

PORTON



Enabling the Public's Early Access to Good Medicines

NEWSLETTER

March 2025

Porton Pharma Solutions Ltd.





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Technical Enabling

Facilitating PROTAC Drugs Development with Innovative Processes

Porton has extensive experience in research and manufacturing services, particularly in the field of PROTAC drug development. We've participated in the development of over ten PROTAC projects for various global clients, providing comprehensive, reliable, rapid, compliant, and one-stop services.

[Read more](#)

Preformulation Strategy- Inception to Completion

Drug discovery is an exceedingly complex process.

Once a new molecule is discovered, different physicochemical properties of the drug substance must be investigated and characterized. This scientific approach is referred to as Preformulation studies.

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Case Study

Facilitating PROTAC Drugs Development with Innovative Processes

CASE STUDY

Introduction

The PROTAC technology, through an innovative mechanism of "degradation rather than inhibition," provides a new pathway for targeting traditionally undruggable proteins and addressing resistance issues. Although it still faces challenges in drug design and delivery, its clinical potential in areas such as cancer and autoimmune diseases has driven pharmaceutical companies worldwide to accelerate their investment in this field in the future. It is expected to become a pivotal breakthrough direction in small molecule drug development. By 2025, nearly 40 PROTAC drugs are anticipated to enter clinical trials, with indications covering cancers (such as breast and prostate cancer), autoimmune diseases, and neurodegenerative disorders. However, as a class of novel API molecules, PROTACs are characterized by large molecular weight and numerous functional groups. The presence of poorly soluble aromatic heterocycles and flexible linker structures that hinder crystallization further complicates these molecules, leading to challenges such as long synthetic routes, complex compatibility and selectivity among functional groups, as well as difficulties in purifying intermediates and final APIs through crystallization. These challenges pose new questions for the development of PROTAC drugs and CMC teams.

reliable, rapid, compliant, and one-stop services. From R&D to delivery, we meet clients' supply chain needs and support the commercial success of their projects.

- Clinical Stage: IND/Phase I to Phase II
- Synthesis Steps: 5 GMP chemical steps
- Production Scale: 50 kg

Project Background

To respond to the rapidly changing market demands, the client needs to swiftly advance a PROTAC innovative drug product through IND registration while facing challenges such as immature processes, difficulties in scale-up, and insufficient impurity control. As a CDMO company serving global innovative drugs, Porton has extensive experience in research and manufacturing services, particularly in the field of PROTAC drug development. We've participated in the development of over ten PROTAC projects for various global clients, providing comprehensive,

A CUSTOMER-CENTRIC, INNOVATIVE AND RELIABLE CDMO WITH GLOBAL SOLUTIONS



Preformulation Strategy- Inception to Completion

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WHITEPAPER

Drug discovery is an exceedingly complex process. Discovering a new chemical entity is in itself a huge accomplishment, which is often possible only after almost two decades of hard experimental work as well as advanced simulation efforts. Therefore, the next stage of the process, assessment of toxicity potential (NCE) are disqualified if the NCE shows a potential toxic effect, despite any possible therapeutic effect. Once the NCE is determined to be safe, the next goal is to ensure availability of the NCE at the site of action in vivo upon administration through an appropriate route. Once bioavailability is confirmed, therapeutic effect must be demonstrated. Practically speaking, these most important challenges require a NCE to undergo animal studies in before its administration into humans, where efficacy is measured. To summarize, a NCE can be deemed effective, safe and stable, if it possesses desirable physicochemical, pharmacokinetic, and pharmacodynamic properties thoroughly characterized by robust design of experiments. A NCE can then be deemed to be an active pharmaceutical ingredient (API). However, it is not yet a drug or therapy. Proper administration of API usually requires suitable pharmaceutical formulation: API bioavailability, stability, and pharmacokinetics all depend upon formulation. Preformulation studies occur concurrently with and inform this activity and involve a multidimensional approach at various stages during the drug product lifecycle. Knowledge of the pharmacology, toxicology, toxicokinetics, chemistry (solid state, medicinal, and analytical), clinical pharmacy, and pharmacokinetics are closely interrelated. The figure below shows activities usually performed step-wise during diverse stages of the drug product life cycle. The overall goal of preformulation studies can be divided into two parts: 1) Preforming a NCE to an API supported by knowledge of proper administration and dosing to the desired target in vivo by formulating practical drug products for animal, as well as, human studies; 2) Improving stability of the drug product by appropriate design and stabilization of the API both itself and its drug product toward environmental de-gradation while also completely characterizing the developed drug product.

