NEWS RELEASE

RaQualia Pharma Inc.
April 10, 2024

Tamibarotene Received a U.S. FDA Fast Track Designation for the Treatment of Acute Myeloid Leukemia (AML)

Nagoya, Japan, April 10, 2024 – RaQualia Pharma Inc. (headquartered in Nagoya; President & CEO: Hirobumi Takeuchi, "RaQualia") is pleased to announce 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 that U.S. Food and Drug Administration (FDA) granted a Fast Track designation to a retinoic acid receptor alpha agonist (generic name: tamibarotene; compound code: TM-411/SY-1425; collectively "tamibarotene"), which TMRC licensed to Syros, for the treatment of acute myeloid leukemia (AML).

Tamibarotene is a selective agonist of the alpha subtype of retinoic acid receptors (RAR alpha) and is expected to have a synergistic effect when combined with other anti-tumor agents because of its potent differentiation activity.
Fast Track is a process designated by the FDA to facilitate the development and expedite the review of drug candidates for treating serious conditions for which non-clinical or clinical data demonstrate the potential to address unmet medical needs. Drug candidates that receive Fast Track designation may be eligible for more frequent interactions with the FDA regarding their development plans. In addition, if supported by clinical data, drug candidates may be eligible for priority review and accelerated approval.

The FDA has granted a Fast Track designation to tamibarotene in combination with azacytidine and venetoclax for the treatment of AML, for which Syros is currently conducting a phase 2 clinical trial, SELECT-AML-1. SELECT-AML-1 was designed for newly diagnosed AML patients with RARA overexpression, who are unfit for the use of conventional chemotherapy. In December 2023, Syros announced initial randomized data from SELECT-AML-1, demonstrating a 100% CR/CRi (complete response/complete response with incomplete hematologic recovery) rate in response-evaluable patients (nine of nine) treated with the triplet regimen of tamibarotene, venetoclax and azacitidine, as compared to 70% among patients (seven of ten) treated with venetoclax and azacitidine alone. Syros expects to report additional data from SELECT-AML-1 in 2024. Syros is also evaluating tamibarotene in combination with azacitidine in newly diagnosed higher-risk myelodysplastic syndrome (HR-MDS) patients with RARA overexpression in a phase 3 clinical trial, SELECT-MDS-1. Enrollment to support the pivotal primary efficacy analysis was completed in the first quarter of 2024, and pivotal complete response data is expected by the middle of the fourth quarter of 2024. In January 2023, the FDA granted Fast Track Designation to tamibarotene for the treatment of HR-MDS patients with RARA overexpression.
For more information, please read Syros's news release: https://ir.syros.com/press-releases/detail/301/syros-receives-fast-track-designation-from-the-fda-for.

AML and MDS are life-threatening diseases, and the market size for therapeutics is growing due to the significant unmet medical needs. According to Syros, the global market for MDS and AML therapies will reach US$7.5 billion and US$4.7 billion by 2028.

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. Although TMRC will receive no lump-sum payment due to the Fast Track designation this time, and there will be no impact on RaQualia's full-year consolidated earnings forecast for the fiscal year ending December 31, 2024 (January 1, 2024 to December 31, 2024), which was announced on February 14, 2024. However, TMRC and RaQualia believe that the Fast Track designation this time will accelerate the development and approval of tamibarotene for the treatment of AML, and will contribute to the enhancement of the value of tamibarotene over the medium to long term.

TMRC and RaQualia are committed to strengthening their partnership with Syros, providing continuous development and marketing support, and achieving milestone and royalty revenues to enhance corporate value.

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