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| **AMENDMENT NO. 1 TO CLINICAL TRIAL AGREEMENT concluded on 2 June 2016**  By and Among  **Masarykův onkologický ústav**, having a place of business at Žlutý kopec 7, Brno, zip code 656 53, Czech Republic, Identification number: 00209805, Tax identification number: CZ00209805, represented by prof. MUDr. Jan Žaloudík CSc., Director (the “**Provider**”), and  **XXXXXXXXX**, having an address at **XXXXXXXXX,** born **XXXXXXXXX** (the “**Investigator**”), and  **IQVIA RDS Czech Republic, s.r.o.**, having a place of business at Pernerova 691/42, 186 00 Prague 8, Karlín, Czech Republic, Identification number: 247 68 651, Tax Identification number: CZ247 68 651, formerly Quintiles Czech Republic, s.r.o. (“**IQVIA**”), and  **Merck KGaA**, having a place of business at Frankfurter Str. 250, Darmstadt, Germany, entered into the B Commercial Registry kept by the Common Court in Darmstadt under number HRB 6164 upon power of attorney represented by IQVIA RDS Czech Republic, s.r.o. (“**Sponsor**”)  is concluded on the date of execution of this Amendment No. 1 with the effective date as of its publication in the Register of Agreements (hereinafter “Effective Date”).  **WHEREAS**, Sponsor has requested the Provider and Investigator to conduct a clinical study entitled “*A Phase III open-label, multicenter trial of avelumab (MSB0010718C) as a third-line treatment of unresectable, recurrent, or metastatic gastric or gastroesophageal junction adenocarcinoma*” (hereinafter referred to as “Study” or “Clinical Trial”) according to Protocol No. **EMR 100070-008** (the "Protocol");  **WHEREAS**, Sponsor, IQVIA, Provider and Investigator entered into the clinical trial agreement on the 2 June 2016 (the “Agreement”); and  **WHEREAS**, Sponsor, IQVIA, Provider and Investigator wish to amend the Agreement effective the date of execution of this Amendment No. 1;  **NOW THEREFORE**, for other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the parties hereto agree as follows:   1. As of the Effective Date, Attachment A - Budget and payment schedule, the “**XXXXXXXXX**” of the Agreement is hereby deleted in its entirety and replaced with the following:   **XXXXXXXXX**   |  |  | | --- | --- | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  |  1. As of the Effective Date, Attachment A - Budget and payment schedule, the “**XXXXXXXXX**” of the Agreement is hereby deleted in its entirety and replaced with the following:   **XXXXXXXXX**   |  |  | | --- | --- | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  |  1. As of the Effective Date, Attachment A - Budget and payment schedule, the “**XXXXXXXXX**” of the Agreement is hereby deleted in its entirety and replaced with the following:   **XXXXXXXXX**   |  |  | | --- | --- | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  |  1. As of the Effective Date, Attachment A - Budget and payment schedule, the “**XXXXXXXXX**” of the Agreement is hereby deleted in its entirety and replaced with the following:   **XXXXXXXXX**   |  |  | | --- | --- | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  |   All other terms and conditions of the Agreement shall remain in full force.  The Parties agree that the visits, examinations and other services (the “services”) provided in the period beginning 20 September 2016 to effectiveness of this Amendment No. 1 will be paied in the amounts negotiated in this Amendment No. 1. The amount for such services, eventually the amount corresponding to difference between the cost for services agreed upon this Amendment No. 1 and the cost already paid is due in the next payment period following the conclusion of this Amendment No. 1.  