Drug Product Lifecycle

Drug Discovery → Pre-clinical Studies → Clinical Studies → Commercialization/Post-Launch

Preformulation Studies

Identify an optimal formulation → Systemic Formulation for animal studies → Systemic Formulation for human studies → Create a formulation for commercialization

Systematic Preformulation

Identify an optimal formulation → Systemic Formulation for animal studies → Systemic Formulation for human studies → Create a formulation for commercialization

Clinical Preformulation

Identify an optimal formulation → Systemic Formulation for animal studies → Systemic Formulation for human studies → Create a formulation for commercialization

Commercialization/Post-Launch

Identify an optimal formulation → Systemic Formulation for animal studies → Systemic Formulation for human studies → Create a formulation for commercialization

Enabling the Public's Early Access to Good Medicines

Services & Solutions

Porton Advanced Announces Collaboration with Eureka Therapeutics to Accelerate T-Cell Therapy Development

March 19, 2025

Porton Advanced is pleased to announce its partnership with Eureka Therapeutics, Inc., a clinical-stage biotechnology company dedicated to developing novel T-cell therapies for both solid tumors and hematologic malignancies.

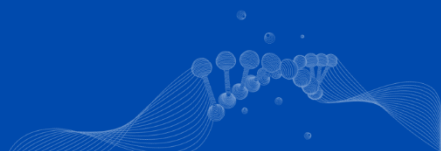
Following the successful technology establishment, Porton Advanced will continue to support Eureka's Investigator-Initiated Trials (IITs) by providing CAR-T manufacturing services that adhere to stringent quality standards. These studies, supported by Porton Advanced's end-to-end CDMO platform, are designed to generate critical data for subsequent clinical milestones to further advance Eureka's innovative T-cell therapies.

Porton Advanced has an extensive track record, cumulatively supporting over 60 ATMP Clinical, IND, and IIT projects in China, with orders exceeding 140 IIT batches and maintaining a flawless release success rate for all completed batches. This record highlights the company's consistent capability to meet high-quality manufacturing standards. Porton Advanced will use all the resources, experience, and skills at the company's disposal to ensure the success of Porton Advanced's collaboration with Eureka.

[Read more](#)

PORTON
ADVANCED

EUREKA
THERAPEUTICS



Porton Advanced Supports Immunofoco's Second IND Clearance from China's CDE for EpCAM CAR-T Therapy in Solid Tumors

March 21, 2025

Porton Advanced is delighted to congratulate our partner, Immunofoco, on receiving clearance from the Center for Drug Evaluation (CDE) under the National Medical Products Administration (NMPA) in China for its second Investigational New Drug (IND) application, with the acceptance number CXSL2400901.

Previously, IMC001 obtained IND approvals in both China and the United States in February 2024 for the treatment of EpCAM-positive advanced gastrointestinal tumors.

As Immunofoco's trusted CDMO partner, Porton Advanced provided comprehensive services for this project, including CAR-T cell process development, GMP manufacturing, and production of samples for Investigator-Initiated Trials (IIT). Additionally, we successfully executed site transfer and comparability studies, ensuring seamless technology transition. Notably, the entire process development phase was completed in under four months, followed by first-time-right success in process transfer, scale-up production, and IIT batch manufacturing – all batches met stringent cell quality standards.

[Read more](#)



Company Events

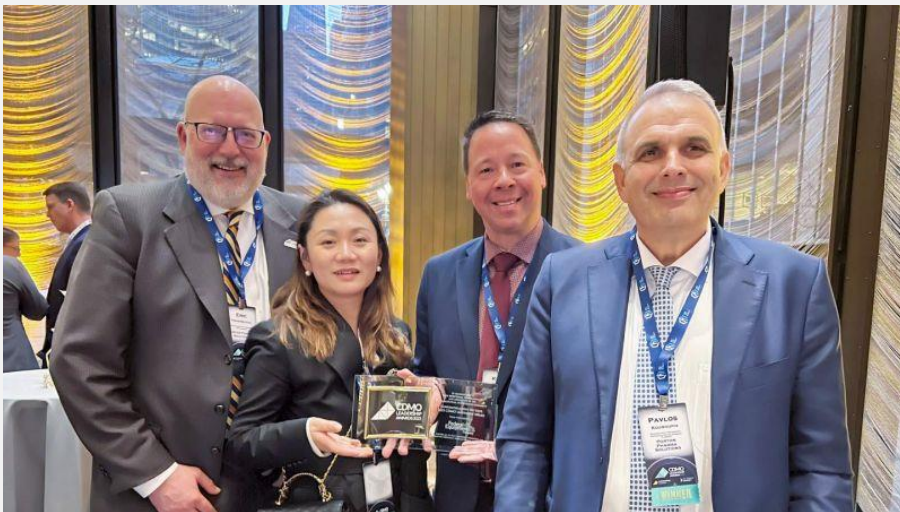
Porton Wins Outsourced Pharma 2025 CDMO Leadership Award

March 7, 2025

In March 2025, Porton Pharma Solutions Ltd. was presented with the prestigious "Global Small Molecule API Excellence Award" at the 14th Outsourced Pharma CDMO Leadership Summit, a testament to its comprehensive end-to-end capabilities spanning the entire drug development continuum—from discovery and manufacturing to commercialization.

