Case Study

tranScrip

Leveraging Phase I Data for a Novel Targeted Oncology Drug

Challenge

An EU-based biotech with a novel targeted oncology drug was facing significant challenges:

Ongoing Phase I Study:
- The SME was in the midst of its Phase I clinical trial.

Limited Internal Oncology Experience:
- The SME lacked substantial in-house expertise in oncology, making it difficult to interpret early-phase data and plan subsequent development stages.

Risk and Opportunity Management:
- There was a pressing need to maximise the potential of the drug while mitigating associated risks.

Solution

To address these challenges, tranScrip assembled a bespoke team to collaborate closely with the biotech's existing Chemistry, Manufacturing, and Controls (CMC) and non-clinical personnel. The tailored clinical team included:

Clinical Leader:
- To oversee the clinical development strategy.

Medical Oncologist:
- To provide expert oncology insights.

Safety Physician:
- To manage patient safety and adverse event reporting.

Biostatistics Expert:
- To handle data analysis and interpretation.

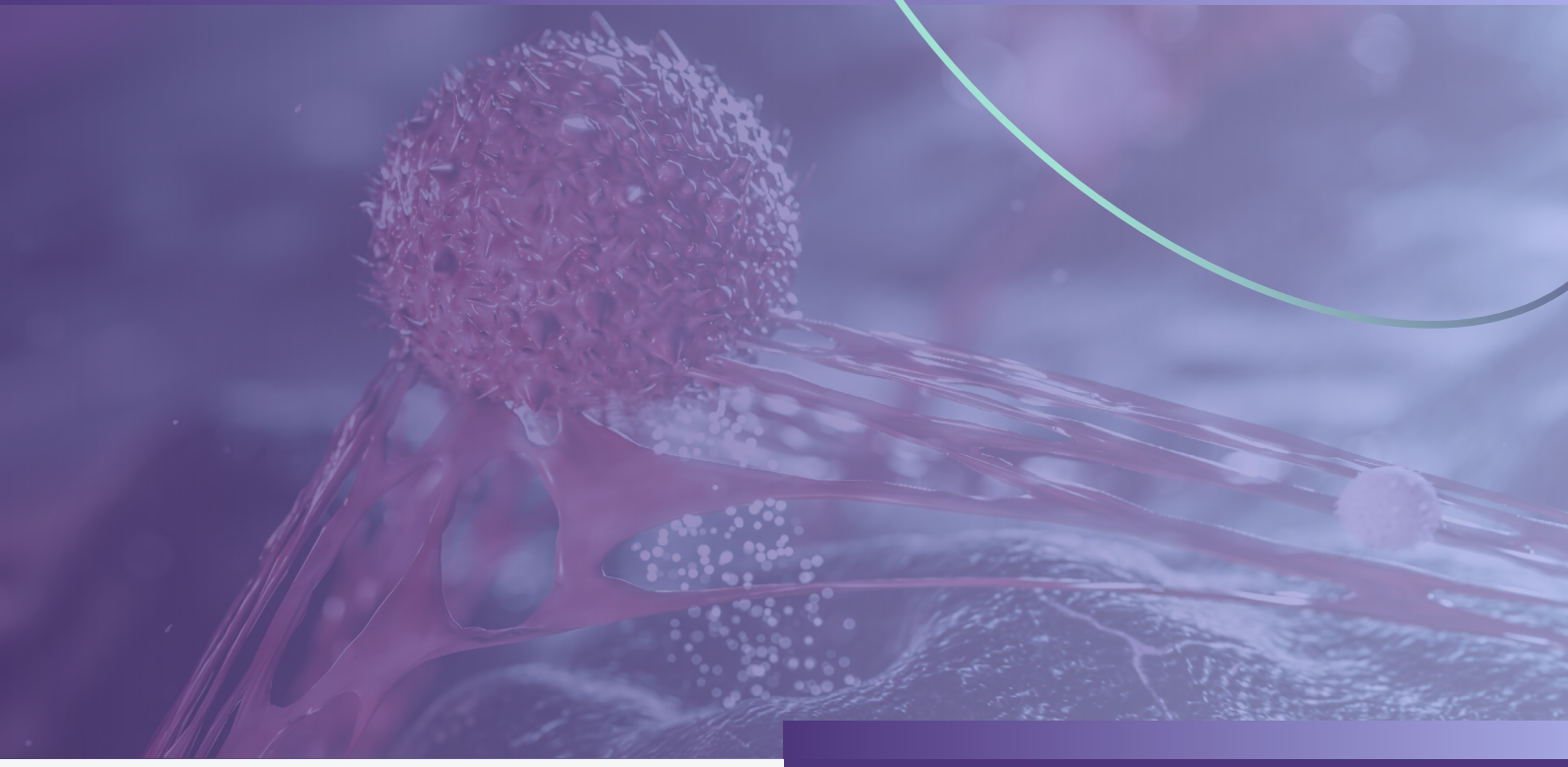
Regulatory Specialists:
- To navigate interactions with regulatory bodies.

Preclinical Immunologist:
- To bridge the gap between preclinical and clinical findings.

Medical Writers:
- To ensure accurate and regulatory-compliant documentation.

Medical Affairs Personnel:
- To prepare for market introduction and engagement with the medical community.

As the biotech achieved positive development milestones, they recruited additional internal staff, allowing for a gradual reduction in the external team's involvement.



Outcome

The collaboration led to the creation and implementation of a comprehensive and robust development programme, which included:

Interpretation and Reporting of Extended Phase I Data:

- **Publication of Findings:** The team ensured that the findings from the Phase I trial were published in a leading oncology journal, enhancing the drug's visibility in the scientific community.
- **Regulatory Interactions:** The team facilitated successful End-of-Phase I (EOPI) and End-of-Phase II (EOPII) meetings with both the FDA and CHMP, ensuring regulatory alignment and support for further development.

Design of Pivotal Study:

- **Synopsis and Full Protocol:** The team designed a detailed and scientifically robust pivotal study protocol, crucial for advancing to Phase II/III trials.

Steering for Pivotal Trial Implementation:

- **CRO Selection:** Assistance was provided in selecting and managing a Contract Research Organisation (CRO) to ensure high-quality and efficient trial execution.

Market Preparation for Launch:

- **Strategic Planning:** Comprehensive market preparation strategies were developed, including early engagement with key opinion leaders and potential commercial partners.

Support for Further Fundraising and Partnering:

- **Investor Relations:** The team supported the biotech in presenting the drug's potential to investors and partners, facilitating successful fundraising rounds and strategic partnerships.

Conclusion

Through the bespoke team provided by tranScrip, the EU biotech was able to effectively interpret and leverage Phase I data, laying a strong foundation for subsequent clinical trials and market introduction.

This collaboration not only mitigated risks associated with limited internal oncology expertise but also maximised the opportunity for the novel targeted oncology drug to succeed in the competitive pharmaceutical landscape.

Visit
transcrip-group.com

Email
info@transcrip-group.com