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| **EUnetHTA 21 Joint Scientific Consultation Secretariat**EUnetHTA21-JSC@g-ba.de | **Date:** Click to select date |

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| **EUnetHTA 21 Joint Scientific Consultation (JSC) Application Form** **EUnetHTA 21 1st Open Call (Nov 2021 – Dec 2021)** |

**Please fill in all the predefined fields as accurately as possible**

|  |  |
| --- | --- |
| **Unique Product Identifier** |   |
| **Substance** |
| * **INN** (if available)
 |   |
| * **Trade name** (if available)
 |   |
| * **Company product code**
 |   |
| **Description of the product & mechanism of the action** |    |
| **Type of product** | [ ]  Chemical [ ]  Generic [ ]  Antisense [ ]  NCE [ ]  Others[ ]  Bio(techno)logical [ ]  Classical biological: [ ]  Blood derived [ ]  Vaccine [ ]  Enzyme [ ]  Other biologicals [ ]  Recombinant DNA derived product: [ ]  Cytokine [ ]  Hormone [ ]  Monoclonal antibody [ ]  Vaccine [ ]  Transgene derived (animal/biopharm) [ ]  Other Recombinant [ ]  Similar biological [ ]  Nucleic acid-Based [ ]  DNA vaccine [ ]  Oncolytic virus[ ]  Advanced Therapy: [ ]  Gene therapy: [ ]  Autologous [ ]  Allogenic [ ]  Xenogenic [ ]  Somatic cell therapy: [ ]  Autologous [ ]  Allogenic [ ]  Xenogenic [ ]  Tissue-engineered product  [ ]  Autologous [ ]  Allogenic [ ]  Xenogenic[ ]  Therapeutic, Scientific, or Technical Innovation |
| **Is the product used together with a digital application?**  | [ ]  YES [ ]  NO If yes, please describe:  |
| **Is the product used together with a medical device or an *in vitro* diagnostic medical device?** | [ ]  YES [ ]  NO If yes, please describe:  |

Comments:

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| --- | --- |
| **Intended indication for the scope of the current JSC** |   |
| **Products with market authorization in similar indication** |   |
| **Products in development with similar indication** |   |
| **Application type EMA (anticipated):** | [ ]  Initial market application (IMA)[ ]  Extension of Indication (EoI)[ ]  Line Extension (LE)[ ]  First in class (FC)[ ]  Priority Medicine (PRIME)[ ]  Accelerated access (AC)[ ]  Orphan designation (OD)if current OD, please provide: OD number: EU/ Date: YYYY-MM-DD Indication for which OD has been granted:  |
| **Therapeutic field**  | [ ]  Cancer [ ]  HIV/AIDS [ ]  Diabetes[ ]  Neurodegenerative disorder [ ]  Viral disease[ ]  Autoimmune disease/dysfunction[ ]  Cardiovascular [ ]  Other |
| **ATC code** (broad or detailed if known) | Click to select. or detail here:  |

Comments**:**

|  |  |
| --- | --- |
| **Applicant** | **Company Name:** **Address:** **Country:**   |
| **Contact Person details** | **Title and Name:** **Direct Tel:** **Fax:** **Email:**  |
| **Alternate Contact Person details[[1]](#endnote-1)** | **Title and Name:** **Direct Tel:** **Fax:** **Email:**  |
| **Financial Contact Person details[[2]](#endnote-2)** | **Title and Name:** **Direct Tel:** **Fax:** **Email:**  |

Comments:

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| --- | --- |
| **Small and Medium Sized Enterprises (SME)** | [ ]  NO – N/A |
| [ ]  YES |
|  - SME Number:  |

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| **Consultant on behalf of Applicant** (if applicable) | Title and Name: Direct Tel: Fax: Email:  |
| **Contact Person details** | Title and Name: Direct Tel: Fax: Email:  |
| **Alternate Contact Person details** (if applicable) | Title and Name: Direct Tel: Fax: Email:  |
| **Letter of authorisation from applicant** | [ ]  NO (to be provided within 15 days)[ ]  YES (please attach) |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Aimed date of the draft Briefing Book ready for submission and deadline to receive final EUnetHTA 21 recommendations**(*please refer to the EUnetHTA 21 Joint Scientific Consultation procedure for the full timeline*) |

|  |  |  |
| --- | --- | --- |
| Please select (multiple choices possible) | Draft Briefing Book submission | EUnetHTA 21 final recommendation |
|[ ]  10 Jan 22 | 22 Apr 22 |
|[ ]  07 Feb 22 | 20 May 22 |
|[ ]  07 Mar 22 | 24 Jun 22 |
|[ ]  04 Apr 22 | 22 Jul 22 |
|[ ]  02 May 22 | 16 Sep 22 |

