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2 STUDY SYNOPSIS

Names of Company: Gluck'Ipē"cpf "Gluck'Nf 0	RP F KXIF WCN"UWVF ["VCDNG"	*Hqt" P cvkqpcrl' Cwj qtkv{ " Wūg' Qpn{ +"
Name of Finished Product: Ngpxcvpkl"G92: 2+"qtcn'vcdrgu	T ghgtt kpi "q'Rctv'K"	
Name of Active Ingredient: Ngpxcvpkl"G92: 2+	Volume:	Page:

Study Title:	Rj cug"4.'O wmkēpvgt.'Qr gp/rēdgn'Ulpi rg'Cto "Vtkri'vq"Gxcnēvg'vj g'Uchgv{ 'cpf "Ghēce{ 'qh' Qtcn'G92: 2'lp'O gf wmt { 'cpf "Kf lpg/353'T gh tcevqt { .Wpt gugevcdrg'F khtg pvcvfg "Vj { tqkf " Ecpegtu.'Utcv'kēgf "d{ 'J ksqmji {
Investigators/ Sites:	O wmkēpvgt<"52'uksu'lp'vj g'WU.'Kcnf . 'Wpksgf 'Mlpi f qo . 'Cwutcrk. 'Rqmpf . 'cpf 'Hēcepe0'C" rku'qh'lp'xguki cvqtu'cpf 'uksu'ku'r tqxkf gf 'lp'Cr r gpf k'38060
Publications based on study:	<p>3+ Uj gto cp'U.'Lct cd'D.'Ecdeplmru'O . 'Nlēktc'N.'Rēcpk'H'O ctv'pu'T. 'gv'crl'0C'r j cug'K' vlcrl'qh'vj g'o wnk'cti gvgf 'h'p'cug'lpj kdkqt'G92: 2'lp'cf xcpegf 'tcf kqkf lpg'*TCK/ tgh tcevqt { 'f khtg pvcvfg 'vj { tqkf "ecpegt '*F VE+']cdutcev_0Rt gugpvcvqp'cv'vj g'69'vj " Co gtlecp'Uqelgv' 'qh'Erlpēcrl'Qpeqmi { 'C ppcwrl'O ggv'kpi =4233' Lxp'6/: =Ej leci q' *K#0 L'Erlp'Qpeqrl'04233-4; *Uwr r n=77250'</p> <p>4+ Uj gto cp'U.'Lct cd'D.'Ecdeplmru'O . 'Nlēktc'N.'Rēcpk'H'O ctv'pu'T. 'gv'crl'0C'r j cug'K' vlcrl'qh'vj g'o wnk'cti gvgf 'h'p'cug'lpj kdkqt'G92: 2'lp'cf xcpegf 'tcf kqkf lpg'*TCK/ tgh tcevqt { 'f khtg pvcvfg 'vj { tqkf "ecpegt '*F VE+']cdutcev_0Rt gugpvcvqp'cv'vj g'; vj " C ppcwrl'O ggv'kpi 'qh'Lcr cp'gug'Uqelgv' 'qh'O gf leci'Qpeqmi { =4233' Lwn'43/45= [qnqj co c' *Lcr cp=0'</p> <p>5+ Uj gto cp'U.'Lct cd'D.'Ecdeplmru'O . 'Nlēktc'N.'Rēcpk'H'O ctv'pu'T. 'gv'crl'0C'G92: 2" *Ngpxcvpkl+'lp' Cf xcpegf 'Tcf kqkf lpg'*TCK/T gh tcevqt { 'f khtg pvcvfg 'vj { tqkf "ecpegt '*F VE+=T guwru'qh'c'O wnk' Egpvgt 'Rj cug'K'v'lcrl'qt'crl' t gugpvcvqp_0Rt gugpvcvqp'cv' vj g'57'vj 'C ppcwrl'O ggv'kpi 'qh'vj g'Gwtqr gcp'Vj { tqkf 'Cuuqelcvqp=4233' Ugr '32/36= 'Mtcnqj '*Rqmpf +04233-QR230' j wr <leqpv'p'v'cti gt'eqo lRtqf wmgF Dlr tqf wmg'cur Av{r ?r f h' f qk? 552787"</p> <p>6+ Dcm'F Y . 'Uj gto cp'U.'Lct cd'D.'Ecdeplmru'O . 'Nlēktc'N.'Rēcpk'H'gv'crl'0C'r j cug'K'v'lcrl' qh'vj g'o wnk'cti gvgf 'h'p'cug'lpj kdkqt'ngpxcvpkl"G92: 2+lp'cf xcpegf 'tcf kqkf lpg" *TCK/tgh tcevqt { 'f khtg pvcvfg 'vj { tqkf "ecpegt '*F VE+<eqt'gr'v'qp'qh'v'g'co gpv' qweqo gu'y kj 'wo qt' i gpgv'e'cpcn'uku.'ugt'wo "dlqo ctngtu'cpf 'r j cto ceqmp'g'v'eu"]cdutcev_0Rt gugpvcvqp'cv'vj g': 3uv' C ppcwrl'O ggv'kpi 'qh'vj g'Co gtlecp'Vj { tqkf " Cuuqelcvqp=4233'Qev'48/52=lp' lcp'Y gmi' *EC-0Vj { tqkf 0'4233'Qev=43*3" Uwr r n=C8/90'</p> <p>7+ Dcm'F Y . 'Uj gto cp'UK'Lct cd'D.'Ecdeplmru'O G.'O ctv'pu'T. 'Uj cj 'O J . 'gv'crl'0 Ngpxcvpkl'v'g'co gpv'qh'cf xcpegf 'TCKtgh tcevqt { 'f khtg pvcvfg 'vj { tqkf "ecpegt '*F VE+<e{ qm'p'g'cpf 'cpi kqi gple' h'cevqt '*ECH+r tqh'k'kpi 'lp'eqo dl'p'cv'qp'y kj 'wo qt' i gpgv'e'cpcn'uku'v'q'k' gp'v'h'f 'o ctngtu'cuuqelcvfg 'y kj 't'gur qpug']cdutcev_0Rt gugpvcvqp' cv'vj g'4234' CUEQ' C ppcwrl'O ggv'kpi =4234' Lxp'3/7=Ej leci q' *K#0L'Erlp'Qpeqrl' 4234-52*Uwr r n=773: 0"</p> <p>8+ Uej nwo dgti gt'O . 'Lct cd'D.'Ecdeplmru'O G.'T qd'lp'p'q'p'D.'Rēcpk'H'Dcm'F Y . 'gv'crl'0C' r j cug'K'v'lcrl'qh'vj g'o wnk'cti gvgf 'h'p'cug'lpj kdkqt'ngpxcvpkl"G92: 2+lp'cf xcpegf " o gf wmt { 'vj { tqkf "ecpegt '*O VE+']cdutcev_0Rt gugpvcvqp'cv'vj g'6: vj "Co gtlecp' Uqelgv' 'qh'Erlpēcrl'Qpeqmi { 'C ppcwrl'O ggv'kpi =4234' Lxp'3/7=Ej leci q' *K#0L'Erlp' Qpeqrl'04234-52*Uwr r n=77: 30'</p>

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	<p>9+ Hwpcj cuj k[. 'Mcf qy cnk'V. 'Vqj {co c'Q. 'O wq'J . 'O cvk'g'le'O. 'Ucej f gx'R'gv'cnf' Ngpxcvkpd"t'gcv o gpv'qh'f k'htg'p'v'cn'j'j { tqkf "ecpegt" *F VE+<'Cpcn' uku'v'q'f'gp'v'h'f " dkqo ctngtu'cuuqek'v'g'f 'y kj 't'gur qpug'j'cdut'cev_0'Rt'gug'p'v'k'p'cv'v'j'g'93"U'cr'cp'gug" Ecpegt'Cuuqek'v'k'p'p'p'w'cn'O'gg'v'p'i . '4234'U'gr "3; /43=U'cr r'qtq. 'L'cr'cp'0' Ugg"Cr r'g'p'f'kz"380030'</p>
Study Period:	28'P'qx"422: "v"33'Cr t"4233"
Phase of Development:	Rj'cug"4"
Objectives:	<p>Primary Objective Kp"uwdlgeu'y kj "o gf wnt { "j { tqkf "ecpegt" *O VE+"qt "tcf k'q'k'f'k'p'g" *353 K/t'g'ht'cev'qt { l'it'g'uk'v'cp'v' f'k'ht'g'p'v'k'v'g'f 'j { tqkf "ecpegt" *F VE+"v'j'g'r't'k'o'c't { "q'd'l'g'e'v'x'g'u'y'g't'g'v'q'<"</p> <ul style="list-style-type: none"> • F'g'v't'o'k'p'g'v'j'g'g'h'g'e'v'q'h'ng'p'x'c'v'k'p'd"q'p'v'j'g'g'q'd'l'g'e'v'x'g'g't'g'ur'q'p'ug't'c'v'g' *QTT+'d'c'ug'f' "q'p' v'j'g'o'q'f'k'ht'g'f' "T'g'ur'q'p'ug' "G'x'c'w'c'v'k'p'p' "E't'k'g't'k' "U'q'rk' "V'wo'q't'u' *T'G'E'K'U'V+'d { "c'p' k'p'f'g'r'g'p'f'g'p'v'o'c'i'k'p'i 't'g'x'k'y' *K'K'+" • F'g'v't'o'k'p'g' "v'j'g" r'j'c't'o'c'e'q'n'p'g'v'e' " *R'M'+" r't'q'h'k'g' "c'p'f' "v'j'g" r'j'c't'o'c'e'q'n'p'g'v'e' l'r'j'c't'o'c'e'q'f { p'c'o'k'e' *R'M'IR'F+'t'g'r'v'k'p'uj'k'r'u'q'h'ng'p'x'c'v'k'p'd'0' <p>Secondary Objectives Kp" uwdlgeu" y kj " O VE" qt "tcf k'q'k'f'k'p'g" *353 K/t'g'ht'cev'qt { l'it'g'uk'v'cp'v' F VE." v'j'g'g'ue'q'p'f'c't { " q'd'l'g'e'v'x'g'u'y'g't'g'v'q'<"</p> <ul style="list-style-type: none"> • F'g'v't'o'k'p'g'v'j'g'g'h'g'e'v'q'h'ng'p'x'c'v'k'p'd"q'p'f'w't'c'v'k'p'q'h't'g'ur'q'p'ug'd { "v'j'g'K'K'+" • O'g'c'u'w't'g'v'j'g'g'h'g'e'v'q'h'ng'p'x'c'v'k'p'd"q'p'v'j'g'g'f'k'ug'c'ug' "e'q'p't'q'n't'c'v'g' *F'ET+'*e'q'o' r'ng'v' t'g'ur'q'p'ug' "J'ET_ "r'c't'v'c'n't'g'ur'q'p'ug' "J'RT_ "q't' 'u'c'd'r'g'f'k'ug'c'ug' "J'UF_+"c'p'f' "e'r'l'p'k'e'r'n'd'g'p'g'h'k' t'c'v'g' *E'DT+'*E'T. 'R'T. "c'p'f' "f'w't'c'd'r'g' "U'F_+"d { "K'K'+" • F'g'v't'o'k'p'g'v'j'g'v'o'g'v'q' "t'g'ur'q'p'ug'd { "K'K'+" • G'x'c'w'c'v'g'v'j'g'g'h'g'e'v'q'h'ng'p'x'c'v'k'p'd"q'p' "r't'q'i't'g'uk'q'p'/h't'g'g' "u'w't'x'k'c'n' "R'H'U_+"d { "K'K'+"c'p'f' q'x'g't'c'n'l'u'w't'x'k'c'n' *Q'U_+" • G'x'c'w'c'v'g'v'j'g'g'c'h'g'v' "c'p'f' "v'q'r'g't'c'd'k'k'v' { "q'h'ng'p'x'c'v'k'p'd" • C'u'g'u'u'v'j'g'g'k'p'h'w'p'eg' "q'h' "F'P'C' "u'g's'w'p'eg' "x'c't'k'c'p'u' "q'p' "o'g'v'c'd'q'r'l'e' "g'p'l { o'g'u' "c'p'f' v't'c'p'ur'q't'v'g't'u' "r'q'u'k'd'n' { "k'p'x'q'k'g'f' "k'p' "x'c't'k'c'd'k'k'v' { "q'h'ng'p'x'c'v'k'p'd" "R'M' "r'c't'c'o'g'v'g't'u' "d { " i'g'p'q'v' "r'k'p'i "u'w'd'l'g'e'v' "i'g'p'q'o'k'e' "F'P'C' "w'uk'p'i "v'j'g'g'c'h' { o'g'v't'k' "F'O'G'V' "c't't'c' { " • F'g'v't'o'k'p'g'v'j'g'g'd'k'q'e'j'g'o'l'c'e'd'i't'g'ur'q'p'ug' "w'uk'p'i "w'o'q't' "o'c't'ng't'u' *g'k'j'g't' "v'j' { t'q'i' "i'd'w'k'p' h'q't' "F'VE" "u'w'd'l'g'e'v' "q't' "e'c'r'e'k'q'p'l'p' "c'p'f' "e'c't' "e'l'p'q'g'o' "d't { p'l'e' "c'p'w'i'g'p' "J'E'G'C_ "h'q't' "O'VE" u'w'd'l'g'e'v'+" • C'u'g'u'u'v'j'g'g'h'g'e'v'q'h'u'q'o'c'v'e' "F'P'C' "u'g's'w'p'eg' "x'c't'k'c'p'u' "k'p' "D'T'C'H' "J' / . "M' "c'p'f' "P' / T'c'u' "c'p'f' "T'G'V'IR'VE'3. "4. "c'p'f' "5. "c'p'f' "i'g't'o' "h'p'g' "F'P'C' "u'g's'w'p'eg' "x'c't'k'c'p'u' "k'p' "T'G'V' "c'p'f' p'g'c't' "H'Q'Z'G'3' *t'u; 87735+'c'p'f' "P'M'Z'4/3' *t'u; 664: ; +'q'p' "u'w'd'l'g'e'v' "t'g'ur'q'p'ug' "v'j' "u'w'f' { " v't'g'c'v'o'g'p'v' " • K'p'x'g'w'k'i'c'v'g'v'j'g'r'q'g'p'v'c'n'l'e'q't't'g'r'v'k'p'q'h'v'j'g'h'q'm'y'k'p'i "d'k'q'o'c't'ng't'u'y'k'j' "g'h'h'e'c'e' { <" É U'g't'w'o' "r't'q'v'g'q'o'g'g'z'r't'g'uk'q'p' *e { v'q'n'k'p'g'c'p'f' "c'p'i'k'q'i'g'p'l'e' "h'c'e'v'q't' "J'E'c'h_+" É U'g't'w'o' "d'k'q'o'c't'ng't'u' "q'h' "c'r'q'r'v'q'u'k'u' *e'c'ur'c'ug' "5'9' "J'E'c'ur' "5'9_ "e { v'q'e'j' "t'q'o'g' "e' J'E { v'q'E_ "c'p'f' "O'52' "p'g'q'c'p'w'i'g'p' "J'O'52_±
Methodology:	<p>Vj'ku"y'cu'c'Rj'cug"4."o'w'k'e'g'p'v't."q'r'g'p'w'd'g'n' "u'k'p'i'ng'c'to' "u'w'f' { . "u'w'c'v'h'g'f' "d { "j'k'w'q'q'i' { " *F'VE' "q't' "O'VE+0'"</p> <p>Vj'ku' "u'w'f' { "e'q'p'v'c'k'p'g'f' "v'j'g'g' "R'j'c'ug' "v'j'g' "R't'g'v't'g'c'v'o'g'p'v' "R'j'c'ug. "v'j'g' "V't'g'c'v'o'g'p'v' "R'j'c'ug. "c'p'f' "v'j'g' " G'z'v'g'p'uk'q'p' "R'j'c'ug'0'"</p>

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	<p>Vj g "Pretreatment Phase" ruvgf "pq" nqpi gt "y cp" 4: "f c { u0 "kphqto gf "eqpugpv'y cu'qdvkpgf" cpf "r tqveqni'gri kdkk { "cpf "f kugcug" ej ctcevgtku'eu' y gt g' guvcdkij gf "r tkqt "vq" tgcvo gp0"</p> <p>Vj g "Treatment Phase" eqpukvgf "qh" c "Vtgcvo o gpv' Rgtkqf "cpf "c" Hq nny /wr "Rgtkqf 0" Vj g "Vtgcvo gpv' Rgtkqf "qh" y j g "Vtgcvo gpv' Rj cug" dgi cp "cv' y j g' vko g' y j g' v' y j g' hktu' uwdlgev' dgi cp uwf { "f twi "cf o kpkutcvkqp" cpf "gpf gf "cv' y j g' vko g' y j g' cm' uwdlgeu' gptqmgf "eqo r rvgvf "gki j v' e { ergu' qh' tgcvo gpv' qt "f kueqpvkpwgf "uwf { "tgcvo gpv' r tkqt "vq" y j g' gki j y j "e { erg0" Cm' uwdlgeu' y j gp' gpv' tgf "y j g' Gz v' p' ukqp "Rj cug 0"</p> <p>Vj g "Extension Phase" eqpukvgf "qh" c "Vtgcvo o gpv' Rgtkqf "cpf "c" Hq nny /wr "Rgtkqf 0" Vj g' Gz v' p' ukqp "Rj cug" dgi cp "cv' lo o gf kvgn' "chgt "y j g' Vtgcvo gpv' Rj cug" gpf gf "cpf "kpenw gf "cm' uwdlgeu' y j cv' y j g' gki j g' tkmitgeglkpi "tgcvo gpv' qt "kp' hq nny /wr 0"</p> <p>Kp' gki j g' y j g' Vtgcvo gpv' Rj cug "qt" Gz v' p' ukqp "Rj cug" y j g' uwdlgev' f kueqpvkpwgf "uwf { "f twi "cf o kpkutcvkqp" y j gp' qpg' qh' y j g' hq nny kpi "qewt gf < "f kugcug" r tqi tguukqp. "y j g' f gxgrq o gpv' qh' w' p' ceegr vcdrg' v' z' k' k' . "y j g' uwdlgeu' y j k' f tcy cni' qh' eqpugpv' hqt "r ctv' k' cvkqp "kp' y j g' uwf { . "qt "y j g' uwdlgeu' y j q' k' e' g' v' q' u' q' r "uwf { "tgcvo gpv' 0" Vj g' f kueqpvkpwgf "uwdlgev' j cf "c" Hkpcn' Xkukv' qt "Vgto k' p' cvkqp "Xkukv' 52" f c { u' hq nny kpi "h' k' p' ni' uwf { "f twi "cf o kpkutcvkqp. "cpf "y cu' hq nny gf "kp' y j g' Hq nny /wr "Rgtkqf "qh" y j g' Vtgcvo gpv' Rj cug "qt" Gz v' p' ukqp "Rj cug" f gr gpf kpi "qp" y j cv' r j cug "y j g' uwdlgev' y cu' kp' y j gp' f kueqpvkpwkqp "qewt gf 0" Vj g' uwdlgev' y j q' f kueqpvkpwgf "uwf { "tgcvo gpv' dghqt g' f kugcug" r tqi tguukqp" cpf "f k' "pqv' y k' f tcy "eqpugpv' eqpvkpwgf "vq" w' p' f' ti q' wo qt" cuuguo gpv' gxgt { "5" o qp' y u' unct' kpi "5" o qp' y u' h' qo "y j g' ruv' wo qt" cuuguo gpv' "cpf "eqpvkpwgf "w' p' k' i' f' qewo gpv' cvkqp "qh' f kugcug" r tqi tguukqp 0" Hqt "uwdlgeu' y j q' f kueqpvkpwgf "y k' j "r tqi tguukxg' f kugcug. "uwt' x' k' c' i' h' q' nny /wr "qewt gf "gxgt { "5" o qp' y u' h' q' t' y j g' hktu' 4" { gctv' qh' uwf { "tgcvo gpv' y j gp' gxgt { "8" o qp' y u' f' w' kpi "I gctv' 5" cpf "6. c' p' f" { gctv' y j g' g' chgt "w' p' k' i' uwdlgev' f' gc' y j "qewt gf 0"</p> <p>Vj g' vko g' qh' f' cv' ew' qh' h' q' t' y j g' r' t' k' o' ct { "uwf { "c' p' c' n' u' k' u' "qewt gf "y j gp' cm' uwdlgeu' gptqmgf "kp' y j g' uwf { "eqo r rvgvf "gki j v' e { ergu' qh' tgcvo gpv' qt "f kueqpvkpwgf "uwf { "tgcvo gpv' r tkqt "vq" y j g' gki j y j "e { erg0"</p>
<p>Number of Subjects (Planned and Enrolled):</p>	<p>Rrppgf < "cr r tqzlo cvgn' "326" uwdlgeu' "Gptqmgf "Uetggpgf + "384" uwdlgeu' "Vtgcvgf < "339" uwdlgeu' "7: 'F VE' uwdlgeu' cpf "7; 'O VE' uwdlgeu' +"</p>
<p>Diagnosis and Main Criteria for Inclusion and Exclusion:</p>	<p>Uwdlgeu' >= 3: "{ gctv' qh' ci g' y k' j "j k' v' q' ni' k' e' c' m' / "qt' e { v' q' ni' k' e' c' m' / eqphkto gf "f k' i' p' q' u' k' u' qh' gki j g' "F VE" qt "O VE" w' p' t' g' u' g' e' v' c' d' r' g' f kugcug' y j cv' y cu' p' q' v' co' g' p' c' d' r' g' v' q' u' w' i' g' t { "y k' j "gxk' f' g' p' e' g' qh' f kugcug" r tqi tguukqp "dcugf "qp" o qf k' h' e' f "TGEKUV" y k' j k' p' 34" o qp' y u' * 3" o qp' y "vq" cm' y "hqt" xctk' p' e' gu' k' p' uwdlgev' uecp' k' pi "k' p' v' t' x' c' n' u' r' t' k' q' t' vq" uwf { "gpv' { "y j g' g' v' g' r' i' k' d' r' g' vq" dg' gptqmgf "kp' y j k' u' uwf { 0"</p> <p>Inclusion criteria:</p> <p>30 Y k' j "j k' v' q' ni' k' e' c' m' / "qt' e { v' q' ni' k' e' c' m' / eqphkto gf "f k' i' p' q' u' k' u' qh' q' p' g' qh' y j g' hq nny kpi < "c0 F VE "k' p' e' n' w' k' pi "cp { "qh' y j g' hq nny kpi "uwdv' r gu< "</p> <ul style="list-style-type: none"> • Rcr k' n' c' t { "y j { tqk' "ec' p' e' g' t "RVE + " <ul style="list-style-type: none"> ▪ Hq n' l' e' w' r' t "xctk' p' v" ▪ Xctk' p' v " k' p' e' n' w' k' pi " dw' " p' q' v' r' k' o' k' s' g' f " vq' v' c' m' e' g' m' e' q' n' w' o' p' c' t " e' g' m' e' t' k' d' t' k' h' q' t' o / o' q' t' w' r' e' t. " u' q' r' k' . " q' z { r j k' n " Y c' t' v' j' k' p' a' v' r' i' n' g. " v' t' c' d' e' g' w' r' e' t. " wo' q' t' y k' j " p' q' f' w' r' t " h' c' u' e' k' k' u' r' i' n' g " u' t' q' o' c. " J A' t' v' j' r' g' e' g' n' i' x' c' t' k' e' p' v' qh' " r' c' r' k' n' c' t' { e' c' t' e' l' p' q' o' c. " r' q' q' t' n' f " f' k' h' e' t' g' p' v' c' v' g' f + " • Hq n' l' e' w' r' t "y j { tqk' "ec' p' e' g' t "HVE + " <ul style="list-style-type: none"> ▪ J A' t' v' j' r' g' e' g' n' i' ▪ E' r' g' c' t' e' g' m' i' ▪ K' p' u' w' r' t " <p>d0 O VE "</p> <p>40 Y k' j "o' g' c' u' w' t' c' d' r' g' f kugcug" o' g' g' v' k' pi "y j g' hq nny kpi "e' t' k' g' t' k' p' < "</p> <p>c0 C' v' r' g' c' u' v' q' p' g' n' g' u' k' p' * >= 30 "eo "kp' n' q' pi' g' u' v' f' k' o' g' y' t "JNF _ "hqt" p' q' p' n' o' r' j "p' q' f' g' u' c' p' f " >= 40 "eo "kp' NF "hqt" h' o' r' j "p' q' f' g' u' + " y j k' e' j "y cu' u' g' t' k' e' m' " cpf "c' e' e' w' t' c' v' g' n' o' g' c' u' w' t' c' d' r' g' " c' e' e' q' t' f' k' pi " vq" o' q' f' k' h' e' f " TGEKUV " w' u' k' pi " g' k' j' g' t' e' q' o' r' w' g' t' k' g' f "</p>

"

	<p>vqo qi tcr j { *EV+qt'o ci pgye'tguqpepeg'ko ci kpi *OTK"</p> <p>d0 Ngukqpu'y cv'j cf 'tgegkxg f "grgestqp'dgco "tcf kqj gtr { *GDTV+o wuv'j cxg'uj qy p"gxkf gpeg"qh'r tqi tguukxg"f kugcug"dcugf"qp"o qf kkgf "TGEKUV"vq"dg" f ggo gf "c'acti gv'ngukqp0"</p> <p>50 Y kj "gxkf gpeg"qh'f kugcug'r tqi tguukqp"d { "TGEKUV"vukpi "v'g'ukgøu'cuuguuo gpv'qh'E V'qt"OTKuecpu'y kj kp"34"o qpj u"*. 3"o qpj "vq'cmjy "hqt'xctkpegu'kp'uwdlgev'uecppkpi "kpvtxcnu+r'tkqt"vq'uwf { "gpvt { "</p> <p>60 Uwdlgeu'y kj "F VE"o wuv'j cxg'dggp"³⁵³Ktghtcevt { Itgukucpv'cu'f ghkpgf "d { "cv'ngcu'v'qpg'qh'v'g'hqmy kpi <"</p> <p>c0 Qpg'qt"o qtg"o gcuwcdng'ngukqpu'y cv'p'xgt" f go qpucv'g"³⁵³Kwr veng"qp"cp { "tcf kqkf kpg'uecp"dcugf"qp'gkj gt"eqmgev'f'uecpu'qt'tgr qtu"</p> <p>d0 Qpg'qt"o qtg"o gcuwcdng'ngukqpu'y kj "f kugcug'r tqi tguukqp"d { "TGEKUV"y kj kp"34"o qpj u"*. 3"o qpj "vq'cmjy "hqt'xctkpegu'kp'uwdlgev'uecppkpi "kpvtxcnu+qh"³⁵³Kj gtr { "f gur kg"³⁵³Kwr veng"qp"tcf kqkf kpg'uecp"dcugf"qp'ukg'cuuguuo gpv'qh'E V'qt"OTKuecpu"</p> <p>e0 Ewo wv'xg'cev'xk { "qh"³⁵³Kqh'@822"o Ek'qt"44"i ki cdgs wgtgnu"¶ Ds + "y kj "v'g'ruv'f'qug'cf o kpkngt'f'cv'ngcu'v'8"o qpj u'r'tkqt"vq'uwf { "gpvt { "</p> <p>70 Y kj "vptgugewcdng'f'kugcug0"Uwdlgeu'wuv'j cxg'pqv'dggp"co gpcdng'vq'uwti gt { 0"</p> <p>80 Uwdlgeu'y kj "F VE"o wuv'j cxg'dggp" tgegkxkpi "v'j { tqz'kpg'ur r tguukqp"v'j gtr { 0" Vj g'v'j { tqkf "uko wv'kpi "j qto qpg" *VUJ + "xcnøu'uj qwf "pqv'j cxg' dggp" grx'cv'g" *VUJ "uj qwf "j cxg'dggp"≤702"o ewlo N+0"Y j gp"v'qrg'cv'g" d { "v'j g'uwdlgev'v'j g'v'j { tqz'kpg'f'qug'uj qwf "j cxg'dggp"ej cpi gf "v'q'cej kxg"VUJ "ur r tguukqp" *VUJ ">202"o ewlo N+"cpf "v'j ku'f'qug'eqwf "j cxg'dggp"ej cpi gf "eqpewt'gpv' "w'qp'v'ct'kpi "ngpx'cv'kpd0"</p> <p>90 Y j q'f'k"pqv'j cxg'ej go qj gtr { . "o clqt"uwti gt { . "o qpqen'p'c'v'kdgf { "v'j gtr { . "qt"gzr gtlo gpv'v'j gtr { "y kj kp"v'j g"52" f c { u'r'tkqt"v'j g'v'ct'v'qh'ngpx'cv'kpd"cf o kpknt'cv'kpp" *8'y ggm" hqt"pktquv'w'gcu"qt"o kqo { ekp"E+0"J qy g'xgt. "r'tkqt"gzr quwt'g"v'q'tgeg'r'v'q't'v'f'qulpg"n'kpcug"kpj kdkqtu"cpf "cp'kpi kqi g'pke"ci gpv" *kpen'f'kpi "dw"pqv' rko kgf "v'q"CGG9: . "CI /235958."COI 928."C\ F4393."dgxcek wo cd."ER/769.854."f'cuc'v'kpd."gp cuc'v'kpd." lo cv'kpd" o gu'v'v'g." ngp'c'k'qo k'g." r'c qr'c'p'kd." uq't'ch'p'kd." uwp'k'k'p'kd." v'j c'k'f'qo k'g."xcv'c'p'kd"JRMØ: 9\ M'4447: 6."XGI H'v'ter."cpf \ F8696+y cu'cmjy gf "y kj "cv'ngcu'v'52" f c { u'd'gwy ggp"v'j ku'v'j gtr { "cpf "v'j g'v'ct'v'qh'ngpx'cv'kpd"v'g'cvo gpv0"</p> <p>: 0 Y kj "cm'ej go qj gtr { "qt'tcf k'v'k'p'p't'gr'v'g"v'qz'k'k'k'g'u't'gu'q'k'g"v'q">"I tcf g"4 "ugx'gt'k { . "gzegr v'ht"cm'r'g'ek"cpf "k'p'ht'v'k'k { "</p> <p>; 0 Rtkqt "v'j { tqkf gev'qo { "y cu'cmjy gf "</p> <p>320 Y kj "dm'q'f"r'tguw'g"v'j cv'y cu'y gm'eqp'v'qmgf "≤3621; 2"o o J i "cv'r'tgt'g'cvo gpv+y kj "qt"y kj qw'v'p'v'j { r'gt'v'p'uk'g"o gf k'ec'v'k'p'u"</p> <p>330 Y j q'y g'g"≥3: " { getu'q'f "</p> <p>340 Y kj "cp'G'cuy'g'p'Eqqr'g'v'c'x'g'Q'p'eq'mi { "I tqw " *GEQI +r'g'ht'qto c'peg'v'c'w'u'qh'2"v'q"4"</p> <p>350 Y j q"uki pgf "c'y tkw'gp "l'p'ht'qto gf "eqp'ug'p'v'r'tkqt"v'q"cp { "uwf { "ur'g'ek'k"e"r'tgt'g'cvo gpv'r'tq'eg'v'w'g'u'y kj "v'j g'v'p'f'g'tu'c'p'f'kpi "v'j cv'v'j g'uwdlgev'o c { "j cxg'y kj f'tcy p"eq'p'ug'p'v'v'cp { "ko g'y kj qw'r'tgl'w'f'k'eg"</p> <p>360 Y j q'y g'g'y k'k'k'pi "cpf "cdng"v'q'eqo r n { "y kj "v'j g'r'tq'v'eq'ni' w'k'f'g'r'k'p'gu'hqt"v'j g'f'v'c'v'k'p'p'qh'v'j g'uwf { 0"</p>
	<p>"</p> <p>Exclusion criteria:</p> <p>30' Cpcr'v'v'k'e"v'j { tqkf "ectel'p'qo c."v'j { tqkf "n { o r j qo c."o gug'pej { o c'ri'wo qtu'qh'v'j g'v'j { tqkf."o g'v'c'v'c'ug'u"v'j g'v'j { tqkf "</p> <p>40' Cp { "qh'v'j g'hqmy kpi "red'q'c'v'q't { "o gcuw'go gpv"<"</p> <p>c0 j go qi n'q'k'p">"; 'i f N*7(8"o o q'ni'N+*o c { "dg'eq't'g'ev'g'f'v'j kj "i tqy v'j "h'ce'v'q't"qt"v'c'p'u'w'k'p'u"</p> <p>d0 pgw't'q'r'j ku">"30" "32: N+r'v'v'g'v'u">"322" "32: N"</p> <p>e0 d'k'k'v'k'p' @30' "ko gu"v'j g" w'r r'g't' rko k'v'qh'p'qto c'ri' *WNP +cpf "q'v'j g't' r'k'x'g't' h'p'v'k'p'p'v'g'u" *CUV."CNV."cpf "c'nn'v'k'p'g"r'j qur'j c'v'c'ug+y kj "x'c'n'g'u"i t'g'c'v'g't'v'j cp"5"ko gu"v'j g'WNP " *k'p"v'j g'ecug"qh'h'k'g't" o g'v'c'v'c'ug'u' @7"ko gu"v'j g'WNP +0"K"i "c'm'v'k'p'g"r'j qur'j c'v'c'ug+y cu'i t'g'c'v'g't'v'j cp"5"ko gu"v'j g'WNP " *k'p"v'j g'cdug'peg'qh' r'k'x'g't"o g'v'c'v'c'ug'u"qt'i t'g'c'v'g't'v'j cp"7"ko gu"v'j g'WNP " *k'p"v'j g'r't'g'ug'peg'qh'h'k'g't"</p>

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	<p>o gvcucuku+ "cpf "vj g"uwdlgev'y cu"npqy p"vq"j cxg"dqpg"o gvcucuku."vj g"rxgt/ur gekhe"cmcrkpg'r j qur j cvcug"o wuv"j cxg"dggp"ugr ctevgf"ht qo "vj g"vqwn'cpf"vj g"rxgt"ur gekhe"cmcrkpg'r j qur j cvcug"crqpg"uj qwrf "j cxg"dggp"uwgf "vq"cuuguu"rxgt"hwpevkp0</p> <p>f0 etgcwkpkg'engctpeg">"82"o Nlo kp'r gt"vj g'Eqenetqhn'cpf"l cwn'hqto wrc""</p> <p>50' Uki plkecpv'ectf kqxcuewrt"lo r ckt o gpv"j kvqt { "qh'eppi gukxg"j gctv'hcwntg"@P gy [qtnl' J gctv' Cuqekvqp"]P [J C_ " Ercau'KK" wpuvdrng" cpi kpc" qt" o { qectf'ken' kphctevqp'y kj kp"8"o qpj u'qhi'uwf { 'uvtv"qt"ugt'kwu'ectf kce'cttj { vj o kc+"</p> <p>60' Cevxg"j go qr v'uku"dtki j v'tgf "dmqf "qh'cv'ngcu" 'v'gcur qqp+"lp"vj g"4: "f c{u'r tkqt"vq"uwf { "gpv { "</p> <p>70' Drggf kpi "qt"vj tqo dqve"l kuqtf gtu'qt"vug"qh'cp'leqci wcpw."uwej "cu'y cthctlp."y kj "c"vj gtr gwle"kpvt'pvcv'p'qto crk'gf "tevk" *K T+"</p> <p>80' Rqukkxg" j kvqt { " qh' J KX."cevx g" j gr cvkku" D"q t" cevxg" j gr cvkku" E"q t" ugxgt'g'hwpeqpv'qngf "lpvgtewt'gpv'kmpguu'qt"lphgevkp"</p> <p>90' Qti cp'cmqi tchm'tgs wtkpi "lo o wpuwr r tguukxg"t'gco gpv"</p> <p>: 0' Rtkqt"o crki pcpv { "qvj gt"vj cp'pqpo grrpgo c"unip"ecpegt"qt"egt'xlecn'ectekpgo c"lp"ukw"wp'guu"vj g'r tkqt"o crki pcpv { "y cu'f kci pqugf "cpf "f gh'pkkxgn' "t'gcvgf "≥7" { gctv r t'gxlqwu" "y kj "pq"uwdugs wgpv'g'xkf gpeg"qh't'gewt'gpeg"</p> <p>; 0' Dtcip"qt"nrg vqo gplki gcn' *egpvt'cn'p'gtxqwu"u{ungo "]EPU_+" o gvcucugu0"Uwdlgevu"y kj "uvcdrng"qt"r t'gxlqwu" "ktcf'k'v'gf "dtclp"o gvcucugu'y gt'g'cnq"gzemf gf 0"</p> <p>320' O ctngf "dcugr'p'g" r tq'qpi cvkqp"qh" S VIS Ve" kpvt'xcr" *S Ve" kpvt'xcr" ≥722" o uge+"wukpi "vj g" Hkf gtekc"o gj qf " *S Ve" ? " S VIT²⁶⁵ +"ht" S Ve"cp'cn' uku"</p> <p>330' I t'gcvgt"vj cp"3- " r tq'v'kw'p'w'le" qp" w'lp'g" f'kr ukem'v'gukpi "qt" @52" o i lf NO"Uwdlgevu"y kj " r tq'v'kw'p'w'le" @3- " qp" w'k'p'g" f'kr ukem'v'gukpi "y qwrf "j cxg"wpf'gti ppg"46/j qvt" w'lp'g"eqmgevkp"ht" s wcp'v'k'v'xg"cuuguu gpv'qh'r tq'v'kw'p'w'le"Uwdlgevu"y kj "46/j qvt" r tq'v'kw'p'w'le" ≥3"i 46"j qwtu'y gt'g'lp'g'ri kdrng0"</p> <p>340' J kvqt { "qh'i cut'q'lp'v'gukp'cn' o crduqtr v'k'p'qt"j cvkpi "wpf'gti ppg"uwti gt { "t'gs wtkpi" i cut'q'lp'v'gukp'cn'cp'cuqo qugu"y kj lp"6"y ggmi"qh'uvt'v'kpi "v j gtr { "qt"vj qug"y j q" j cxg"pqv't'geq'x'gt'f"ht qo "o clqt"uwti gt { "y kj lp"6"y ggmi"qh'uvt'v'kpi "vj gtr { "</p> <p>350' Y qo gp"y j q"y gt'g"r t'gi pcpv'qt"dt'g'cv'g'gf kpi =y qo gp"qh'ej k'f dgctkpi "r q'v'p'v'cn' y kj "c"r qukkxg"r t'gi pcpv { "v'g'v'c'v'r t'g'v'g'co gpv'qt"pq"r t'gi pcpv { "v'g'u0"Y qo gp"qh'ej k'f dgctkpi "r q'v'p'v'cn'wp'guu" *3+"uwti k'cm' "uvt'k'g'qt" *4+"wukpi "cf'gs w'v'g"o g'cuwt'gu' qh'eqp't'cegr v'k'p' *k'p'nmf kpi "y q"ht'o u"qh'e'q'p't'cegr v'k'p'."ppg"qh'y j lej "o wuv'd'g'c' d'ctt'kt"o gj qf "+"lp"vj g"qr'lp'k'p'qh'vj g"lp'x'g'uki cvqt0"Rgtko g'p'q'w'c'w'ny qo gp"o wuv' j cxg" dggp" co gp'q'tt'j'gle" hqt" cv' ngcu" 34"o qp'j u" vq" dg'e' q'p'k'f'gt'gf" qh' p'q'p'ej k'f dgctkpi "r q'v'p'v'cn'0" H'g't'v'k'g" o crgu"y kj "hgo crg"r ct'v'p'g'tu"y j q"y gt'g'p'q'v' y k'k'p'i "vq"uwg"eqp't'cegr v'k'p'qt"y j qug'hgo crg"r ct'v'p'g'tu'y gt'g'p'q'v'wukpi "cf'gs w'v'g" eqp't'cegr v'k'g'r tq'v'kw'p'w'le"y gt'g'gzemf gf 0"</p> <p>360' Qvj gt"uki plkecpv'f kugcug"qt" f kuqtf gt"vj cv"lp"vj g"lp'x'g'uki cvqt'au"qr'lp'k'p'."y qwrf "gzemf g"vj g"uwdlgev'ht qo "vj g'uwf { "</p> <p>370' R'g'x'k'q'w'u'ng'p'x'c'v'p'k'd"vj gtr { "</p> <p>380' R'g'x'k'q'w'u"t'g'co gpv' y kj "cp"lp'x'g'uki cvk'p'cn'f'f'w'i . "y kj "vj g"gzegr v'k'p'qh'vj qug" k'f g'p'v'k'g'f "lp" k'p'enuk'p' Etk'g't'k'p' %0." y kj lp"vj g"52" f c { u'r tkqt"vq"vj g"uvt'v'q h' ng'p'x'c'v'p'k'd"cf o k'p'k'v'c'v'k'p"</p> <p>390' J kvqt { "qh'creqj q'ruo . "f'w'i "cf'f'k'v'k'p'."r u'ej k'v'k'le"qt"r u'ej q'ri k'ec'n'eq'p' k'k'p'."qt" u'q'ek'cn'uk'w'c'v'k'p"y j lej . "lp"vj g"qr'lp'k'p'qh'vj g"lp'x'g'uki cvqt."y qwrf "lo r ckt"uwf { " eqo r r'k'p'eg"</p> <p>3: 0' Ngi cnl'p'ecr cekf 0</p>
<p>Test Treatment, Dose, Mode of Administration, and Batch Numbers:</p>	<p>Ngpxcv'p'k'd"y cu'cf o k'p'ngt'gf "lp"y q" f quci gu" f wtkpi "vj ku'uwf { 0" Ceeqtf kpi "vq"vj g"qt'ki k'p'cn' r tq'v'eqn"vj g" f quci g"y cu"ppg"32" o i "v'cd'ng"y k'g" f ckn' " *DKF +0" V'y q"uwdlgevu"y gt'g'v'g'cv'f "y kj "vj ku' f quci g0" Vj g" f quci g"y cu'ej cpi gf "vq"46" o i "q'p'eg" f ckn' " *S F +y j lej "eq'p'uk'v'gf"qh' v'q"32" o i "v'cd'ng"u'cpf "q'pg"6" o i "v'cd'ng" *Co g'p'f o gpv'23+0" C"v'q'wn'qh'337" uwdlgevu"y gt'g' v'g'cv'f "y kj "vj ku' f quci g0" "Ngpxcv'p'k'd"y cu' ugh'cf o k'p'ngt'gf " q'c'm' " d { " uwdlgevu0" Ugg " V'cd'ng"4" hqt"dc'vej "p'wo d'gtu0</p>

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Reference Therapy, Dose, Mode of Administration, and Batch Numbers:"	P qv'cr r ñecdrğ
Duration of Treatment:	Uwdlgew'y gtg"vtgcvgf "kp'v j g" Vtgcwo gpv' Rgtkqf "qh' vj g" Vtgcwo gpv' Rj cug" cpf " Gz vgpukqp Rj cug0" Vj g" uwdlgev' eqpłkpwgf "uwf { "vtgcwo gpv'wpłk'f kugcug" r tqi tguukqp. "f gxgrqr o gpv'qh' wpceegr vcdrg" vqzłeks{ . "f gcvj . "uwdlgew'u" y kj f tcy cñ'qh'e qpugpv' ltqo " r ctvłekr cvkqp "kp" vj g" uwf { . "qt' uwdlgew'u'ej qłeg'vq' uqr "uwf { "vtgcwo gpv0
Criteria for Evaluation:	<p>Efficacy:</p> <p>Tumor Assessments for Response Assessment:</p> <p>Tumor Assessments for Subjects with DTC: Rtgtgcwo gpv' wo qt "cuuguuo gpw' wulpi "EV"qh' vj g" pğemlej guvkdf qo gp'lr grklu" cpf "qj gt" ctgcu'qh' npqy p' f kugcug'qt' pgy n' "uwur gevğ f "f kugcug" y gtg" vj j cxcg' dggp" r gt hqto gf "y kj kp'6" y ggmu' r tkqt "vq" vj g' hktuv' f qug' qh' rğp xcvłkd" cf o kłkntcvkqp. "r tğtgcwo gpv' wo qt "cuuguuo gpw' wulpi "EV"qh' vj g" pğemlej guvkdf qo gp'lr grklu" cpf "qj gt" ctgcu'qh' vj g' ddf { "o c { "j cxcg' dggp" f qpg" y kj "O TKłpugcf "qh' EV. "dw' gxcnvcvqp" y cu' vj g' ej guv' y gtg" vj j cxcg' dggp" f qpg" y kj "EV0" E V" uecpu" y gtg" vj j cxcg' dggp" r gthqto gf "y kj "qtcr' cpf " kqf kpcvğf "kx0' eqpłcv' cpf "O TKuecpu" y kj "kx0' i cf qłkpkwo "ej grvğ" wprguu' vj gtg" y cu' c" o gf lecn' eqpłcv' kpcvğf "v' eqpłcv'0"</p> <p>Hqmjy /wr " wo qt "cuuguuo gpw' qh' vj g" pğemlej guvkdf qo gp' cpf "qj gt" ctgcu' qh' npqy p' f kugcug' cv' Rtgtgcwo gpv' qt' pgy n' "uwur gevğ f "f kugcug" y gtg" vj j cxcg' dggp" r gt hqto gf "qpeg' gxgt { "qj gt" e { eng' dgy ggp" F c { u'43" cpf "4: "qt' uqpgt "h' vj gtg' y cu' gxf gpeg' qh' r tqi tguukg' f kugcug" cpf "uj qwf" j cxcg' wklk' gf " vj g" uco g" o g'j qf qm' { "EV"qt" O TK" cpf " uecp' ces wklkqp" vğej pls wgu' "łpen' kpi "wug" qt' pqpwug" qh' kx0' eqpłcv' cu' y gtg' w ugf "hqt" vj g' Rtgtgcwo gpv' cuuguuo gpw'0" C" ej guv' z/ t c { "qt' ungrv' n' z/ t c { "v' cv' erçtn' "f go pu' tcvğf "c' pgy " o g' cv' v' k' r' g' ukqp" o c { "j cxcg' dggp" wugf "v' f qewo gpv' r tqi tguukqp "kp' r' kw' qh' vj g' EV" qt" O TK uecpu0"</p> <p>Vwo qt "cuuguuo gpv' cv' vj g' Hkpcn' Xkuk' y cu' qpn' "p geguuct { "h' p' qv' f qpg' y kj kp'6" y ggmu' qh' r' cu' v' wo qt "cuuguuo gpv'0</p> <p>EV" cpf "O TK ces wklkqp" i w' k' gr' p' gu' hqt' uwdlgew' y kj "F VE" y gtg' f g' v' k' k' f "kp' vj g' Vğej p' lecn' Ukg" O cpw' n' r' tqx' k' f "v' q" g' cej "ukg' d { "v' g" ko ci kpi "ETQ" f' guki p' cvğf "d { "v' g" ur' q' pu' qt" v' r' gthqto "v' j g' l' p' f' gr' p' f' gp' v' t' g' x' l' g' y "qh' vj g' wo qt "cuuguuo gpv'0</p> <p>Tumor Assessments for Subjects with MTC: Y kj kp'6" y ggmu' r tkqt "v' q" vj g' hktuv' f qug' qh' rğp' xcvłkd" cf o kłkntcvkqp. "r tğtgcwo gpv' wo qt "cuuguuo gpw' wulpi "EV"qh' vj g' pğemlej guv'lr grklu" cpf "qj gt" ctgcu'qh' npqy p' f kugcug'qt' pgy n' "uwur gevğ f "f kugcug" y gtg" vj j cxcg' dggp" r gt hqto gf "qpeg' gxgt { "qj gt" e { eng' dgy ggp" F c { u'43" cpf "4: "qt' uqpgt "h' vj gtg' y cu' gxf gpeg' qh' r tqi tguukg' f kugcug" cpf "uj qwf" j cxcg' wugf "v' g' uco g" o g'j qf qm' { "EV"qt" O TK" cpf " uecp' ces wklkqp" vğej pls wgu' "łpen' kpi "wug" qt' pqpwug" qh' kx0' eqpłcv' cu' y gtg' w ugf "hqt" vj g' r' tğtgcwo gpv' cuuguuo gpw'0" C" ej guv' z/ t c { "qt' ungrv' n' z/ t c { "v' cv' erçtn' "f go pu' tcvğf "c' pgy " o g' cv' v' k' r' g' ukqp" o c { "j cxcg' dggp" wugf "v' f qewo gpv' r tqi tguukqp "kp' r' kw' qh' vj g' EV" qt" O TK uecpu0"</p> <p>Hqmjy /wr " wo qt "cuuguuo gpw' qh' vj g" pğemlej guvkdf qo gp' cpf "qj gt" ctgcu' qh' npqy p' f kugcug' cv' Rtgtgcwo gpv' qt' pgy n' "uwur gevğ f "f kugcug" y gtg" vj j cxcg' dggp" r gt hqto gf "qpeg' gxgt { "qj gt" e { eng' dgy ggp" F c { u'43" cpf "4: "qt' uqpgt "h' vj gtg' y cu' gxf gpeg' qh' r tqi tguukg' f kugcug" cpf "uj qwf" j cxcg' wugf "v' g' uco g" o g'j qf qm' { "EV"qt" O TK" cpf " uecp' ces wklkqp" vğej pls wgu' "łpen' kpi "wug" qt' pqpwug" qh' kx0' eqpłcv' cu' y gtg' w ugf "hqt" vj g' r' tğtgcwo gpv' cuuguuo gpw'0" C" ej guv' z/ t c { "qt' ungrv' n' z/ t c { "v' cv' erçtn' "f go pu' tcvğf "c' pgy " o g' cv' v' k' r' g' ukqp" o c { "j cxcg' dggp" wugf "v' f qewo gpv' r tqi tguukqp "kp' r' kw' qh' vj g' EV" qt" O TK uecpu0"</p> <p>O TK y kj "cpf" y kj qw' eqpłcv' qt "EV"qh' vj g' cdf qo gp' y kj "v' k' r' g' r' j' cu' g" ko ci kpi "qh' vj g'</p>

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<p>rikg0"C"ej guv"z/tc{ "qt'u ngrgvn/z/tc{ "vj cv' ercni{ "f go qpucvxf "c"pgy "o gvcvke"ngukp o c{ 'j cxg'dggp'wugf "q'f qewo gpv'r tqi tguukp'lp'hgw'qh'j g'EV'qt "O TKuecpu0"</p> <p>Vvo qt "cuuguu gpv'cv'j g'Hkpcn'Xkuk'y cu'qpn{ 'p geguuct { "h'pqv'f ppg'y kj lp'6'y ggmi'qh'j g ruv'wo qt "cuuguu gpv0"</p> <p>EV'cpf "O TKces wukukp"i wkf grkpgu'htq "uwdlgeu'y kj "O VE'y gtg'f gvckgf "lp'j g'Vej plecn' Ukg"O cpwcn'r tqxf gf "v" gcej "ukg'd { "j g" lo ci lpi "ETQ'f guki pcvxf "d { "j g"ur qpuqt "v" r gthqto "j g'lpf gr gpf gpv'tgkgy "qh'j g'wo qt "cuuguu gpv0"</p> <p>For All Subjects: Vj g'r tghgtgf "v' r g'qh'tcf kqmi lecn'uecp'y cu'c'f lci pquve's wcnk{ 'ur kcn'qt "o wnkf gvgevt 'EV' uecp'y kj "k0'cpf "qten'eqvtcu0"Kk0'eqvtcu'y cu'eqvtckpf lecvgf . "j g'ej guv'gxcnvcv'kq' y cu'r gthqto gf "y kj "pqpeqvtcu'EV'cpf "j g'cdf qo gp lr grku'gxcnvcv'kq'f ppg'y kj "O TK' Dtclp"uecpu. "y j gtg'tgs wktgf . "y gtg'r gthqto gf "y kj "k0'eqvtcu'wukpi "gkj gt "O TK*y kj " i cf qnkpw "ej grv'eqvtcu'wrguu'j gtg'y cu'c'eqvtckpf lec'vq'v'j ku'v' r g'qh'eqvtcu'qt " EV0'Nqy "f qug'EV'uecpu" hqo "c'eqo dlpcv'kq' RGV/EV'uecppgt" y gtg'pqv'ceeg r vdrng' Wntcuw'pf "cpf "hwqtkp/3: /4/hwqtk/4/f gqz { /F/i meqg/r quktq" go kukp" vqo qi tcr j { " *HI /RGV+ "y gtg'pqv'v'j "j cxg" dggp" wugf "htq" tcf kqi tcr j le" wo qt "cuuguu gpv0" k'y cu" tgeqo o gpf gf "j cv' ur kcnlo wnkf gvgevt "EV" dg" r gthqto gf "y kj "c" ≤ "7" o o "eqvki vqwu" tgeqvtv'kq'cni qtkj o 0'K'dqf { "O TKuecpu'y gtg'r gthqto gf . "j g' { "y gtg'tgeqo o gpf gf "v" dg" f ppg" y kj "eqvki vqwu" urlegu'q h' ≤ "7" o o 0' "K'wde wcpqgw" o cuugu" qt "pqf gu" y gtg' r cr cdrng "g0 0'dwn { + "cpf "y gtg" cuuguudrg" d { "dqj "eriplecn'cpf "tcf kqi tcr j le" vej pls wgu." j g'tcf kqi tcr j le "EV" qt "O TK' vej pls w' y cu'v'j "j cxg" dggp" wugf "htq" j g' cuuguu gpv' qh' vti gv' cpf "pqpvti gv' ngukpu0" Cuuguu gpv' y cu' r gthqto gf "cv' j g' ukg" d { "cr r tqr tkvgn" s wcnk'gf "r gtuqppgn" tcf kqmi ku'lp' eqplwv'kq' y kj "eriplecn'kpxguki cvqt + "cpf "tguwuy" gtg' tgeqtf gf "qp' j g' cr r tqr tkv'g' ETH' r ci g* u0"</p> <p>"</p> <p>Target and Nontarget Lesions:</p> <p>Measurable Disease: Ceeqtf lpi "v'j g' qtki lpcn' TGEKUV'cpf " o qf kkgf " TGEKUV. "o gcuwcdrg" f kugcug' y cu' f ghkpf "d { "j g' r tgupeg'qh'cv'ngcu'v'pg'o gcuwcdrg'ngukp0"C"o gcuwcdrg'ngukp'ku'qpg'v' cv' eqwf "dg'ceewtcvgn" o gcuwgf "lp'cv'ngcu'v'pg'f ko gvt "cv'ngcu'32" o o "lp'NF" d { "ur kcn'EV' uecp" qt "cv'ngcu'42" o o "d { "ucpf ctf "EV" qt "O TK'vej pls wgu" qt "d { "eriplecn' o gcuwgo gpv0' Hqt" j ku' tlcn' cmuwdlgeu' y gtg' tgs wktgf "v'j" cxg'cv'ngcu'v'pg'ngukp" ≥ "30" eo "lp'NF" hqt' pqrn' o r j "pqf gu'cpf " ≥ "40" eo "lp'NF" hqt' n' o r j "pqf gu'v' cv' y gtg'ug' tcm { "cpf "ceewtcvgn" o gcuwcdrg' ceeqtf lpi "v'j" o qf kkgf " TGEKUV" wukpi "gkj gt "EV" qt "O TK" "Ngukpu" v' cv' j cf' tgegkxgf "GDTV" o wuv' j cxg' u'j qy p' gxf gpeg' qh' r tqi tguukg' f kugcug' dcugf "qp" o qf kkgf " TGEKUV" v' dg' f ggo gf "c'vti gv'ngukp0" K'c' ngukp' y cu'cuuguudrg" d { "dqj "tcf kqmi lecn'cpf " eriplecn' vej pls wgu. "tcf kqmi lecn' vej pls wgu" y gtg' v'j "j cxg" dggp' wugf 0' K'j g'o gcuwcdrg' ngukp' y cu'c' h' o r j "pqf g. "k' o wuv' j cxg' o gcuwgf "cv'ngcu'42" o o "lp'NF" 0' K'c' ukpi ng'ngukp' y cu'kf gpv' kkgf "cu'v'j g'vti gv'ngukp. "c'e' v'qmi lecn'qt" j ku'qmi lecn'eqpht o cv'kq' qh'v' { tqk' ectekpqo c'y cu'tgs wktgf 0"</p> <p>Vcti gv' ngukpu' y gtg'ug'v'v'g' q' p' v'j g' dcuku' qh' v'j g' uk' g' *NF + "cpf " v'j g' uk'cdk'k' "htq" ceewtcv' tgr gv'v'g' "o gcuwgo gpv0" Cni' o gcuwcdrg'ngukpu' w' "v'c' o czko wo "qh'7" ngukpu' r gt' qti cp' lukg' cpf "32" ngukpu' lp' v'cn' v' cv' y gtg' tgr tgupeg'v'k'g' qh' cni' lpxqk'gf "qti cp' lukgu' y gtg' kf gpv' kkgf . "o gcuwgf . "cpf "tgeqtf gf "cu'vti gv'ngukpu' qp' v'j g' cr r tqr tkv'g' dcugr'kpg' ETH' Vj g' uco g' ngukpu' y gtg' o gcuwgf "cpf "tgeqtf gf "cv'cn' h' qm' y /w' "ko g' r qkp' u0"</p> <p>Cm' q'j gt "ngukp' lukgu" qh' f kugcug' y gtg' kf gpv' kkgf "cu' pqpvti gv' f kugcug' . tgeqtf gf "qp" v'j g' dcugr'kpg' ETH' cpf " cuugu'f " cv'cn' h' qm' y /w' " ko g' r qkp' u" cu' opq' ej cpi glwcdrg. ö' ö'cdug'v'lf kucr r gctgf . ö' ö'wpgs w'xqecni' y qtug' lpi . ö' qt "ö' q'j gt "ur gekh' + ö' " Cp { "pgy "ngukpu' f gv'v'g' "tcf kqi tcr j lecn' y gtg' tgeqtf gf "qp' v'j g' cr r tqr tkv'g' pqpvti gv'ngukp' ETH' r ci g0"</p> <p>Clinically Evaluable Disease: Eriplecn' "gxcnvcv'ngukp' lukgu" qh' f kugcug' *wej "cu' r ngwcn' gh'wukp. "cuekgu. "ewcpgqwu"</p>

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	<p>n{ o r j cpi kku+ y gtg kf gpvklgf " cpf " tgeqtf gf " cu" pqpvti gv' ngukpu" qp" vj g" cr r tqr tkvg' dcugrkg"ETHO"O gcuwtgo gpv'qh'v' g'g'ngukpu'y gtg'p'qv'tgs wktgf "dw'v'j g{ 'y gtg'hqmy gf' cpf "tgeqtf gf "cu"öpq'ej c pi g luvdrö"öcdugp'v'f kuc r gctgf .ö"öwpgs w'k'qec'n'y qtuglpi .ö"qt öqj gt "ur gekh{ -ö"kp'v'j g'r quwtgcvo gpv'ETHO"C f f k'k'p'c'n'f . "vj g"cr r gctcpeg"qh'cp{ "pgy' erlplecm' "gxcnwdng'ngukpu'y cu'tgeqtf gf "qp'v'j g'r quwtgcvo gpv'ETHO"</p> <p>Bone Scan: C"r tgv'gvo gpv'dqpg"uecp"y cu'r gthqto gf "y kj kp"8"y ggmu'r tkqt"vq"cf o k'p'k'v'c'k'p'q'h'v'j g' hktuv'f qug'qh'ngpxc'v'p'kd0"Vj g'dqpg"uecp"y cu'tgr gcv'gf "g'xgt { "6'e{ ergu'dgw ggp'F c { u'43"cpf " 4: "cpf "cv'v'j g'H'p'c'n'X'k'k'v'p'rguu'c'uecp"y cu'q'v'c'k'p'g'f "rguu'v'j cp"38"y ggmu'r tkqt"vq"v'j g'H'p'c'n' X'k'k'v'0"C"dqpg"uecp"y cu'tgs wktgf "cv'v'j g"eqp'k'to cvqt { "v'o g'r q'k'p'v'k'p'c'm'iu'w'd'geu'y kj "ET" cpf "RT0"HF I "RGV" y cu'p'q'v'c'p'ceeg r v'cdng'cngt'p'v'k'xg"vq"v'j g'u'w'c'p'f'c'tf' ; ; o "v'gej p'g'v'k'wo r qn'r j qur j q'p'c'v'g"dqpg"uecp0" Y j q'rg"dqf { "O T K o c { "j c'x'g"dg'g'p"u'w'g'f "cu'c'p" cngt'p'c'v'g"vq' dqpg"uecpu'c'v'r tgv'gvo gpv'cpf "h'q'm'y /w "k'h"u'w'g'f "e'p'k'v'g'p'v'k'f "c'et'q'u'i'c'n'i't'g's w'k't'g'f "v'o g' r q'k'p'v'0"Dqpg"uecpu'y gtg'w'g'f "v'f'g'v'g'v'p'gy "dq'p { "ng'k'p'v'0"K'c'p'g'y "ng'k'p'v'c'r r g'c't'g'f "q'p'c' h'q'm'y /w "dqpg"uecp .k'v'y cu't'geqo o g'p'f'g'f "v'j c'v'z/tc { .E.V."qt"O T K d'g'w'g'f "v'j g'eqp'k'to "v'j g' o c'k'i'p'c'p'v'c'w'g'q'h'v'j g'p'gy "t'c'g't'w'v'c'ng'0"</p> <p>Evaluation of Tumor Response: Vvo qt" t'g'ur'q'p'ug" y cu'g'x' c'w'c'v'g'f " cv'v'j g" u'k'g'd { " s'w'c'n'k'k'g'f " r g'tu'q'p'p'g'i' *c" t'c'f'k'q'j'k'v' k'p' e'q'p'l'w'p'v'k'p'p"y kj "vj g'erlplecn'k'p'x'g'v'k'i'c'v'q't+'w'ul'p'i "o q'f'k'k'g'f "T'G'E'K'U'V'0"C'p" K'K"q'h"wo qt" t'g'ur'q'p'ug'u'y cu'c'n'q'r' g'th'q'to gf "d { "E'q't'g'r'c'd'R'c't'v'p'g'tu'0"t'g'ur'q'p'ug'u'y g't'g'c'u'g'u'g'f "c'ee'q't'f'k'p'i "v'q" o q'f'k'k'g'f "T'G'E'K'U'V .f'g'v'c'k'g'f "k'p'c'p"K'f'g'r'g'p'f'g'p'v'k'o'c'i'k'p'i "T'g'x'k'g'y "E'j'c't'v'g't .y j'k'ej "y cu'k'u'w'g'f r' t'k'q't "v'q"v'j g'u'c't'v'q'h'v'j g'k'p'f'g'r'g'p'f'g'p'v'k'g'v'0"K'p'x'g'v'k'i'c'v'q't'u'y g't'g't'g's w'k't'g'f "v'q'r' t'q'x'k'f'g' e'q'r'k'g'u' *r'g'h'g't'c'd'n' "k'p'f'k'i'k'c'n'k'q'to'c'v'q'h'l'o'c'i'g'u'k'q't"wo qt"cu'g'u'g'o gpv'*E.V."O T K'd'q'p'g'uecpu'v'q"v'c' e'g'p't'c'n'f'c'k'k'v'0"C"o' c'p'w'c'n'f'g'v'c'k'k'p'i "t'g'eqo o g'p'f'g'f "u'ec'p'k'p'i "r'c't'c'o'g'v'g'tu .k'o'c'i'g'j' c'p'f'k'p'i . c'p'f' "u'j'k'r'k'p'i "y cu'r' t'q'x'k'f'g'f "v'j g'c'ej "u'k'g'0"V'j'k'u'f'q'ewo gpv'k'u'h'q'c'v'g'f "k'p'v'j g'v't'k'c'n'o'c'u'g't' "h'k'g'0 V'j g'K'K" "g'x'c'n'w'c'k'p'p"y cu'w'g'f "h'q't"v'j g'r' t'k'o'c't { "c'p'f "u'g'eq'p'f'c't { "g'h'l'c'c'e { "c'u'g'u'g'o gpv'q'h'v'j g' u'w'f { 0"</p> <p>K'p'q't'f'g't "h'q't"v'j g'U'F "f'g'u'k'i'p'c'v'k'p'v'q"v'g'd'g'i'k'x'g'p' "h'q't"dg'u'v'q'x'g't'c'n't'g'ur'q'p'ug"*D'Q'T+ "c'v'ng'c'u'v'p'q'g' r'q'u'w't'g'c'v'o gpv'o g'c'u'w't'g'o gpv'o w'v'v'j c'x'g'o' g'v'v'j g'U'F "e't'k'g't'k'c"o' k'p'k'o'w'o "q'h'9"y ggmu'c'h'g't' h'k't'v'w'w'f { 'f' t'w'i "c'f' o' k'p'k'v'c'k'p'0"C'ET"qt"RT"cu'g'u'g'f "c'v'c"o' k'p'k'o'w'o "q'h'9"y ggmu'c'h'g't' "u'c't'v' q'h'v'g'c'v'o gpv'y kj q'w'c' "e'q'p'k't'o' c'v'k'p'q'h'RT"q't'ET"c'v'ng'c'u'v'6"y ggmu'h'v'g't'd { 'h'q'm'y /w "uecpu . dw'v'j c'x'k'p'i "c"u'w'd'g's w'g'p'v'r' t'q'i' t'g'u'k'x'g'f'k'g'c'g' "c'u'g'u'g'o gpv."y cu'e'q'p'k'f'g't'g'f "U'F "h'q't"v'j g'd'g'u'v' t'g'ur'q'p'ug0"J'q'y'g'x'g't .ET"qt"RT"cu'g'u'g'f "ng'u'v'j' c'p"9"y ggmu'c'h'g't' "u'c't'v'q'h'v'g'c'v'o gpv'y kj "c' u'w'd'g's w'g'p'v'r' t'q'i' t'g'u'k'x'g'f'k'g'c'g' "y cu'e'q'p'k'f'g't'g'f "r' t'q'i' t'g'u'k'x'g'f'k'g'c'g' "h'q't"v'j g'd'g'u'v' t'g'ur'q'p'ug0"</p> <p>E'q'p'k't'o' g'f "t'g'ur'q'p'ug"*E'T"q't"RT+"y' g't'g'f'g'v'g't'o' k'p'g'f "c'v'c't'g'r'g'c'v'w'o'q't" "g'x'c'n'w'c'k'p'p'c'v'ng'c'u'v'6" y ggmu'c'h'g't' "d'g'k'p'i "h'k't'v'q'd'g'x'g'f "d { "g'k'j'g't' "v'j g" "k'p'x'g'v'k'i'c'v'q't"q't"K'K"y j'q"o'c'f'g'v'j g" "k'p'k'c'n' c'u'g'u'g'o gpv0"V'j g'p'g'z'v'g'x'c'n'w'c'k'p'p' "h'q't"r'q'v'p'v'c'n' "e'q'p'k't'o' c'v'k'p'q'h'v'j g'h'k't'v'RT"q't"ET"e'q'w'f " j'c'x'g"y'c'k'g'f "w'p'v'k'i'v'j g'p'g'z'v't'g'i'w'c't'n' "u'ej'g'f'w'g'f "w'o'q't"cu'g'u'g'o gpv0"V'w'o'q't"cu'g'u'g'o gpv'c'v' v'j g'H'p'c'n'X'k'k'v'y cu'q'p'n' "p'g'g'eu'c't { "k'h'p'q'v'f'q'p'g'y'k'j'k'p"6"y ggmu'q'h'v'j g'ng'u'v't'g'c'v'o gpv'e { eng0 