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| **OFFER FORM**  **APPENDIX 01 TO THE RFQ No. 16 12 2025 T** | | | | |
| Full Company Name: |  | | | |
| Registered Address: |  | | | |
| EU VAT no.: |  | | | |
| Person authorised to contact the Ordering Party: | | | | |
| Name and surname: |  | | | |
| Telephone numer: |  | | | |
| E-mail address: |  |  |  |  |

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| **Part 1 - the Efficacy and PK/PD studies in BRE cancer CDX model.**  CPV name and code: 73110000-6 Research services. | | |
| ­**Cell lines and animals**  The costs of *in vivo* studies after subcutaneous inoculation of **NCI-N87** cells into female immunodeficient mice (preferentially nude mice), age-matched, will be provided by the Contractor. Cells will be cultured by the Contractor before inoculation.   1. **PK/PD experiment in immunodeficient mice**   **1.1 Inoculation of the cells and randomization**  Cells will be inoculated subcutaneously into one flank of the mouse. Randomization of animals to experimental groups will be performed once the average tumor volume reaches ~150 mm3.  **1.2 Compounds and ADC administration**  The ADCs from group 5-7 will be provided by the Sponsor. Reference compound and antibody should be provided by the Contractor. Compound, ADC, antibody and vehicles will be administered intravenously (IV), twice weekly (BIW), for about 3 weeks. Option: once weekly (QW) dosing for about 3 weeks. The provisional plan of the experiment is presented in **Table 1**.  **Table 1**. The general plan of the efficacy experiment:   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Group** | **Compound** | **Dose mg/kg** | **Route** | **Schedule** | **Cell-line** | **Inoculation** | **Gender** | **Animal Number\*** | | 1 | Vehicle 1 | - | IV | BIW or QW | NCI-N87 | SC | F | 12 | | 2 | Ref compound 1 | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 12 | | 3 | Vehicle 2 | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 12 | | 4 | Antibody | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 12 | | 5 | Isotype ADC | - | IV | BIW or QW | NCI-N87 | SC | F | 12 | | 6 | ADC 1 | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 12 | | 7 | ADC 1 | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 12 |   Legend: IV – intra venous; QW– once weekly, BIW – twice a week; SC – subcutaneously  F – female; \*animal number per group after randomization.  **1.3 Evaluated parameters**  Clinical signs will be checked daily, body weight will be checked 2-3 times per week, and tumor volume will be measured two times per week. The Contractor should inform about the availability of the data during the study course and about the frequency of updates.  **1.4 Sample collection**  Survival blood sampling (for plasma preparation) within working hours from 6 mice/group will be performed after dose 1 (3 mice/group at 1h and 1 day; 3 mice/group at 3 days and 6 days) and dose 6 (3 mice/group at 1h and 1 day; 3 mice/group at 3 days and 6 days). Tumor sampling will be done within working hours from the remaining 6 mice/group at 48h after dose 1 (3 mice/group) and dose 3 (3 mice/group). Additionally, tumor sampling will be done at 48h after dose 6 (3 mice/group with survival blood sampling at 1h and day 1). Plasma leftovers and tumors will be frozen and sent to the Sponsor.  Option (QW): Survival blood sampling (for plasma preparation) within working hours from 6 mice/group will be performed after dose 1 and dose 3 (3 mice/group at 1h and 1 day; 3 mice/group at 3 days and 6 days). Tumor sampling will be done within working hours from the remaining 6 mice/group at 48h after dose 1 (3 mice/group) and dose 2 (3 mice/group). Additionally, tumor sampling will be done at 48h after dose 3 (3 mice/group with survival blood sampling at 1h and day 1). Plasma and tumors will be frozen and sent to the Sponsor.   * 1. **Shipment**   Samples will be stored at -80oC until shipment on dry ice to Sponsor, which must be organized as soon as possible after the experiment (within 5 working days after study completion). Shipment costs to Poland should be included in the quotation.  **1.7 Report**  Non-GLP study and report.  **2. Efficacy study in immunodeficient mice**  **2.1 Inoculation of the cells and randomization**  Cells will be inoculated subcutaneously into one flank of the mouse. Randomization of animals to experimental groups will be performed once the average tumor volume reaches ~100 mm3.  **2.2 Compounds and ADC administration**  The ADCs from group 7 -10 will be provided by the Sponsor together with formulation instructions. Reference compound, antibody and ADC should be provided by the Contractor. Compound, ADC, antibody and vehicles will be administered intravenously (IV), twice (BIW) weekly, for maximum 4 weeks. Option: once weekly (QW) dosing for maximum 4 weeks. The provisional plan of the experiment is presented in **Table 2**.  **Table 2**. The general plan of the PK/PD experiment:   |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Group** | **Compound** | **Dose mg/kg** | **Route** | **Schedule** | **Cell-line** | **Inoculation** | **Gender** | **Animal Number\*** | | 1 | Vehicle 1 | - | IV | BIW or QW | NCI-N87 | SC | F | 10 | | 2 | Ref ADC | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 10 | | 3 | Vehicle 2 | - | IV | BIW or QW | NCI-N87 | SC | F | 10 | | 4 | Ref Compound | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 10 | | 5 | Vehicle 3 | - | IV | BIW or QW | NCI-N87 | SC | F | 10 | | 6 | Antibody | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 10 | | 7 | Iso ADC | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 10 | | 8 | ADC 1 | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 10 | | 9 | ADC 1 | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 10 | | 10 | ADC 1 | Tbd | IV | BIW or QW | NCI-N87 | SC | F | 10 |   Legend: IV – intra venous; QW– once weekly, BIW – twice a week; SC – subcutaneously  F – female; \*animal number per group after randomization.  **2.3 Evaluated parameters**  Clinical signs will be checked daily starting from the treatment commencement, body weight will be checked 2-3 times per week, and tumor volume will be measured two times per week. The contractor should inform about the availability of the data during the study course and about the frequency of updates.  OPTION (Efficacy follow-up): The Sponsor anticipates the possibility of observing the tumors and body weight after completion of administration, approximately 2 weeks.   * 1. **Sample collection**   Terminal blood (plasma preparation) and tumor sampling in one timepoint (48h) after last dose (within working hours). Plasma and tumors will be frozen and sent to the Sponsor.   * 1. **Shipment**   Samples will be stored at -80oC until shipment on dry ice to Sponsor, which must be organized as soon as possible after the experiment (within 5 working days after study completion). Shipment costs to Poland should be included in the quotation.  **2.6 Report**  Non-GLP study and report.  \*\*\*   * Minimum contract volume: 0 PK/PD experiment in immunodeficient mice, 0 efficacy study in immunodeficient mice study. * Maximum contract volume: Up to 2 PK/PD experiment in immunodeficient mice, Up to 2 efficacy study in immunodeficient mice study. * The Ordering Party does not guarantee commissioning a minimum number of studies. The execution of individual studies will depend on the actual needs of the Ordering Party. * The study may be performed either BIW (twice-weekly) or QW (once-weekly), depending on the Ordering Party’s requirements. * Orders will be placed in parts, in the form of Purchase Orders issued throughout the duration of the contract. | | |
|  | **Reposnse** | **Comments** |
| **Does your organization confirm the ability to perform the work described in the scope?** | YES / NO |  |