5. CONTRACTS REGISTRY  Notwithstanding the foregoing, Provider, Sponsor and IQVIA hereby acknowledge that this Amendment shall be published together with the Agreement pursuant to Act no. 340/2015 Coll., on Agreements Register. As and between the Parties, Provider agrees to publish this Amendment together with the Agreement pursuant to the foregoing. Any information which constitutes trade secret of either Party is exempted from such publication. For the purposes of this Amendment and the Agreement, such trade secrets include, but are not limited to, Attachment A - Budget and payment schedule, minimum enrollment goal, expected number of Study subjects enrolled, the expected duration of the Study, Protocol and Certificate of Insurance. Furthermore, personal data of individuals are also exempt from such publication, unless they have been previously published in another public register. The Provider is obliged to publish this Amendment together with the Agreement in accordance with the article herein above. The Provider will inform IQVIA of publishing this Amendment together with the Agreement in the Agreements Register by designating the following email address: **XXXXXXXXX** as the email address to which a notification of publication in the Agreements register shall be sent. Should the Provider fail to publish this Amendment together with the Agreement within 5 working days from its full execution by all parties, it may be published by the IQVIA or Sponsor.  The estimated value of financial payment under this Amendment No.1 shall be approximately CZK 980 000.  IN WITNESS WHEREOF, the parties hereto have caused this Amendment No. 1 to be executed by their duly authorized representatives as of the date last signed below:  **IQVIA on behalf of the Sponsor**  Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Under a Power of Attorney IQVIA RDS Czech Republic, s.r.o.  25. 6. 2018  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **IQVIA**  Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Under a Power of Attorney IQVIA RDS Czech Republic, s.r.o.  25. 6. 2018  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Masarykův onkologický ústav**  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    29. 6. 2018  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **XXXXXXXXX**  Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_      29. 6. 2018  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **DODATEK Č. 1 KE SMLOUVĚ O KLINICKÉM HODNOCENÍ uzavřené dne 2. 6. 2016**  Mezi  **Masarykův onkologický ústav**, se sídlem Žlutý kopec 7, Brno, PSČ 656 53, Česká republika, Identifikační číslo: 00209805, Daňové identifikační číslo: CZ00209805, zastoupený prof. MUDr. Janem Žaloudíkem, CSc., ředitelem („**Poskytovatel**“), a  **XXXXXXXXX**, s adresou **XXXXXXXXX**, datum narození: **XXXXXXXXX** („**Zkoušející**“), a  **IQVIA RDS Czech Republic, s.r.o.**, se sídlem Pernerova 691/42, PSČ 186 00, Praha 8, Karlín, Česká republika, IČ: 247 68 651, DIČ: CZ247 68 651, dříve Quintiles Czech Republic, s.r.o.(„**IQVIA**“), a  **Merck KGaA**, se sídlem Frankfurter Str. 250, Darmstadt, Německo, zapsaný v části B Obchodního rejstříku vedeného Regionálním soudem v Darmstadtu pod č. HRB 6164, zastoupený na základě plné moci společností IQVIA RDS Czech Republic, s.r.o. („**Zadavatel**“)  se uzavírá ke dni podpisu tohoto Dodatku č. 1, a to s účinností ke dni jeho uveřejnění v registru smluv (dále označovaný jen jako „Den účinnosti“).  **VZHLEDEM K TOMU, ŽE** Zadavatel požádal poskytovatele a zkoušejícího, aby provedli klinické hodnocení nazvané **„***Otevřené multicentrické klinické hodnocení fáze III posuzující avelumab (MSB0010718C) jako léčbu třetí linie neresekovatelného recidivujícího nebo metastazujícího adenokarcinomu žaludku nebo gastroezofageální junkce*“ (dále jen „studie“ nebo „klinické hodnocení“) v souladu s Protokolem č. **EMR 100070-008** (dále označovaný jen jako „protokol“);  **VZHLEDEM K TOMU, ŽE** zadavatel, IQVIA, poskytovatel a zkoušející uzavřeli dne 2.6.2016 smlouvu o klinickém hodnocení (dále označovaná jen jako „Smlouva“); a  **VZHLEDEM K TOMU, ŽE** zadavatel, IQVIA, poskytovatel a zkoušející si přejí doplnit Smlouvu s účinností k datu podpisu tohoto Dodatku