

23 September 2024

Roquefort Therapeutics plc
("Roquefort Therapeutics" or the "Company")

Grant of Japan MK Cell Patent

Roquefort Therapeutics (LSE:ROQ) the Main Market listed biotech company focused on developing first in class medicines in the high value and high growth immunology and oncology markets, is pleased to announce that the Japan Patent Office has granted the patent for its Mesodermal Killer ("MK") cell therapy.

The granting of the MK cell patent by the Japan Patent Office follows the granting of the European patent announced on 2 September 2024, thereby expanding patent protection to the UK, EU and Japan.

Novel Cellular Immunology / Oncology Medicine

Mesodermal Killer cells are a novel therapeutic cell type developed from the pioneering work of Roquefort Therapeutics' non-executive director, Nobel Laureate, Professor Sir Martin Evans. MK cells display a novel immunophenotype^[i] and thus represent a new class of cell, which is confirmed by the granting of patents by the European Patent Office and the Japan Patent Office. The MK cells form an off-the-shelf (allogenic) cellular immunotherapy, with both a direct effect and the ability to recruit and activate Natural Killer ("NK") cells^[ii] to modulate an immune response in immunology and oncology indications.

Commercial Opportunity in Japan

There is a two-fold commercial significance to the granting of the MK cell patent in Japan. Firstly, the Japan patent enables the opportunity to licence the MK cells to Japan Big Pharma companies for the Japan market alone, where the Roquefort Therapeutics' Board has extensive experience of working and partnering (including with Big Pharma companies such as Daiichi Sankyo, Astellas and Chughai).

Secondly, the granted Japan patent allows the Company to access an accelerated route-to-market for promising cellular medicines in Japan. The accelerated designation not only speeds up drug development, but also the market approval (MAA) assessment. The attractive benefit package that this designation confers includes market approval granted based on Phase 1 and 2 clinical trials if safety is confirmed^[iii]. This may significantly increase the value of cellular medicines as this enables a cheaper and faster route to market.

Pre-Clinical Development

Since Roquefort Therapeutics acquired the MK cell program as part of the Oncogeni acquisition in 2022, the Company has tested the MK cells in combination with NK cells. MK cells were shown to activate Natural Killer cells and this activation produced up to a two-fold increase in NK efficacy, indicating the potential for MK + NK combination medicines in the high value difficult to treat immunology and oncology disease areas. The Company now plans to complete *in vivo* studies in preparation for a key value inflection point of initiating a clinical study. This clinical trial may utilise the favourable clinical trial and tax regimes in Japan and Australia to enable faster and cheaper routes to market.

Roquefort Therapeutics CEO Ajan Reginald commented:

"The granting of this Japan patent for MK cell therapy highlights both the quality of our intellectual property and the novelty of the MK cells together with the enhanced commercial opportunity in Japan. The granted patent creates the opportunity for the Company to out-license the MK cell rights for the territory of Japan to a Japanese Big Pharma company. Japan is the most sophisticated cell therapy market, with a high number of potential partners and an appealing accelerated pathway to market. The Roquefort Therapeutics Board has the personal experience and a strong network from completing deals with Japan Big Pharma. We have initiated these discussions and will update the market in due course"

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About Roquefort Therapeutics

Roquefort Therapeutics (LSE:ROQ) is a Main Market listed biotech company developing first in class drugs in the high value and high growth immunology and oncology markets prior to partnering or selling to big pharma.

Roquefort Therapeutics' portfolio consists of five novel patent-protected pre-clinical anti-cancer medicines. The highly complementary profile of five best-in-class medicines consists of:

- Midkine antibodies with significant *in vivo* efficacy and toxicology studies;
- Midkine RNA therapeutics with novel anti-cancer gene editing action;
- Midkine mRNA therapeutics with novel anti-cancer approach;
- STAT-6 siRNA therapeutics targeting solid tumours with significant *in vivo* efficacy; and
- MK cell therapy with direct and NK cell-mediated anti-cancer action

For further information on Roquefort Therapeutics, please visit www.roquefortplc.com and @RoquefortTherap on X (formerly Twitter).

^[i] which is different from any other cell type including MSCs and includes expression of CD16, CD96, CD112, CD137L, FasL, TRAIL and CD277 and some NK cell

^[ii] L. Chapman, J. Abdi, S. Galvez-Peisl, A. Keating, Immunophenotypic and functional characterization of Mesodermal Killer (MK) cells: a novel cell type and potential cellular therapy for cancer Cytotherapy, Volume 22, Issue 5, Supplement, 2020, Page S121, ISSN 1465-3249, <https://doi.org/10.1016/j.jcyt.2020.03.226>.

^[iii] <https://www.tandfonline.com/doi/full/10.1080/14712598.2022.2093637#d1e2011>

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