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| **CONDITIONS FOR PARTICIPATION IN THE PROCEEDINGS** | **Reposnse** | **Comments** |
| **Experience with Tumor Model and Operational Capacity**  We hereby declare that:  - We have experience with relevant tumor models - we have worked with NCI-N87 tumor model, as demonstrated by the historical results on tumor growth kinetics of the NCI-N87 cell line (preferentially in female nude mice); and  - We have the operational capacity to conduct PK/PD studies and efficacy studies in parallel.  **Supporting Documents:** Historical results on tumor growth kinetics of NCI-N87 cell (preferentially in female nude mice). | YES / NO |  |
| **Country of Establishment and Place of Performance**  We declare that:  - Our registered office or place of business is located in:  a. a Member State of the European Union, or  b. a country that is a party to an international agreement currently in force with the European Union concerning public procurement, such as GPA, TCA, CETA, EFTA, or other applicable international agreements on public procurement concluded by the European Union.  - The contract will be executed within the territory of one of the above countries. | YES / NO | Country of Establishment: …  Place of Contract Performance: … |
| **No Grounds for Exclusion under National Security Regulations**  We declare that we are not subject to exclusion under Article 7(1) of the Act of 13 April 2022 on special solutions for counteracting support for aggression against Ukraine and serving the protection of national security (Journal of Laws, item 835)\* | YES / NO |  |
| **No Conflict of Interest**  I confirm that there are no personal or financial ties or other relationships between our organization and the Ordering Party that could be deemed a conflict of interest as defined in the procedure\*\* | YES / NO |  |