č. 1;  **PROTO NYNÍ,** vzhledem k dobré a hodnotné úplatě, jejíž obdržení a dostatečnost se tímto potvrzují, se smluvní strany tohoto Dodatku dohodly takto:  1. Ke Dni účinnosti tohoto Dodatku se tímto v Příloze A Smlouvy - Rozpočet a platební přehled v plném rozsahu vymazává tabulka „**XXXXXXXXX**“ a nahrazuje se následujícím zněním:  **XXXXXXXXX**   |  |  | | --- | --- | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  |   2. Ke Dni účinnosti tohoto Dodatku se tímto v Příloze A Smlouvy - Rozpočet a platební přehled v plném rozsahu vymazává tabulka „**XXXXXXXXX**“ a nahrazuje se následujícím zněním:  **XXXXXXXXX**   |  |  | | --- | --- | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  |   3. Ke Dni účinnosti tohoto Dodatku se tímto v Příloze A Smlouvy - Rozpočet a platební přehled v plném rozsahu vymazává tabulka „**XXXXXXXXX**“ a nahrazuje se následujícím zněním:  **XXXXXXXXX**   |  |  | | --- | --- | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  |   4. Ke Dni účinnosti tohoto Dodatku se tímto v Příloze A Smlouvy - Rozpočet a platební přehled v plném rozsahu vymazává tabulka „**XXXXXXXXX**“ a nahrazuje se následujícím zněním:  **XXXXXXXXX**   |  |  | | --- | --- | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  |   Všechny ostatní podmínky Smlouvy zůstávají v plné platnosti.  Smluvní strany se dále dohodly, že návštěvy, vyšetření a další služby (dále jen „služby) poskytnuté v době od 20. 9. 2016 do nabytí účinnosti tohoto Dodatku č. 1 budou hrazeny v cenách sjednaných tímto Dodatkem č. 1. Částka za takové služby, příp. částka odpovídající rozdílu mezi cenou za služby sjednanou tímto Dodatkem č. 1 a cenou již uhrazenou je splatná v nejbližším platebním obdobím následujícím po uzavření tohoto dodatku.  5. REGISTR SMLUV  Bez ohledu na výše uvedené, poskytovatel, zadavatel a IQVIA tímto berou na vědomí, že tento Dodatek bude zveřejněn společně se Smlouvou v souladu se zák. č. 340/2015, o registru smluv. Za zveřejnění dle předchozí věty odpovídá poskytovatel. Takovémuto zveřejnění nepodléhají ty údaje, které tvoří obchodní tajemství některé ze smluvních stran. Pro účely tohoto Dodatku a Smlouvy se obchodním tajemstvím rozumí zejména Příloha A Smlouvy - Rozpočet a platební přehled, minimální cílový počet zařazení, očekávaný zařazený počet subjektů, očekávaná délka trvání studie, protokol a osvědčení o pojištění. Dále nebudou takovémuto zveřejnění podléhat osobní údaje fyzických osob, ledaže jsou již zveřejněny v jiném veřejně přístupném registru. Za zveřejnění Dodatku a Smlouvy dle předchozího odstavce odpovídá poskytovatel. Poskytovatel vyrozumí IQVIA o zveřejnění Dodatku a Smlouvy v registru smluv tak, že ve formuláři používaném ke zveřejnění smlouvy zadá adresu **XXXXXXXXX** jako emailovou adresu, na kterou má být zaslána notifikace o uveřejnění. Není-li Dodatek společně se Smlouvou zveřejněn poskytovatelem ve lhůtě 5 pracovních dní od jeho podpisu všemi smluvními stranami, jsou k jejich zveřejnění oprávněni IQVIA či zadavatel.  Předpokládaná hodnota finančního plnění dle podmínek tohoto Dodatku č.1 činí přibližně 980 000 Kč.  NA DŮKAZ ČEHOŽ nechaly smluvní strany k poslednímu níže uvedenému datu tento Dodatek č. 1 podepsat svými řádně zmocněnými zástupci:  **IQVIA jménem zadavatele**  Podpis:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Na základě plné moci IQVIA RDS Czech Republic, s.r.o.  25. 6. 2018  Datum: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **IQVIA**  Podpis:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Na základě plné moci IQVIA RDS Czech Republic, s.r.o.  25. 6. 2018  Datum: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Masarykův onkologický ústav**  Podpis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    29. 6. 2018  Datum: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **XXXXXXXXX**  Podpis:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_      29. 6. 2018  Datum: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |