

Seznam dokumentů – Iniciální podání
List of documents – Initial Submission

Protokol číslo / *Protocol Number*: J2N-MC-JZNX

EU identifikační číslo klinického hodnocení / *Clinical trial EU number*: 2024-515689-15-00

Název protokolu / *Protocol Title*: **Otevřená, randomizovaná studie fáze 2 hodnotící účinnost a bezpečnost 3 dávek pirtobrutinibu u účastníků s relabující nebo refrakterní chronickou lymfocytární leukemií /lymfomem z malých lymfocytů, kteří v minulosti obdrželi léčbu kovalentním inhibitorem Brutonovy tyrozinkinázy / A Study Evaluating the Efficacy and Safety of Pirtobrutinib in Participants with Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Who Previously Received Treatment with a Covalent Bruton Tyrosine Kinase Inhibitor**

Document name	Version	Date
Form section		
Cover Letter	1.0	07-Oct-24
Part I		
D1_Protocol synopsis_CZ_2024-515689-15-00_Redacted	a	24-Sep-24
D1_Protocol synopsis_CZ_2024-515689-15-00_Unapplied	a	24-Sep-24
D4_Patient facing documents_Dosing Diary_paper	1.0	30-Jul-24
Part II		
K1_Recruitment Arrangements Statement	1.0	15-Jul-24
K1_Recruitment and ICF Procedure	1.0	12-Sep-24
K2_List of sites	1.0	12-Sep-24
L1_SIS and ICF_JZNX_Main ICF_Redacted	1.0	12-Jul-24
L1_SIS and ICF_JZNX_Main ICF_Unapplied	1.0	12-Jul-24
L1_SIS and ICF_JZNX_DPA ICF	1.0	12-Jul-24
L2_Compensation Sheet	1.0	12-Sep-24
L2_Participant Welcome Letter	1.0	20-Jun-24
L2_Study Guide_Redacted	2.0	03-Sep-24
L2_Study Guide_Unapplied	2.0	03-Sep-24
L2_Visit Card	1.0	24-Jul-24
L2_Patient Information Card	2.0	02-Aug-23
M1_CV Investigator_Dr Martin Simkovic	1.0	16-Aug-24
M1_CV Investigator_Dr Martin Spacek	1.0	10-Sep-24
M1_CV Investigator_Prof Michael Doubek	1.0	03-Aug-24
M1_CV Investigator_Doc Jan Novak	1.0	12-Sep-24
M2_Financial Disclosure Form_Simkovic	1.0	11-Sep-24
M2_Financial Disclosure Form_Spacek	1.0	09-Sep-24
M2_Financial Disclosure Form_Doubek	1.0	09-Sep-24
M2_Financial Disclosure Form_Novak	1.0	12-Sep-24
N1_Site suitability form_VFN	1.0	10-Sep-24

N1_Site suitability form_FNHK	1.0	11-Sep-24
N1_Site suitability form_FN Brno	1.0	09-Sep-21
N1_Site suitability form_FNKV	1.0	12-Sep-24
O1_Trial participant insurance certificate	1.0	29-Aug-24
O2_Czech Insurance Policy	1.0	01-Jan-20
P1_Compensation and Financial Details	1.0	11-Sep-24
P2_Colpitts Clinical KYC letter	1.0	08-May-24
P2_Colpitts_Global Visa Card	1.0	27-Jun-24
P3_List of submitted documents	1.0	11-Oct-24
R1_Compliance on the collection and use of personal data	1.0	12-Sep-24
S1_Compliance on the collection use and storage of biological samples	1.0	02-Aug-24