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| **PRICING**   * The study may be performed either BIW (twice-weekly) or QW (once-weekly), depending on the Ordering Party’s requirements. * Net Price for evaluation will be calculated using the maximum contract volume and the BIW unit price, regardless of the actual number of studies commissioned. * If the price is expressed as a range, the higher value will be used for evaluation purposes. * The offered price must include all costs associated with the service, including shipment to Poland. | | | | |
| **Study Type** | **Cell line** | **Schedule (BIW/QW/Option)** | **Unit Price (Currency)** | **Cost breakdown\*\*\*** |
| PK/PD experiment in immunodeficient mice | NCI-N87 | QW |  |  |
| PK/PD experiment in immunodeficient mice | NCI-N87 | BIW |  |  |
| Efficacy study in immunodeficient mice | NCI-N87 | QW |  |  |
| Efficacy study in immunodeficient mice | NCI-N87 | BIW |  |  |
|  |  |  |  |  |
| OPTION – Efficacy follow-up | NCI-N87 | post-administration observation (~2 weeks) |  |  |

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| **Net Price for** **Evaluation**  **(BIW Unit Price for PK/PD × 2) + (BIW Unit Price for Efficacy × 2) =** |  |

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| **Payment Terms:** | Payment period for invoices of not less than **30 calendar days**.  *The payment period is an admission condition, offers indicating a shorter payment deadline will be rejected.* |
| **Turnaround Time:** | By the end of **Q1 2026**.  *Turnaround time is an admission condition, offers indicating a longer completion deadline will be rejected.* |
| **Contract term:** | The deadline for completion of the contract is **31st March 2026**.  In the event of an extension of the Project completion date, the contract may be prolonged in accordance with changes to the Project's co-financing agreement. |
| **Shipment of Samples After Experiment Completion:** | within 5 working days after study completion.  This period covers the preparation of all samples, their proper storage and the arrangement and dispatch of the shipment to the Ordering Party, including obtaining a tracking number. |
| **Validity of Offer:** | This offer is valid until **31st March 2026**. |

I declare that the information provided herein is true and complete. We accept the terms of participation and agree to be bound by confidentiality and compliance requirements.

**Name: Date:**

**Position: Company Stamp** *(if applicable):*

**Signature:**

*In accordance with the registration documents or a valid power of attorney. Acceptable forms of signature: qualified electronic signature, trusted signature (trusted profile), platforms such as DocuSign or AdobeSign, or scanned handwritten signature.*

\* The Bidder must not be subject to exclusion under Article 7(1) of the Act of 13 April 2022 on Special Measures to Counteract the Support of Aggression Against Ukraine and to Protect National Security (Journal of Laws, item 835). Pursuant to this article, the following entities are excluded from the procedure: an economic operator listed in the annexes to Council Regulation (EC) No 765/2006 of 18 May 2006 concerning restrictive measures in view of the situation in Belarus and the involvement of Belarus in the Russian aggression against Ukraine (Official Journal of the EU L 134 of 20.05.2006, p. 1, as amended), hereinafter referred to as "Regulation 765/2006", and Council Regulation (EU) No 269/2014 of 17 March 2014 on restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty, and independence of Ukraine (Official Journal of the EU L 78 of 17.03.2014, p. 6, as amended), hereinafter referred to as "Regulation 269/2014", or listed pursuant to a decision establishing inclusion on the list referred to in Article 1(3) of the aforementioned Act; an economic operator whose beneficial owner, as defined in the Act of 1 March 2018 on the Prevention of Money Laundering and Terrorist Financing (Journal of Laws of 2022, items 593 and 655), is a person listed in Regulation 765/2006 or Regulation 269/2014 or included on the national list as of 24 February 2022, provided such person has been listed pursuant to a decision referred to in Article 1(3) of the Act of 13 April 2022; and an economic operator whose parent entity, as defined in Article 3(1)(37) of the Accounting Act of 29 September 1994 (Journal of Laws of 2021, items 217, 2105, and 2106), is an entity listed in Regulation 765/2006 or Regulation 269/2014 or included on the national list as of 24 February 2022, provided such entity has been listed pursuant to a decision referred to in Article 1(3) of the aforementioned Act.

\*\* The Bidder must not be related to the Ordering Party either by capital or personal ties. This means there must be no mutual relationships between the Bidder and the Ordering Party, including any persons authorized to incur liabilities on behalf of the Ordering Party or involved in the preparation and conduct of the selection procedure. Capital or personal ties shall be understood as relationships including, in particular: participation in the same company as a partner in a civil law partnership or other personal partnership; holding at least 10% of shares or stocks in the same entity; serving as a member of a supervisory or management body, proxy, or attorney in the same entity; or being married, related by blood or affinity in a direct line, or in the second degree of kinship or affinity in a collateral line, or being in a relationship of adoption, custody, or guardianship.

\*\*\*The breakdown can be submitted either as a separate document or included directly in the offer form.