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Comments:

|  |  |
| --- | --- |
| **Clinical trial phase(s) for which JSC is requested** | [ ]  Phase I [ ]  Phase II [ ]  Phase III [ ]  Phase IVIf the clinical trial phase for which JSC is requested is not Phase III: Is a Phase III study planned: [ ]  YES [ ]  NOIf no, please explain why not:  |
| **Are the trial(s) for which advice is requested on-going?** | [ ]  YES [ ]  NOIf yes, please specify study registry/ID number:

|  |  |
| --- | --- |
| Study title | registry/ID-number |
|   |   |
|   |   |
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| **Does the product target an unmet need?** | [ ]  YES [ ]  NOIf yes, please describe:  |
| **Is the product the first in its class?** | [ ]  YES [ ]  NOIf yes, please describe:  |
| **Does the product have potential impact on patients, public health, or healthcare systems?** | [ ]  YES [ ]  NOIf yes, please describe:  |
| **Will the product have significant cross-border dimension?** | [ ]  YES [ ]  NOIf yes, please describe:  |
| **Will the product have a major Union-wide added value?** | [ ]  YES [ ]  NOIf yes, please describe:  |
| **Does the product address the union clinical research priorities?**  | [ ]  YES [ ]  NOIf yes, please describe:  |
| **Does the product target a life-threatening or chronically debilitating disease?** | [ ]  YES [ ]  NO If yes, please describe:  |
| **Can the product be considered breakthrough technology as defined below?[[3]](#endnote-3)** | [ ]  YES [ ]  NOIf yes, please specify why:  |
| **Summary of expected information (study phase, minimum information on PICO scheme) annexed[[4]](#endnote-4)** | [ ]  YES [ ]  NO |

Comments:

|  |  |
| --- | --- |
| **Other scientific advice (received or planned)** | EMA Scientific Advice: [ ]  NO [ ]  YES Date: Click to select datePrevious EUnetHTA Early Dialogue (ED)[ ]  NO [ ]  YES, ED-Number: Date: Click to select dateOther scientific advices with individual HTA bodies:  [ ]  NO / Not planned [ ]  YESWhich countries:  |

Comments:

|  |  |
| --- | --- |
| **Status of the product / pipeline** | [ ]  MA Granted in another indication[ ]  MA not yet granted[ ]  N/A |
| **Marketing Authorisation (MA) already granted in another indication** | Date of MA granting: Route of MA: [ ]  National Procedure[ ]  MRP/Decentralised Procedure[ ]  Centralised ProcedureSpecify in which indication:  |
| **MA not yet granted** | MA Application planned date: Route of MA planned: [ ]  National Procedure[ ]  MRP/Decentralised Procedure[ ]  Centralised Procedure (according to Reg. (EC) No 726/2004) |

Comments:

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| --- | --- |
| **Area of Advice** | Please briefly outline the scope/content of each question, for each area of advice following topic order proposed below:[ ]  Target Population: [ ]  Intervention: [ ]  Comparator choice: [ ]  Outcomes choice: [ ]  Study Design including statistical analysis method: [ ]  Post-Launch Evidence Generation (only in conjunction with request for pivotal trial): [ ]  Health Economics:  |

Comments:

**Important application submission instructions:**

1. Please send this form in Word format do not convert it into PDF.
2. The Application Form for Joint Scientific Consultation should be submitted to the EUnetHTA 21 JSC secretariat via E-Mail (EUnetHTA21-JSC@g-ba.de).
1. An additional alternate contact person is requested in case the main contact point is unavailable. All official correspondence will be sent to both contact persons. If a consultant is acting on behalf of the applicant, the alternate contact person details are not requested. [↑](#endnote-ref-1)
2. Please provide details of a contact person in case fees will have to be paid to some HTA bodies participating in the Joint Scientific Consultation. [↑](#endnote-ref-2)
3. Breakthrough technology: Preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint (could include impact on a surrogate or clinical intermediate endpoint or pharmacodynamic biomarker that strongly suggests the potential for a clinically meaningful effect on the underlying disease; improved safety profile or quality of life) or a substantial improvement in practicality or convenience of use or care pathways (organizational impact). [↑](#endnote-ref-3)
4. As available, a summary of expected information (study phase, high level design with minimum information on Population, Intervention, Comparator, Outcomes (PICO)) for the intended product and indication must be annexed when submitting the Application Form. [↑](#endnote-ref-4)