C'ej'g'u'v'z/tc { "q't' "u'ng'g'v'c'n'z/tc { "v'j c'v'eng'c't'n' "f'g'o'q'p'u'c'v'g'f "c'p'g'y "o'g'c'u'c'v'e'ng'k'p'v'o'c { "j'c'x'g' d'g'g'p"u'w'g'f "v'j'f'q'ewo gpv'r' t'q'i' t'g'u'k'p'p .k'p'k'g'w'q'h'v'j g'E'V"q't"O T K'ue'c'p'u'0"</p> <p>Tumor Assessments if Subjects Discontinued from Study Treatment Without Progressive Disease: K'i'w'd'l'g'eu'f'k'ue'q'p'v'k'p'w'g'f "h'q'to "u'w'f { "t'g'c'v'o gpv'y kj q'w'r' t'q'i' t'g'u'k'x'g'f'k'g'c'g' "c'p'f "f'k' "p'q'v' y kj f't'c'y "e'q'p'g'p'v'w'o'q't"cu'g'u'g'o gpv'u'y g't'g'r'g'th'q'to' g'f "c'v'v'j g'H'p'c'n'X'k'k'v"y kj k'p"52"f'c { u'q'h' v'j g'ng'u'v'w'w'f { 'f' t'w'i "c'f' o' k'p'k'v'c'k'p'p+k'h'p'q'v'r' g'th'q'to' g'f "y kj k'p'v'j g'r' t'g'x'k'q'w'a"6"y ggmu .c'p'f "v'j g'p' g'x'g't { "5"o'q'p'v'j u'c't'v'k'p'i "h'q'to "v'j g'ng'u'v'w'o'q't"cu'g'u'g'o gpv'w'p'v'k'i'r' t'q'i' t'g'u'k'x'g'f'k'g'c'g' .f'g'c'v'j .q't" v'j g' "u'c't'v'q'h'c'p'q'j g't"c'p'v'c'p'eg't"v'j g't'c'r { "q'ee'w't'g'f'0"</p> <p>Pharmacokinetics: N'g'p'x'c'v'p'k'd" r'ng'u'o'c" "e'q'p'g'p't'c'v'k'p'p" f'c'v'c'y'g't'g' "e'q'm'g'v'g'f'c'p'f" "d'g'ec'w'ug" q'h'v'j g' "u'r'c't'ug" R'M' u'c'o' r'k'p'i "v'o'g'u"y cu'r'q'q'ng'f"y kj "vj g" "k'p'v'g'p'v'k'x'g" R'M'f'c'v'c "h'q'to "v'j t'g'g'r' t'g'x'k'q'w'a" R'j'c'ug"3" u'w'f'k'g'u'k'p"u'w'd'l'g'eu'y kj "u'q'k'f" "w'o'q'tu"*G92: 2/G266/323."G92: 2/C223/324."c'p'f "G92: 2/</p>
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	<p>I2: 3/325+'hqt'RM'o qf grif gxmqr o gpw0"</p> <p>Hqt'yj g'y q'uwdlgeu'y j q'y gtg'tgcwgf 'y kj 'rgpxcwkpd'32'o i "DIF ."c'vqcn'qh'33'RM'dmqqf 'uco r rgu'y gtg'qdvckp'gf 'r gt'uwdlgeu'Uco r rgu'y gtg'qdvckp'gf 'qp'E {erg'3'F c {u'3'cpf '4'cpf 'qp'E {erg'4'F c { '30'Hqt'yj g'tgo ckp'kpi '337'uwdlgeu'y j q'tgegkxgf 'rgpxcwkpd'46'o i "S F ."c'vqcn'qh'p'kpg'RM'd mqqf "uco r rgu'y gtg'qdvckp'gf 'r gt'uwdlgeu'Uco r rgu'y gtg'qdvckp'gf 'qp'E {erg'3'F c {u'3'cpf ". 'E {erg'4'F c { '3.'cpf 'E {erg'5'F c { '30"</p> <p>Pharmacokinetic/Pharmacodynamic (PK/PD):</p> <p>Cpcn'ugu'y gtg'eqpf wewgf "d { "o qf grkpi "vq" gZR nqtg" gZR quwtgótgur qpug" tgrwkp'uj kr u" hqt' uchgw { 'cpf 'ghlece { 0"</p> <p>Pharmacodynamics:</p> <p>Vj g" r rppgf " RF " cuuguu gpw' kpenw gf 'y g" hqm'y kpi " ugtwo " dkqo ctngtu< " 3+" yj { tqkf " hmpewkp' vguu' kpenw kpi " hgg" V6'c pf " VUJ = 4+v'j { tqi mdrwkp " *F VE " uwdlgeu' qpn { = 5+ ecrekxkp'cpf " EGC " *O VE " uwdlgeu' qpn { = 6+ dkqo ctngtu' qh' cr qr vaku " *Ecur " 5'9. " E { vqE. " cpf " O 52 = 7+ r tqwgo g" ECH' dkqo ctngtu' qh' cpi kqi gple li tqy yj " hcevtu. " kpenw kpi ej go qnkpg. " gpf qy grkwo " hmpewkp. " cpf " kpvgrw'wkp lko o wpg" tgur qpug= Rj cto ceqf { pco ke' cpf " wo qt' t'gur qpug' tgrwkp'uj kr u'y gtg' gZR nqtg f 0"</p> <p>"</p> <p>Pharmacogenomics:</p> <p>Vj g" r rppgf " r j cto ceqi gpqo ke " *RI +cuuguu gpw' kpenw gf " yj g" hqm'y kpi < " 3 + " wo qt' o wcvkp' u' uqo c'wle " F P C " ugs wpep' xctkcpw+lp " BRAF, H-, K- " cpf " N-Ras, " cpf " RET/PTC1, 2, " cpf " 3" cuuguu gf " lp" hqto c'k'p/hkz gf " r ctch'kp/go dgf f gf " *HHRG+ " wo qt' " vkuw'g'cp f " 4+ i gto rkp'g " F P C " ugs wpep' xctkcpw+lp " i gpgu' kpxq'xgf " lp " C F O G " cu'y gni'cu " RET " cpf " F P C " xctkcpw+pgct " FOXE1 " *rs965513+ " cpf " NKX2-1 " *rs944289+ " cuuguu gf " hqto " uwdlgeu' dmqqf uco r rgu' " Rj cto ceqi gpqo ke " cpf " v wo qt' " t'gur qpug" tgrwkp'uj kr u' y gtg' r rppgf " vq" dg' gZR nqtg f 0"</p> <p>Safety:</p> <p>Uchgw { " cuuguu gpw' eqpukwgf " qh' o qpkqtkpi " cpf " tgeqtf kpi " cni'cf xgtug" gxgpw " *CGu+ " cpf " ugtk'kw " cf xgtug" gxgpw " *UCGu= " eqpeqo kcpv' o gf k'ecv'kp'u. " tgi wct " o qpkqtkpi " qh' j go cvqmi { . " dmqqf " ej go kwt { . " cpf " wtkpg' xcwgu= " r g'k'kf ke " o gcuwtgo gpv' qh' xk'vni' uki pu. " GEQI " r gthqto cpeg" ucw'u. " P [J C " cuuguu gpw. " grg'eqctf kqi tco u' " *GEI u+ " gejq'ectf kqi tco u= " cpf " r gthqto cpeg' qh' r j { ulecn'gzco k'p'cv'kp'u0"</p>
Bioanalytical Methods:	<p>Rreuo c " eqpep'tev'kp'u' qh' r ctg'p' f twi " y gtg' s wcp'w'k'gf " d { " rls w'k' " ej tqo cvqi tcr j { lo cuu' ur g'vtqo g'vt { lo cuu' ur g'vtqo g'vt { " *NE IO UIO U+ " o gy qf qm'j { " wukpi " c " r t'g'x'kw'w' { " x'c'k'f' cv'gf " cuuc { 0"</p>
Statistical Methods:	<p>F cv' " qdvckp'gf " w " vq " yj g' f cv' ewqhh' f cv' qh' 33 " Cr t " 4233 " ctg' kpenw gf " lp " yj ku' tgr qtv0 " k'p' cf f k'k'q. " f cv' hqt " cuuguu gpv' l'x'gp'u " y kj " c' u'ctv'f " cv' " r t'k'q " vq " yj g' ewqhh' f cv' " yj cv' eqpv'kw'gf " ch'gt " yj g' ewqhh' f cv' " ctg' cnuq " kpenw gf " *g'f 0 " CG. e' qpeqo kcpv' o gf k'ecv'kp. " r tqegf wtg. " cpf " uwwf { " tgcvo gpv'0 " Hwt yj gto qtg. " uwxk'cn'f' cv' " eqng'ewgf " ch'gt " yj g' ewqhh' f cv' ctg' cnuq " kpenw gf " lp " q'f' gt " vq " qdvckp' uwdlgeu' u' w' xk'cn' u' c' w' u' c' v' yj g' ewqhh' f cv' g'0"</p> <p>Vj g' k'p'gpv' vq " Vtgc'v' *KV+ " Rqr w'cv'kp' kpenw gf " cni' uwdlgeu' y j q' tgegkxgf " cv' r'gcu'v' qpg' f qug' qh' yj g' uwwf { " f twi " cpf " y cu' yj g' r tlo ct { " cpcn' uku' ugv' wugf " hqt' ghlece { " cpcn' ugu'0 " Vj g' Ghlece { " Gx'cn'cd'rg " Rqr w'cv'kp' kpenw gf " cni' uwdlgeu' y j q' tgegkxgf " cv' r'gcu'v' qpg' f qug' qh' yj g' uwwf { " tgcvo gpv. " j cf " c " dcugn'kp' cpf " cv' r'gcu'v' qpg' r quwtg'cvo gpv' wo qt' t'gur qpug' g'x'cn'cv'kp. " cpf " hwt'k'ngf " kpenw'k'p' " et'k'gt'k' " 3. " 4. " 5. " cpf " 60 " Vj g' Uchgw { " Rqr w'cv'kp' kpenw gf " cni' uwdlgeu' y j q' tgegkxgf " cv' r'gcu'v' qpg' f qug' qh' uwwf { " f twi " cpf " j cf " cv' r'gcu'v' qpg' r quwtg'cvo gpv' uchgw { " cuuguu gpv' cpf " y cu' yj g' r tlo ct { " cpcn' uku' ugv' hqt' " cni' uchgw { " f cv'0 " Vj g' uchgw { " cpcn' ugu' y gtg' eqpf wewgf " d { " utcw " *F VE " cpf " O VE " ugr c'c'v'gn' " cp f " y kj " yj g' y q' utcw " eqo d'kp'g f 0 " k'p' cf f k'k'q. " yj g' y q' " F VE " uwdlgeu' g'p't'q'ngf " w'p'f' gt " yj g' q' tki k'p'cn' r t'q'v'eqn' y kj " k'p'k'cn' " DIF " f quk'pi " y gtg' cpcn' gf " ugr c'c'v'gn' " cu' c' i' tqwr. " cn uq " vqi g'j g' y kj " cni' q'j g' t " uwdlgeu' cu' yj g' q'x'g't'cn' uwo o ct { " hqt' yj g' uwwf { 0"</p>

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cuugugf "hqt"j { r gtvgpukqp"cpf "r tqvklpwtk0"Qvj gt"uchgv"r ctco gygtu'y gtg"cnq"i ter j kecmf
 cuugugf "hqt"j g'tgrvklpuj kr "y kj "ngpxcvklpd"gzr quwtg'y j lej "kpenwf gf "yj g'CGu'qh'f lcttj gc.
 hcvk wg."f getgcugf "cr r gvkg."pcwgc."cpf "y gli j v'f getgcug."cpf "rdqtcvqt {"r ctco gygtu"qht
 j go cvqmi {<"j go cvqetk."j go qi mdkp."y j kg'drqf "egm."pgwtqr j kn"cpf "r nvgv'eqwpu=
 hqt" dkqej go kvw {<" cmvklpg" r j qur j cvug." dkkwdk." cmvklpg" co kqvtcpuhgtcug." cur ctvcg
 co kqvtcpuhgtcug."ugt wo "cndwo kp."ugt wo "etgcvklpg."cpf "vqcn'it tqvklp-0"

Tgrvklpuj kr u'y gtg'gzr mtgf "dgv ggp"ngpxcvklpd"gzr quwtg"cpf "yj g'hmqy kpi "dkqo ctngtu"
 dkqej go keci'o ctngtu"*j { tqi mdkp'hqt"yj g'F VE"eqj qtv."ecrekqkp"cpf "EGC'hqt"yj g'O VE"
 eqj qtv." cpf " y { tqf " hwpvklp" vguvt guw nu" *ft gg"V6 " cpf " ht gg"VUJ " hqt" cni'wd lgeu=
 dkqo ctngtu" qh' cr qr vuku" *Ecur " 59." E { vqE." cpf "O 52+" cpf "ugt wo " r tqvqo g" ECH
 dkqo ctngtu." kpenwf kpi " cpi kqi gple li tqy yj " hcvqt." ej go qmkg." gpf qj grko " hwpvklp."
