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TheraCryf plc

("TheraCryf", the "Company" or the "Group")

Ox-1 Patent Grant and Positive Development Programme Update

Alderley Park, 4 September 2025 - TheraCryf plc (AIM: TCF), the clinical stage drug development company focussing on brain disorders, provides an update on key activity in its Ox-1 development programme.

Korean Patent Grant for Ox-1
The Company received a notification of a Decision to Grant a Patent for its Orexin-1R antagonist in addiction from the Korean Intellectual Property Office (KIPO). This grant complements TheraCryf's already broad coverage across the major commercial markets including US, EU and other Asian territories. The patent cover for this programme is composition of matter (CoM), the strongest form of patent cover available.

Additionally, the Company is pleased to report on significant development progress on the Orexin programme. The manufacturing campaign continues on-track and to-plan to produce multi kilogram quantities. An optimal formulation of the lead compound has recently been identified and, based on new data, the non-rodent species has been selected for the 28-day toxicity studies that will commence in early 2026.

Formulation
A number of potential Amorphous Solid Dispersions (ASD) of the lead compound were screened *in vitro* and the optimal formulation taken forward into an *in vivo* pharmacokinetics (PK) study. The chosen formulation has optimal features allowing for the utilisation of a straightforward drug-in-capsule drug delivery approach for first-in-human studies, and provides enhanced oral absorption and exposure, meaning less product will be required to achieve the blood levels needed for potential effectiveness.

Second preclinical species selection
The lead compound was tested *in vivo* in an alternative non-rodent species for the first time, where it exhibited highly favourable handling properties. This has enabled the confirmation of this species, which has comparability with human metabolism and is accepted by major regulatory agencies, for the 28-day repeated dose toxicity studies, data from which will form an essential element of the clinical trial application next year.

Dr Helen Kuhlman, COO of TheraCryf commented:
"Our Intellectual Property cover for all major territories for our lead programme in addiction is very nearly complete. We are also pleased that the key pre-clinical activities needed in our Ox-1 development programme before first-in-human trials can be initiated are progressing on-time and to-plan.

"We now have a tractable formulation for both animal and human use and our second toxicology species, as required by regulatory authorities, has been confirmed by new data showing appropriate handling of our Ox-1 lead compound in blood following oral administration.

"We anticipate updating the market over the coming weeks and months on further substantial progress. This will include completion of the 0.5 and 10kg scale manufacturing campaigns, further dose range finding studies to enable the initiation of the toxicology studies and the start and finish of the regulatory standard 28-day toxicology studies. We will also provide updates on the manufacture of bulk and capsule material to a standard acceptable for human administration, along with our interactions with appropriate regulatory agencies in preparation for our clinical trial application.

"In short, with this substantial recent progress we remain confident that we are on target to achieve the data required to support a clinical trial submission for this exciting programme according to the plan we have outlined."

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Enquiries

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About TheraCryf plc

TheraCryf is the clinical stage drug development company focussing on brain disorders. The Company has a broad clinical and preclinical pipeline in indications including addiction, anxiety, fatigue, narcolepsy, glioblastoma* and neurodevelopmental disorders [*orphan indication].

neurodevelopmental disorders (orphan indication).

The Company's strategy is to generate compelling data sets to preclinical and/or clinical proof of concept and partner its clinical programmes with mid-size to large pharma for larger trials and commercialisation. It also has a number of industry partnerships with companies, including Stalicla SA, in neurodevelopmental disorders. The Company has sourced know-how for programmes from companies such as Shire (now Takeda).

TheraCryf has worked with and has ongoing collaborations with major universities and hospitals such as the University of Manchester, La Sapienza (Università di Roma), the Erasmus Medical Centre, Rotterdam, Kings College London and the University of Michigan.

The Company has its headquarters and registered office at Alderley Park, Cheshire. It is quoted on AIM in London and trades under the ticker symbol TCF.

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