# Annex No. 5 – Offer Form

Bidder Information

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| --- | --- |
| Full company name |  |
| Registered office address |  |
| TIN (Tax Identification Number)/ National Court Register (KRS) number |  |
| Contact person (name, surname, position) |  |
| Phone / e-mail |  |
| Website (if applicable) |  |

## Offer

1. Request for Quotation (RFQ) number: .....................................................
2. Date of offer submission: .................................................................
3. Total net cost of Study A (Fasted) (PLN/EUR/USD): .........................................................
4. Total net cost of Study B (Fed) (PLN/EUR/USD): .........................................................
5. Payment terms: .................................................................
6. Total Study A implementation time: ..................... weeks
7. Total Study B implementation time: ..................... weeks

## Estimated Study A Timeline

- Time to receive approval from the Regulatory Authority (HA): ....................

- Time to receive approval from the Ethics Committee (EC) (if applicable): ............

- Proposed drug administration schedule: ...........................................

- Preliminary results delivery date: .....................................

- Draft Clinical Study Report (CSR) delivery date: .........................................................

## - Time of FPI - FPO - DB lock (total) [weeks] : .........................................................

## - Time of bioanalysis (total) [weeks] : .........................................................

## - Time of PK/Stats analysis (total) [weeks] : .........................................................

## - Time of CSR\* preparation & finalization (total) [weeks] : .........................................................

## \*including module 2.7.1 table 2.2, 4.1, 4.2, 4.3

## Estimated Study B Timeline

- Time to receive approval from the Regulatory Authority (HA): ....................

- Time to receive approval from the Ethics Committee (EC) (if applicable): ............

- Proposed drug administration schedule: ...........................................

- Preliminary results delivery date: .....................................

- Draft Clinical Study Report (CSR) delivery date: .........................................................

## - Time of FPI - FPO - DB lock (total) [weeks] : .........................................................

## - Time of bioanalysis (total) [weeks] : .........................................................

## - Time of PK/Stats analysis (total) [weeks] : .........................................................

## - Time of CSR\* preparation & finalization (total) [weeks] : .........................................................

## \*including module 2.7.1 table 2.2, 4.1, 4.2, 4.3

## Documents Required for Submission to HA and EC

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## Bidder’s Declaration

I hereby declare that the offer includes all activities specified in the Request for Quotation and has been prepared in accordance with the requirements of the Contracting Authority.

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Place, date Signature and stamp of the Bidder