Commemorating the company's 20th anniversary, this accolade underscores Porton's sustained technical innovation in small molecule active pharmaceutical ingredient (API) and drug product development, while reinforcing its position as a premier global CDMO partner through fully integrated service offerings.

By leveraging cutting-edge platforms and quality-by-design methodologies, Porton continues to deliver robust solutions that accelerate pharmaceutical innovation worldwide.



[Read more](#)

Porton's 2024 Annual Report Released

March 29, 2025

In 2024, we undertook a comprehensive management reassessment, navigating pressures and challenges with unwavering resolve while maintaining our commitment to continuous improvement. We advanced initiatives aligned with our four strategic pillars established at the start of the year: enhancing market expansion and order capture capabilities, driving cost optimization and efficiency improvements, strengthening governance and operational excellence of overseas subsidiaries, and leveraging ESG frameworks to foster sustainable growth.



[Read more](#)

ESG

Porton's Near-Term Target Validated by the SBTi

March 20, 2025

March 20, 2025, Porton Pharma Solutions announced that its near-term greenhouse gas emissions reductions targets have been formally validated by the Science Based Targets initiative (SBTi).

This milestone not only signifies its strategic breakthrough in climate governance, but also demonstrates that its decarbonization roadmap is aligned with the 1.5°C climate mitigation pathway.



[Read more](#)

Porton's 2024 ESG Report Released

March 31, 2025

Porton is committed to integrating sustainable development into its daily management and operations. Guided by its ESG concept of "Green Development, Promote Common Progress, Build a Healthy Society Together, and Enhance Corporate Governance," Porton continuously advances ESG management enhancements, actively addresses stakeholder concerns, strengthens material topics and key performance management, and supports the achievement of the United Nations Sustainable Development Goals (UN SDGs) through concrete actions.

Moving forward, we remain steadfast in our mission, enabling the public's access to good medicines, and look forward to collaborating with partners worldwide to advance global sustainable development.



[Read more](#)

Marketing Activities

Previous Events

2025 IBI EXPO

March 1-2

Suzhou China

The 9th Annual FTD Forum

March 14

San Diego

DCAT Week 2025

March 17-20

New York

ACS San Diego

March 26-27

San Diego



World ADC London

March 3-6

London UK

Bio-Europe Spring 2025

March 17-19

Milan Italy

2025 CMAC

March 18-20

Suzhou China



Upcoming Events

[Stay Updated on the Latest Developments, Click to Schedule Your Appointment](#)

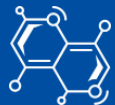
Events	Date	Venue	Booth
CPHI Japan 2025	April 9-11	Tokyo, Japan	5Q-18
Applied Pharmaceutical Chemistry 2025	April 10	Boston MA, United States	/
20th Annual Garnet E. Peck Symposium	April 10	West Lafayette, IN, United States	/
11 STILLE	April 26	Colorado State University, United States	/
Swiss Biotech Day	May 5-6	Basel, Switzerland	/
2nd ADC Linker & Conjugation Summit	May 6-8	Boston MA, United States	/
BIO Korea 2025	May 7-9	Seoul, Korea	J30
ASGCT Annual Meeting	May 13-17	Portland, United States	1448
Boston ABI Lab Lunch and Learn	May 15	Natick MA, United States	/
The Fifth China Gene & Cell Therapy Innovation Forum (CGCT 2025)	May 16-17	Shenzhen, China	/
CPhI Americas 2025	May 20-22	Pennsylvania Convention Center, Philadelphia, United States	405
API China 2025	May 21-23	Guangzhou, China	10.3H05

Customized Development and Manufacturing Technical Solutions for Conventional and New Drug Modalities

OEB 1 to 5

Sub-g to Metric-ton Scale

Pre-clinical to Commercial



Small
Molecules



Tides



Biologics and
Conjugates



Advanced Therapy
Medicinal Products

Operational Excellence

IP

QA

EHS

RA

PM

Supply Chain

Global Site Compliance



PORTON



A Customer Centric, Innovative, and Reliable CDMO with Global Solutions

Please contact us to help you on your next development project and achieve your business goals.



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