

310830-2026 - Direct award preannouncement

Denmark – Research services – Purchase of Formulation development and GMP manufacture of tablets for early clinical development

OJ S 87/2026 06/05/2026

Voluntary ex-ante transparency notice

Services - Supplies

1. Buyer

1.1. Buyer

Official name: Danmarks Tekniske Universitet - DTU

Email: piabl@dtu.dk

Legal type of the buyer: Body governed by public law

Activity of the contracting authority: Education

2. Procedure

2.1. Procedure

Title: Purchase of Formulation development and GMP manufacture of tablets for early clinical development

Description: DTU intends to purchase Formulation development and GMP manufacture of tablets for early clinical development from Porton Pharmaceutical Chemicals GmbH. The acquisition concerns specialized pharmaceutical development and manufacturing services required to enable a first-in-human clinical study within the Microbiome Health Initiative (MHI). The services include formulation development, analytical method development and validation, non-GMP and GMP manufacture of an oral solid dosage form (tablets), stability studies, and preparation of documentation to support regulatory submissions (IND/IMP). The work covers the full IND-enabling drug product package for a novel small-molecule compound within the bile acid class, intended for use in a Phase I human intervention study. The services are highly specialized, research- and development-driven, and closely linked to the specific and regulatory requirements of the project.

Procedure identifier: 5d948ed8-1f35-40c3-9b27-4eef3da5a5dc

Internal identifier: 10954

Type of procedure: Negotiated without prior call for competition

2.1.1. Purpose

Main nature of the contract: Services

Additional nature of the contract: Supplies

Main classification (cpv): 73110000 Research services

2.1.2. Place of performance

Anywhere

2.1.4. General information

Legal basis:

Directive 2014/24/EU

5. Lot

5.1. Lot: LOT-0000

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Internal identifier: 10954

5.1.1. Purpose

Main nature of the contract: Services

Additional nature of the contract: Supplies

Main classification (cpv): 73110000 Research services

5.1.2. Place of performance

Anywhere

5.1.6. General information

The procurement is covered by the Government Procurement Agreement (GPA): yes

5.1.16. Further information, mediation and review

Mediation organisation: Konkurrence- og Forbrugerstyrelsen

Review organisation: Klagenævnet for Udbud

Organisation providing more information on the review procedures: Danmarks Tekniske Universitet - DTU

6. Results

Value of all contracts awarded in this notice: 185 530,00 EUR

Direct award

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Justification for direct award: The contract can be provided only by a particular economic operator because of an absence of competition for technical reasons

Other justification: Prior to selecting Porton Pharmaceutical Chemicals GmbH, DTU Food carried out a targeted market assessment to identify potential suppliers capable of supporting the IND enabling activities required for this project. As part of this assessment, several CDMOs were approached in December 2025 and January 2026 for preliminary discussions on their general capabilities and interest in the scope. These included Eurofins CDMO, SGS Pharma, Seda, HWI Pharma Services GmbH, and Bioneer. The discussions were exploratory in nature and aimed at understanding overall technical fit and feasibility. Based on this assessment, Porton Pharmaceutical Chemicals GmbH was selected due to a combination of technical, practical, and project specific considerations. In particular, Porton demonstrated a clear and realistic approach to supporting an integrated scope covering formulation development of a delayed release oral tablet, non GMP and GMP manufacturing for early

phase clinical use, ICH compliant stability studies, and preparation of documentation relevant for IND/IMPD submissions. A key consideration for the project is the sourcing, handling, and processing of the active pharmaceutical ingredient, which presents specific technical and operational challenges. Porton presented a well defined and feasible strategy addressing this aspect, providing confidence in their ability to deliver the required services within the project timelines and budget. Furthermore, one of the partner institutions within the Microbiome Health Initiative has prior experience working with Porton on a comparable early phase development project, with positive outcomes. This experience, combined with DTU's internal expertise in pharmaceutical development and CDMO collaborations, supported the assessment that Porton represents a reliable and suitable supplier for this highly specialized service.

6.1. Result lot identifier: LOT-0000

6.1.2. Information about winners

Winner:

Official name: Porton Pharmaceutical Chemicals GmbH

Tender:

Tender identifier: 10954 - Purchase of Formulation development and GMP manufacture of tablets for early clinical development

Identifier of lot or group of lots: LOT-0000

Contract information:

Identifier of the contract: 10954 - Purchase of Formulation development and GMP manufacture of tablets for early clinical development

8. Organisations

8.1. ORG-0001

Official name: Danmarks Tekniske Universitet - DTU

Registration number: 30060946

Postal address: Anker Engelunds Vej 1

Town: Kgs. Lyngby

Postcode: 2800

Country subdivision (NUTS): Københavns omegn (DK012)

Country: Denmark

Contact point: Pia Blume

Email: piabl@dtu.dk

Telephone: +45 93511388

Internet address: <https://www.dtu.dk>

Buyer profile: <https://eu.eu-supply.com/ctm/company/companyinformation/index/165863>

Roles of this organisation:

Buyer

Organisation providing more information on the review procedures

8.1. ORG-0002

Official name: Klagenævnet for Udbud

Registration number: 37795526

Postal address: Nævnenes hus, Toldboden 2

Town: Viborg

Postcode: 8800

Country subdivision (NUTS): Østjylland (DK042)

Country: Denmark

Email: kfu@erst.dk
Telephone: +45 35291000
Internet address: <http://www.kfu.dk>

Roles of this organisation:

Review organisation

8.1. ORG-0003

Official name: Konkurrence- og Forbrugerstyrelsen
Registration number: 10294819
Postal address: Carl Jacobsens Vej 35
Town: Valby
Postcode: 2500
Country subdivision (NUTS): Byen København (DK011)
Country: Denmark
Email: kfst@kfst.dk
Telephone: +45 41715000
Internet address: <http://www.kfst.dk>

Roles of this organisation:

Mediation organisation

8.1. ORG-0004

Official name: Porton Pharmaceutical Chemicals GmbH
Town: Lucern
Postcode: 6039
Country subdivision (NUTS): Luzern (CH061)
Country: Switzerland

Roles of this organisation:

Tenderer

Winner of these lots: LOT-0000

8.1. ORG-0005

Official name: Merzell Holding ASA
Registration number: 980921565
Postal address: Askekroken 11
Town: Oslo
Postcode: 0277
Country subdivision (NUTS): Oslo (NO081)
Country: Norway
Contact point: eSender
Email: publication@mercell.com
Telephone: +47 21018800
Fax: +47 21018801
Internet address: <http://mercell.com/>

Roles of this organisation:

TED eSender

Notice information

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