 kvgtgrwklp'lko o wpg'tgur qpug'hcvqtu."cpf "qj gt'hcvqtu0"

Uchgv" f cvc."kpenwf kpi "CG"cpf "rdqtcvqt {"xcnmu."r tlqt"cpf "eqpeqo kcpv'o gf kecvklp."cpf
 uwf {"f twi "gzr quwtg."GEI "cpf "gej qectf kqi tco "hkp kpi u."y gtg"cpncf { gf "wukpi "f guetkr vxg
 uc'vku" *p."o gcp."o gf kcp."ucpf ctf "f gxkcvklp." tci g+"hqt" eqvklpwqwu"o gcuwgu." cpf
 kpek gpeg'eqwpu"*pwo dgt"cpf "r gtegpv'hqt"ecvgi qtleci'xctkcdrgu0"

<p>Results:</p>	<p>Analysis Sets</p> <p>Vj g'KVVRqr wvklp"cpf "yj g'Uchgv"Rqr wvklp"y gtg'yj g'uco g'kp"yj ku'uwf {<"c'vqcn'qh'339" uwdlgeu"tgcvgf =7: "uwdlgeu"lp"yj g'F VE"eqj qtv"*y q"f qugf "32"o i "DKF"cpf "78"f qugf "46" o i "S F -"cpf "7; "uwdlgeu"lp"yj g'O VE"eqj qtv"f qugf "46"o i "S F 0"Vj g'Gh'cece {"Gxcnwdrg Rqr wvklp"kpenwf gf "77"uwdlgeu"lp"yj g'F VE"eqj qtv"cpf "72"uwdlgeu"lp"yj g'O VE"r qr wvklp *, 7" "cpf": 7 "qh'yj g'KVVRqr wvklp."tgr gevkgf +0'</p> <p>Subject Disposition"</p> <ul style="list-style-type: none"> Qh'yj g'7: "uwdlgeu"lp"yj g'F VE"eqj qtv"yj g'y q"uwdlgeu"y j q"y gtg'f qugf "y kj ngpxcvklpd" 32"o i " DKF" f kueqpvklpwgf " yj g" Vtgcvo gpv' Rj cug" f wg" vq" f kugcug r tqi tguukqp"cpf "f kf "pqv'eqvklpwgf"tgcvo gpv'lpv"yj g'Gzvgpukqp"Rj cug0"Qh'yj g'78" uwdlgeu" y kj " F VE" f qugf " y kj " ngpxcvklpd" 46" o i " S F ." 45" *63" + "eqvklpwgf tgcvo gpv' lp" yj g'Gzvgpukqp" Rj cug" cp f " 55" *7; ' + y gtg' f kueqpvklpwgf "ht qo " yj g' tgcvo gpv' lp" yj g'Vtgcvo gpv' Rj cug0" Ukvggp" uwdlgeu" *4; ' +lp" yj g' S F " f qulpi i tqwr "f kueqpvklpwgf "f wg"vq" f kugcug" r tqi tguukqp0" C"vqcn'qh'37" uwdlgeu" *49' +lp" yj g' S F " f qulpi " i tqwr " f kueqpvklpwgf " f wg"vq" CGu" 36" *47' + y kj " CG* u" cu' yj g' r tko ct { " tgcup" hqt" f kueqpvklpwklp" cpf " 3" uwdlgev" y kj " uwdlgev' ej qlkg" cu' yj g" r tko ct { " tgcup" hqt" f kueqpvklpwklp" cpf " y kj " cp" CG" cu' yj g" ugeqpf ct { " tgcup0 Qpg" cf f kqpcr' uwdlgev' f kueqpvklpwgf "f wg"vq" uwdlgev' ej qlkg" cpf " cpqj gt" uwdlgev y kj f tgy "eqpugv' cu' r tko ct { " tgcup" hqt" f kueqpvklpwklp0" Qh'yj g'7; "uwdlgeu" y kj " O VE." 4; " *6; ' +eqvklpwgf "tgcvo gpv' lp" yj g'Gzvgpukqp Rj cug" cpf " 52" *73' + y gtg' f kueqpvklpwgf "ht qo " yj g" Vtgcvo gpv' Rj cug0" Hkvggp uwdlgeu" *47' +f kueqpvklpwgf "f wg"vq" f kugcug" r tqi tguukqp0" C"vqcn'qh'36" uwdlgeu *46' +f kueqpvklpwgf "f wg"vq" CG* u" 35" *44' +j cf " CG* u" cu' yj g' r tko ct { " tgcup" hqt" f kueqpvklpwklp" *kpenwf kpi " 3" uwdlgev' y kj " dqj " yj g' r tko ct { " cpf " oqj gt o' tgcup"]kp cf f kqpcr' vq" yj g' r tko ct { " tgcup_ hqt" f kueqpvklpwklp" pqv'f " cu' dglpi " f wg"vq" CGu cpf " 3" uwdlgev' y kj " uwdlgev' ej qlkg" cu' yj g' r tko ct { " tgcup" hqt" f kueqpvklpwklp" cpf y kj " cp" CG" cu' yj g' ugeqpf ct { " tgcup0" Qpg" cf f kqpcr' uwdlgev' f kueqpvklpwgf "f wg"vq" uwdlgev' ej qlkg" cu' yj g' r tko ct { " tgcup" hqt" f kueqpvklpwklp0' Cv'yj g' vko g" qh' f cvc" ewqhl' hqt" yj ku" EUT" *33 " Cr t" 423 3+ " 74" uwdlgeu" *45" lp" yj g' F VE" eqj qtv" cpf " 4; " lp" yj g' O VE" eqj qtv" y gtg" uknit gegklpi " tgcvo gpv' lp" yj g' Gzvgpukqp" Rj cug0' <p>Exposure</p> <ul style="list-style-type: none"> Hqt" yj g' F VE" eqj qtv" yj g' o gf kcp" f wcvklp" y cu" 5; 50" f c { u" tci p g < " 4 2" vq" 75: " f c { u" 0" Vj g' o gcp" pwo dgt" qh' e { ergu' y cu" 3307. " yj g' o gf kcp" pwo dgt" qh' e { ergu' y cu" 3507. " cpf " yj g' o kpo wo " cpf " o czko wo " pwo dgt" qh' e { ergu' y cu" 3" cpf " 3; .
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	<p>tgur gevkgf(0"</p> <ul style="list-style-type: none"> • Hqt"vj g"O VE"eqj qtv"vj g"o gf kcp"f wcvkqp"y cu"4860"f c{u"*tpci g<"3 5"vq"769" f c{u:0"Hqt"vj g"O VE"eqj qtv"vj g"o gcp"pwo dgt"qh'e{ ergu"y cu"; 09."vj g"o gf kcp" pwo dgt"qh'e{ ergu"y cu"320."cpf"vj g"o kpk wo "cpf"o czko wo "pwo dgt"qh'e{ ergu" y cu"3'cpf"42."tgur gevkgf(0" <p>Efficacy</p> <ul style="list-style-type: none"> • Ghhece{ "gpfr qkpw"y gtg"cuuguf "kp"vj g"KV"Rqr wcvkqp"wpiguu"qj gty kug"pqvf 0" Vj g"r tko ct{ "gpfr qkpw"qh"vj g"uwf { "y cu"vj g"QTT"dcugf "qp"vj g"cuuguo gpw'd{ "vj g" KKT"Vj g"QTT"y cu"72' "kp"vj g"VE"eqj qtv'cpf"58' "kp"vj g"O VE"eqj qtv"0" • Ugeqpf ct{ "ghhece{ "tguwu"htq"vj g"VE"eqj q t'v'y gtg"cu"hqmy u0"Cv'c'o kpk wo "hqmy /w"r gtlqf "qh"36"o qpj u."vj g"o gf kcp"guvko cvg"qh"RHU"dcugf "qp"KKT"y cu" 340"o qpj u0"Vj g"8/o qpj "RHU"tcvg"y cu"9: ' "cpf"vj g"34/o qpj "RHU"tcvg"y cu" 77' 0"Vj g"o gf kcp"QU"dcugf "qp"Mc rrp/O gkt"cpch uku"eqwf "pqv"dg"tgrkdn{ guvko cvg 0"Vj g"qxtcm"uwtxkcn"tcvg"y cu": 8' "cv"34"o qpj u'cpf"y cu"9: ' "cv'dqj 3: "cpf"46"o qpj u0"Vj g"o gf kcp"hqmy /w"vko g"y cu"380"o qpj u0"Dcugf"qp" cuuguo gpw'd{ "vj g"KKT."vj g"FET"y cu"; 5' "cpf"vj g"EDT"y cu"9: ' 0"Vj g"o gf kcp" f wcvkqp"qh"tgur qpug"ht"uwdlgeu"y kj "c"DQT"qh"ET"qt"RT"*p?4; +y cu"340" o qpj u0"Vj g'o gf kcp"vko g"vq"tgur qpug"ht"uwdlgeu"y kj "c"DQT"qh"ET"qt"RT"kp" yj g"Ghhece{ "Gxcncdng"Rqr wcvkqp"*p?4: +y cu"50"o qpj u0" • Ugeqpf ct{ "ghhece{ "tguwu"htq"vj g"O VE"e qj qtv"y gtg"cu"hqmy u0"Cv'c'o kpk wo "hqmy /w"r gtlqf "qh": "o qpj u."vj g"o gf kcp"guvko cvg"qh"RHU"y cu"; 0"o qpj u0"Vj g" 8/o qpj "RHU"tcvg"y cu"89' "cpf"vj g"34/o qpj "RHU"tcvg"y cu"68' 0"Vj g"o gf kcp" QU"dcugf "qp"Mc rrp/O gkt"cpch uku"eqwf "pqv"dg"tgrkdn{ "guvko cvg 0"Vj g"qxtcm" uwtxkcn"tcvg"y cu"98' "cv"34"o qpj u'cpf"y cu"pqv"guvko cdng"cv3: "cpf"46"o qpj u0" Vj g"o gf kcp"hqmy /w"vko g"y cu"330"o qpj u0"Dcugf"qp"cuuguo gpw'd{ "vj g"KKT." yj g"FET"y cu": 2' "cpf"vj g"EDT"y cu"86' 0"Vj g"o gf kcp" f wcvkqp"qh"tgur qpug"ht" uwdlgeu"y kj "c"DQT"qh"ET"qt"RT"*p?43+y cu"pqv"tgej gf 0"Vj g"o gf kcp"vko g"vq" tgur qpug"ht" uwdlgeu"y kj "eqphko gf "c"DQT"qh"ET" qt"RT"kp"v j g" Ghhece{ " Gxcncdng"Rqr wcvkqp"*p?3; +y cu"50"o qpj u0" • Hqt"vj g"VE"eqj qtv"vj g"QTT."dcugf"qp"cuuguo gpw'd{ "vj g"KKT."y cu "7; ' "kp" uwdlgeu"y kj "r tkt"XGI H"vcti gvgf "tgcvo gpv"*p?39+cpf"y cu"68' "kp"uwdlgeu" y kj qw'r tkt"XGI H"vj gter { "*p?63+0"Hqt"vj g"O VE"eqj qtv"vj g"QTT"y cu"vko kkt" kp"uwdlgeu"y kj "r tkt"XGI H"vj gter { "*p?48+eqo r ctgf"y kj "vj qug"y kj qw'r tkt" XGI H"tgcvo gpv"*p?55+*57' "cpf"58' ."tgur gevkgf(0" • Ugeqpf ct{ "ghhece{ "gpfr qkpw"y gtg"cuq"dcugf "qp"vj g"kpvguvi cvqtu0"cuuguo gpw'd{ Vj g"ugeqpf ct{ "ghhece{ "gpfr qkpw"uj qy gf "pq"o clqt" f hgtgpegu"dcugf "qp"vj g"y q" uqwtgu"qh"cuuguo gpw'd{ <p>Pharmacokinetics/Pharmacodynamics</p> <ul style="list-style-type: none"> • Vj g"RM"qh"ngpxcvkpd"kp"vj g"eqo dkgf "VE"cpf"O VE"eqj qtv"y gtg"vko kkt"vq" yj cv"qdugtxgf" kp"vj g"Rj cug"3"uv wf lgu0" "P q" f ktgev" tgrcvkqpj kr" qh" ngpxcvkpd gzr quwtg"*uvpcf { "ucv"WE"eqwf "dg"qdugtxgf"y kj "QTT"cpf"RHU" <p>Safety</p> <ul style="list-style-type: none"> • Cm' uwdlgeu"kp"dqj "eqj qtv" gzr gtlqpegf "cv'hcuv"qpg"v tgcvo gpv go gti gpv"CG" *VCGG" cpf" cv' ngcu"qpg"VCGG"tg r qtv"cu"tgcvo gpv tgrcvgf 0"Vj g" o quv htgs wgpw{ "tgr qtv" "VCGG"62' "qh"uwdlgeu"kp"gkj gt" eqj qtv"y gtg" f kctj gc." j { r gtvgpukp."r tqvlpwtk."hvi wg."y gli j v'f getgcugf."f getgcugf"cr r gvkg."pcwugc." j gcf cej g."eqw j ."cpf" f { ur j qpk0" • Vqzlekkgu"y gtg"o cpci gf" d{ "uwf { "f twi" kpvtwrvkqp" cpf" uwdugs wgpv" f qug" tgf wcvkqp"vq"tgf weg"vj g"pgeguks{ "ht"uwf { "f twi"y kj f tcy ctd"VCGG"hgcf lpi"vq" uwf { "f twi"y kj f tcy ctd"qeevttgf"kp"37"uwdlgeu"48' +kp"vj g"VE"eqj qtv'cpf"kp" 36"uwdlgeu"46' +kp"vj g"O VE"eqj qtv"0"
