Job Title : Medical Director

OCTIMET Oncology NV is a company that acts as a translational accelerator, focusing on creating value for investors and patients by providing rapid clinical proof of concept for cancer therapies through innovative clinical development strategies and patient centered biomarker approaches. The current focus is on its clinical stage asset OMO-1, a highly selective small molecule MET inhibitor that will be developed with specific biomarkers. Due to emerging clinical data, we are currently looking to expand the number of trial sites to increase patient recruitment and reach our next clinical milestone.

In order to strengthen our team, we are currently looking for a **Medical Director**.

Minimum Requirements:

- Based in Beerse office, Belgium, at least 4 days a week
- Graduate of a recognized school of medicine with an M.D. degree or equivalent
- >5 years clinical research expertise in oncology therapy area, in designing, monitoring and implementing clinical trials and interpreting trial results
- Specialty training or board eligibility
- Significant leadership experience
- >5 years early phase drug development experience:
- A thorough understanding of pharmaceutical safety reporting and surveillance processes and biostatistics
- Translational research expertise, including experience in designing, monitoring, executing and interpreting first time in man clinical trials, with an understanding of the use of biomarkers
- Proven teamwork and collaboration skills
- Technical (medical and scientific) experience evaluating targets/agents for in -licensing or internal development
- Ability to travel nationally and internationally
- Organize and deliver Advisory Boards with international KOLs

Internal and External Contacts/Customers

- A member of the Clinical Project Team
- Strong worldwide external awareness, good scientific and external decision-maker-networks
- Regulatory and Pricing/value awareness
- Credible in scientific and commercial environments

Reporting Relationship
Reports Directly to CMO

The Medical Director will have the following **responsibilities**:

Investigator Brochure (IB)

- Generation of first version and regular updating of clinical sections of IB

Trial Design

- Core member of study delivery team
- Generation of study design concept (SDC) and interpretation protocol design
- Write medical components of clinical study protocol (CSP)
- Introduction

- Background to drug/comparator/challenge agent
- Ensure safety monitoring as per patient risk management plan (PRMP)
- Write benefit/risk assessment for CSP
- Review other contributions to CSP
- Medical contribution to bid defence meetings, if relevant
- Incorporate feedback from these meetings
- Presentation of CSP to PI/clinical research organisation (CRO)

Conduct of trial

Prior to start

- Review study specific informed consent form (ICF)
- Prepare additional supporting documentation for independent ethics committee (IEC) and regulatory submissions
- Medical oversight of case record form (CRF) development
- Medical oversight of clinical study report (CSR) template development
- Presentation at Investigator and/or monitor meetings
- Contribution to statistical analysis plan (SAP)

During study

- Relationship with principle investigators (PIs)
- Ensure have regular review of emerging data
- AEs, laboratory data, ECG, vital signs, biomarker results
- Safety review committees
- Internal safety management team meetings
- Pre-safety evaluation and review meeting (SERM) discussion documents
- Dose escalation meetings (if relevant)
- Issue management
- internal and external information
- Protocol amendments and admin changes
- IEC and regulatory updates
- Contribution to SAP if not completed prior to study start

Data interpretation

- Review of draft data output
- Contribute to data interpretation meeting
- Identification of additional analyses

Reporting of trial

- Medical contribution to CSR
- Preparation of trial data for internal and external audiences and communications/publications

To apply, please send your current CV and salary expectation to:

Prof Glen Clack (CMO)

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