting the phase III clinical trial, SELECT-MDS-1, evaluating tamibarotene in combination with azacitidine for the treatment of high-risk MDS patients with RARA overexpression. On November 12 (local time), Syros announced that the primary endpoint of the study, the complete response rate (CR rate), had not been achieved and that Syros would terminate the study. Syros also announced that it would carefully review the clinical trial data and consider the next steps. In addition, Syros reported that the failure of the SELECT-MDS-1 trial to achieve its primary endpoint constitutes an event of default under an existing loan facility.

For more information, please read Syros’s news release: <https://ir.syros.com/press-releases/detail/312/syros-announces-topline-data-from-select-mds-1-phase-3>

In September 2015, TMRC entered into a license agreement with Syros for the rights to develop and market tamibarotene as a cancer therapeutic in North America and Europe. Under the terms of the agreement, TMRC has the right to receive milestone and post-marketing royalties. The impact on RaQualia’s full-year consolidated earnings forecast for the fiscal year ending December 31, 2024 (January 1, 2024 to December 31, 2024), announced on February 14, 2024, is immaterial. At this time, RaQualia will not revise its consolidated earnings forecast for the current fiscal year ending December 31, 2024. RaQualia will examine the medium to long-term impact, and if it becomes necessary to revise its future earnings and business plans, it will promptly announce the details as soon as they are confirmed.

TMRC and RaQualia are committed to working closely with Syros to collect information on this matter and provide appropriate and timely updates moving forward.

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