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	<ul style="list-style-type: none"> • VGCGu"qh'ur gekcn'kp'vgtgu'lpemf gf "j { r gt vgpukqp"cpf "r tqvklpwk."y j lej "ctg"CGu npqy p"vq"dg"cuuqekvxf "y kj "tgcvo gpv'y kj "ngpxcvkpd"cpf "qvj gt"XGI H'vcti gvxf "ci gvu0"J { r gt vgpukqp"y cu"vq"dg"tgcvgf "y kj "cpvj { r gt vgpukg"tgcvo gpv'cpf "y kj uwf { "f twi " lpvgttw vqp" cpf " uwdugs wgpv' f qug" tgf vevkq0 "Vj ku" o cpci go gpv uej go g'cr r gctgf "vq"dg"ghgevkxg0"Vj g'o clqtkv' "qh'gxgpw'y gtg'I tcf g"3"qt"I tcf g"40"O quv'qh"y j g'gxgpw'qh'j { r gt vgpukqp"cpf "r tqvklpwk."y gtg'o cpci gf "y kj qw uwf { "f twi "y kj f tcy cny' kj f tcy cn'htqo "y j g'uwf { "tgcvo gpv'f wg"vq"j { r gt vgpukqp qeewtgf "kp"ppg"uwlgev'gcej "lp"y j g'F VE" cpf "O VE"eqj qtv0" Rt qvklpwk"rgf "vq" uwf { "f twi "y kj f tcy cn'lp"y j tgg"uwlgeu'lp"y j g'F VE"eqj qtv'cpf "pq"uwlgeu'lp"y j g'O VE"eqj qtv0"P q"I tcf g"6"qt"I tcf g"7"j { r gt vgpukqp"qt"r tqvklpwk"gxgpw'y gtg' tgr qtvf 0"J { r gt vgpukqp."cu'cp"UCG."qeewtgf "lp"y q"uwlgeu'lp"y j g'F VE"eqj qtv' cpf "kp"ppg"uwlgev'lp"y j g'O VE"eqj qtv0"Rt qvklpwk."cu'cp"UCG."qeewtgf "kp"ppg' uwlgev'lp"y j g'F VE"eqj qtv'cpf "pqv'lp"cp { "uwlgev'lp"y j g'O VE"eqj qtv0" • Kp"y j g'F VE"eqj qtv."y j g'o quv'htgs wgpw' "tgr qtvf "I tcf g"5"VGCGu"qeewt'kpi "lp" cr r tqzko cvgn' "32' "qh'uwlgeu"y gtg'y gki j v'f getgcugf .f kcttj gc."j { r gt vgpukqp. cpf "r tqvklpwk0"Uz" I tcf g"6"VGCGu"qeewt'gf <"j { r qecre go kc."j { r gtnre go kc. cdcuk."cpf "cewg"o { qectf ken'lp'htevkq" *ppg"tgr qtv' gcej + "cpf "y q'tg r qtv"qh' r wv qpct { "go dqruo 0"Kp"y j g'O VE"eqj qtv."y j g'o quv'htgs wgpw' "tgr qtvf "I tcf g"5" VGCG" *qeewt'kpi "lp" cr r tqzko cvgn' "32' "qh'uwlgeu"qh'uwlgeu"y cu'f kcttj gc0 Hxg"I tcf g"6"VGCGu"qeewt'gf <"co { rug"lp'etgcugf . "nr cug"lp'etgcugf . "r pgwo qpk' cur kcvkq. "gz'hnkcvkxg'tcu'j . "cpf "ceekf gp'cn'ixgtf qug" *ppg"tgr qtv'gcej +0" • UCGu" *dqy "h'rcv'cpf "pqp'hcvcn"qeewt'gf "lp"4: "uwlgeu" *6: " +lp"y j g'F VE"eqj qtv' cpf "lp"52"uwlgeu" *73' +lp"y j g'O VE"eqj qtv0"UCGu"y j lej "qeewt'gf "lp"cv'ngcu' y q" uwlgeu" y gtg" cu' hqny u< "kp" dqy " eqj qtv." r wv qpct { " go dqruo " cpf f gj { f tcvkq= qpn' " lp" y j g' F VE" eqj qtv." ny gt" cdf qo kpcn' r clk." j { r qv'gpukqp. j { r gt vgpukqp."cpf "ectf kce"hc'kwtg=cpf "qpn' "lp"y j g'O VE"eqj qtv."cdf qo kpcn' r clk. npi "lp'hgevkq."f getgcugf "cr r gvkg."cpf "r tgo cwt'g'o gpqr cvwg0" • F gcj .f wtkpi "tgcvo gpv'qt'y kj lp"52"fc { u'qh'y g'rcu'f qug'qh'uwf { "f twi ."qeewt'gf "lp"cv'ngcu'qh'ugxgp"uwlgeu'lp"y ku'uwf { <"y tgg"lp"y j g'F VE"eqj qtv'cpf "hwt"lp"y j g'O VE"eqj qtv0"Vy q'f gcj u."ppg"lp"y j g'F VE"eqj qtv'cpf "ppg"lp"y j g'O VE"eqj qtv. y gtg"tgr qtvf "f wg"vq"erikplecn'r tqi tguukqp"qh'f kugcug0"Hxg" f gcj u'y gtg"tgr qtvf "cu'cp"qweqo g'qh'cp"UCG<"y q "lp"y j g'F VE"eqj qtv'cpf "y tgg"lp"y j g'O VE"eqj qtv0 Y kj "y j g'gx'cn'cvkq"qh'y j g'kphqto cvkq"cxckndrg"ht' y j g'ug'hxg'f gcj u'cuuqekvxf "y kj "UCGu"qp g'qh' y j g' y q'f gcj u'lp"y j g'F VE"eqj qtv' y cu'f gvto kpgf "vq"dg' cuuqekvxf "y kj "r tqi tguukqp"qh'f kugcug."cpf "y j g'qvj gt" f gcj "y cu'f wg"vq"ectq'kf ctvt { "j go qttj ci g'y j lej "y cu'tgrv'gf "vq"necn'lp'hc'o o cvkq"qh'y j g'xgu'gn'htqo "c r t'gxkqwu"tcej gquvqo { 0"Kp"v j g'O VE"eqj qtv."y j g'v'j tgg" f gcj u'cuuqekvxf "y kj UCGu"y gtg" f gvto kpgf "vq"dg'cuuqekvxf "y kj "r tqi tguukqp"qh'f kugcug0"Vj gtghqtg' qh'y j g'ugxgp" f gcj u'qeewt'kpi "f wtkpi "tgcvo gpv'qt'y kj lp"52"fc { u'qh'y j g'rcu'f qug' qh'uwf { "f twi ."ulz"y gtg'cuuqekvxf "y kj "r tqi tguukqp"qh'f kugcug."cpf "ppg"y cu'y j g' qweqo g'qh'cp"UCG0 • P q"erikplecn' "ko r qt'v'p'ej cpi gu'lp"o gcp"j go cvqni { "cpf "dkqej go knt { "xcn'gu' htqo "dcug'kpg"vq"y j g'gp' "qh'y j g'xctkqwu'e { erig'y gtg'qdugt'xgf 0" T guwmu'ht' o gcp" r n'vrgv'cpf "pgwtqr j kn'eqwpu'uj qy "c'u nki j v'f getgcukpi "vtgp'f . "dw'y gtg'y kj lp' pqto cn'tepi g'ht'gcej " r ctco gvt0"Vj g'ug"tguwmu'y gtg'uggp"lp"dqy "F VE"cpf " O VE"eqj qtv0"Vj g'uj kn'cpcn'uku'ht'EVECG'i tcf gu'tgx'crgf "pq"uj kn'qh'erikplecn' eqpegt'p'ht'j go cvqni { "qt'erikplecn'ej go knt { "r ctco gvtu'htqo "dcug'kpg"vq"y j g'gp' qh'gcej "e { erig0"Kp'etgcugu'lp"r tqvkl'lp"y j g'vt'kpg'y gtg'qdugt'xgf "qxgt"ko g'y j lej "ku' eqpukngpv'y kj "y j g'qeewt'gpeg'qh'r tqvklpwk"tgr qtvf "cu"VGCGu0" • Erikplecn' "ko r qt'v'p'ej cpi gu'lp"o gcp" xkcn'uki pu'htqo "dcug'kpg"vq"y j g'gp' r qkpu' cv'xctkqwu" xkuku"y gtg' qdugt'xgf 0" Dnqf "r tguuwt'g'ej cpi gu'qeewt'gf "cpf "y gtg' tgr qtvf" cu' VGCGu" kn' f ggo gf " erikplecn' " ko r qt'v'p' d { " y j g' lp'xguk' cvqt0 Ngpxcvkpd"tgcvo gpv'y cu'eqtt'grv'gf "y kj "cp"lp'etgcug"lp"draqf "r tguuwt'g0"O quv'qh' y j g' lp'etgcugu"lp" dnqf " r tguuwt'g' qeewt'gf " f wtkpi " y j g' htu'v' e { erig0" Chgt " y j g'
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	<p>lpetgcug."f qy py ctf "tgpfu"lp"dqj "UDR"cpf "F DR"y gtg"qdugtxgf "r tko ctlnf "f wg"vq" tgcvo gpv" y kj " cpvj { r gtvgpukxg" o gf lecvkqpu" cpf lqt" f qug" lpygtt w vkqp" qt tgf wevkqp0'</p> <ul style="list-style-type: none"> • P q"eriplecni { "tgrxcpv"hpfi lpi u"lqt"ej cpi gu"lp"GEI u"qt"gej qectf kqi tco u"y gtg qdugtxgf 0"
<p>Conclusions:</p>	<p>Kp" vj ku" Rj cug" 4" uwf { " lp" uwdlgeu" y kj " gkj gt" O VE"qt " F VE" Kif lpg/353" tghtcevt { . wptgugevcdng" f kugcug" y kj " gxf gpeg"qh" f kugcug" r tqi tguukqp."rgpxcvkpld" y cu"cf o kplngt gf "cv" c"uvt vpi "f qug"qh"46"o i "S F ."gzegr v"lqt"y q"uwdlgeu"y j q"y gtg"tgcvgf "cv"y g" f qug"qh"32" o i "DKF ."cu"r nppgf "lp"y g"qtki kpcnr tqvqeqr0"Uwdlgeu"eqpvkpwgf "tgcvo gpv"wpkrf kugcug" r tqi tguukqp."f gxmqr o gpv"qh"wpceegr vcdng"vzkek { ."f gcj . "qt"y kj f tcy cni"qh"eqpugp0"Vj g" o gf lcp" f wcvkqp"qh"tgcvo gpv"y cu"5; 50" f c { u"t cpi g<"42"vq"75: "f c { u"lqt"y g" F VE"eqj qtv" cpf "4860" f c { u"t cpi g<"35"vq"769" f c { u"lqt"y g" O VE"eqj qtv" C vj g" vko g"qh" f cv"ewqhl"lqt" y ku"EUT" *33" Cr t"4233+ "74" uwdlgeu" *45" lp" y j g" F VE"eqj qtv" cpf "4; "lp" y j g" O VE"eqj qtv" y gtg"vknit"gegkxkpi "tgcvo gpv"lp" y j g" Czvgpukqp" Rj cug0'</p> <p>Vj g"RM"qh"rgpxcvkpld"lp" y j g" F VE"cpf "O VE"eqj qtv"y gtg"uko kct"vq" y j g" cv"qdugtxgf "lp" y j g" Rj cug"3" uwf lgu0" P q" f lgevt"grcvkqpuj kr "qh"rgpxcvkpld" gzr quwt g" *ugcf { "ucvc" C WE" +eqwf " dg"qdugtxgf "y kj "QTT"cpf "RHU0'</p> <p>Ngpxcvkpld"uj qy gf "o gcpkpi hmi"cpvkw o qt"cevkkv { "lp"dqj "y j g" F VE"cpf "O VE"j knqmi lecnf eqj qtv0"Vj g" r tko ct { "gpf r qkp"v"qh"y j g"uwf { ."QTT"dcugf "qp"y j g"cuugu o gpw" d { "y j g" KKT . y cu"72' "lp" y j g" F VE"eqj qtv" cpf "58' "kp" y j g" O VE"eqj qtv0"Uge qpf ct { "ghlece { "tguwnu" uj qy gf "y j g"QTT."dcugf "qp"cuugu o gpw" d { "y j g"lpxgunki cvqtu."y cu"75' "lp" y j g" F VE"eqj qtv" cpf "6; ' "lp" y j g" O VE"eqj qtv0" F hgtgpegu"dgwy ggp" y j g"tguwnu"qdvkpgf "d { "y j g" KKT" cpf "y j g" lpxgunki cvqtu"y gtg"gzr gevdf ."cpf "qxgtcm"y j g"tguwnu"ctg"lp"eqpe qtf cpeg0"Qj gt"ugeqpf ct { "ghlece { "gpf r qkpw."lpenwf lpi "F ET."EDT." cpf "RHU."cnuq"uj qy g f "cpvkw o qt"cevkkv { "qh" rgpxcvkpld0"Hqt"y j g" F VE"eqj qtv"y kj "c" hqmjy /w" vko g"qh"36"o qpj u."y j g"o gf lcp" guko cvg" qh"RHU"y cu"340"o qpj u."cpf "lqt"y j g" O VE"eqj qtv"y kj "c" hqmjy /w" vko g"qh": 0"o qpj u."y j g"o gf lcp" guko cvg" qh" RHU"y cu"; 0"o qpj u0" Hqt"y j g" F VE"eqj qtv"y kj "c" v"34"o qpj u"cpf "y cu" 9: ' "cv"dqj "3: "cpf "46"o qpj u0" Hqt"y j g" O VE"eqj qtv"y kj "c"o gf lcp" hqmjy /w" vko g"qh" 330"o qpj u."y j g"qxgtcm"uwxkcn"tcvg"y cu"98' "cv"34"o qpj u"cpf "y cu"p qv" guko cdng"cv"3: "cpf "46"o qpj u0" O gcp lpi hmi"cpvkw o qt"cevkkv { "y cu"cnq"qdugtxgf "lp"uwd lgeu"y j q"j cf r tgxkqwnf " dggp" tgcvgf "y kvj " qj gt" r tkt" XGI H"vcti gvgf " ci gpw0" Vj g"ghlece { "f cvc qdugtxgf "lp" y j ku"uwf { "eqo r ctg" hcxqtcn { "y kj " r wdkuj gf "f cv"lqt"qj gt"cpv"XGI H"ci gpw0' Kp" y j ku"uwf { ." rgpxcvkpld" j cf " cp"ceegr vcdng" uchgv { " r tqhkg"lqt"u wdlgeu" y kj " tghtcevt { " y j { tqkf "epeg0" P q"pgy "uchgv { "eqpegtpu"y gtg"qdugtxgf 0" Cu" r tgxkqwnf "uggp"kp" qj gt uwf lgu."j { r gtvgpukqp"cpf " r tqvkwkpc"y gtg"uchgv { "eqpegtpu"y kj "rgpxcvkpld."cu"y kj "qj gt f twi u" y j cv" chgev" y j g" XGI H" uki pcrkpi " r cvj y c { 0" D qj " j { r gtvgpukqp" cpf " r tqvkwkpc" f gxmqr gf "gctn { "lp" y j g"eqwtug"qh"uwf { "f twi "cf o kplntcvkqp0"Kp" i gpgtcn { "j { r gtvgpukqp"y cu" y gmi"eqpvqmgf "y kj "cpvj { r gtvgpukxg"o gf lecvkqpu"cpf lqt" f qug"lpygtt w vkqp"qt" tgf wevkqp"qh" rgpxcvkpld0"</p> <p>Vj ku"uwf { "uwi i guv"y j cv"r tqo kulpi "cpvkw o qt"cevkkv { "cpf "cp"ceegr vcdng"uchgv { " r tqhkg"ecp" dg"cej lxxgf "wukpi "y j g" f qulpi " r ncp."y j lej "lplkcvu"y j gter { "cv"y j g"o czko wo "vqngtcvgf "f qug" *O VF "+"vq"lpf weg"y j g"dguv"qxgtcm"wo qt"tgr qpug"cpf "y j gp"lpf kxf wcnf gu"y j g" f qug"dcugf "qp"qdugtxgf "uchgv { " r ctco gvgtu."wukpi " r nppgf "f qug" tgf wevkqpu"qh"rgpxcvkpld0"Vj ku" f qulpi " r ncp"y knidg" gxcnvcvgf "hmtj gt"lp"uwdugs vgpv"cpf "rci gt"uwf lgu0"Vj g"ghlece { "cpf "uchgv { "qh" rgpxcvkpld"ku"ewt gpw" dglpi "vgvgf "lp" c" Rj cug"5"vknit"lp"uwdlgeu"y kj " F VE0"</p>
<p>Date of Report:</p>	<p>27/HGD/4236</p>