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**2 STUDY SYNOPSIS**

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

<b>Study Title:</b>	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 khtgtpvcvfg "Vj { tqkf " Ecpegtu.'Utcv'kēgf "d{ 'J ksqmji {
<b>Investigators/ Sites:</b>	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
<b>Publications based on study:</b>	<p>3+ Uj gto cp'U.'Lct  cd'D.'Ecdeplmru'O . 'Nlēktc'N.'Rēclpk'H'O ctv'pu'T. 'gv'c'f0C'r j cug'K' vtkri'qh'vj g'o wnk'cti gvgf 'h'p'cug'lpj kdkqt'G92: 2'lp'cf xcpegf 'tcf kqkf lpg"TC K/ tgh tcevqt { 'f khtgtpvcvfg "vj { tqkf "ecpegt "F VE+"]cdutcev_0Rt gugpvcvqp'cv'vj g'69vj " Co gtlecp"Uqelgv'qh'Erlpēcni'Qpeqmi { 'C ppcni'O ggv'pi =4233' Lxp'6/: =Ej leci q"KN+0 L'Erlp"Qpeqni04233-4; *Uw r n=77250'</p> <p>4+ Uj gto cp'U.'Lct  cd'D.'Ecdeplmru'O . 'Nlēktc'N.'Rēclpk'H'O ctv'pu'T. 'gv'c'f0C'r j cug'K' vtkri'qh'vj g'o wnk'cti gvgf 'h'p'cug'lpj kdkqt'G92: 2'lp'cf xcpegf 'tcf kqkf lpg"TC K/ tgh tcevqt { 'f khtgtpvcvfg "vj { tqkf "ecpegt "F VE+"]cdutcev_0Rt gugpvcvqp'cv'vj g' ; vj " C ppcni'O ggv'pi '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.'Rēclpk'H'O ctv'pu'T. 'gv'c'f0C'G92: 2" *Ngpxcvpkl+lp' Cf xcpegf "Tcf kqkf lpg"TC K/T gh tcevqt { 'f khtgtpvcvfg "vj { tqkf "ecpegt "F VE+=T guwru'qh'c'O wnk' E gpvgt 'Rj cug'K'vtkri'qt cni'r t gugpvcvqp_0Rt gugpvcvqp'cv' vj g'57vj 'C ppcni'O ggv'pi 'qh'vj g'Gwtqr gcp'Vj { tqkf "Cuuqelcvqp=4233' Ugr "32/36= 'Mtcnqj "Rqmpf +04233-QR230' j wr &lt;leqpv'p'cti gt'eqo lrtqf wmgF Dlr tqf wmg'cur Av{r ?r f h' f qk? 552787"</p> <p>6+ DēniF Y . 'Uj gto cp'U.'Lct  cd'D.'Ecdeplmru'O . 'Nlēktc'N.'Rēclpk'H'gv'c'f0C'r j cug'K'vtkri' qh'vj g'o wnk'cti gvgf 'h'p'cug'lpj kdkqt'ngpxcvpkl"G92: 2+lp'cf xcpegf 'tcf kqkf lpg" *TC K/tgh tcevqt { 'f khtgtpvcvfg "vj { tqkf "ecpegt "F VE+&lt;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 ceq'np'g'v'eu" ]cdutcev_0Rt gugpvcvqp'cv'vj g': 3uv' C ppcni'O ggv'pi 'qh'vj g'Co gtlecp'Vj { tqkf " Cuuqelcvqp=4233' Qev'48/52=lp' lcp'Y gmi"EC-0Vj { tqkf 0"4233' Qev'43*3" Uw r n=C8/90'</p> <p>7+ DēniF Y . 'Uj gto cp'UK'Lct  cd'D.'Ecdeplmru'O G.'O ctv'pu'T. 'Uj cj 'O J . 'gv'c'f0 Ngpxcvpkl't'g'co gpv'qh'cf xcpegf "TC K'tgh tcevqt { 'f khtgtpvcvfg "vj { tqkf "ecpegt "F VE+&lt;e{ qm'p'g'cpf 'cpi kji g'p'e'h'cevqt "ECH+r tqh'k'pi 'lp'eqo dl'p'cv'qp'y kj 'wo qt' i gpgv'e'cpcn'uku'v'k'f'gp'v'h'f 'o ctngtu'cuuqelcvfg "y kj 't'gur'qpug']cdutcev_0Rt gugpvcvqp' cv'vj g'4234' CUEQ' C ppcni'O ggv'pi =4234' Lxp'3/7=Ej leci q"KN+0L'Erlp"Qpeqni'0 4234-52*Uw 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.'Rēclpk'H'DēniF Y . 'gv'c'f0C' r j cug'K'vtkri'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'Erlpēcni'Qpeqmi { 'C ppcni'O ggv'pi =4234' Lxp'3/7=Ej leci q"KN+0L'Erlp" Qpeqni'04234-52*Uw 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'ij { tqkf "ecpegt" *F VE+&lt;'Cpcn' uku'v'q'f'gp'v'h'f "                  dkqo ctngtu'cuuqek'v'g'f 'y kj 't'gur qpug' ]cdut'cev_0'Rt'gug'p'v'k'p'cv'v'j'g'93' "Lcr cp'gug"                  Ecpegt'Cu'q'ek'v'k'p'p'p'w'cn'O'gg'v'p'i . '4234'U'gr "3; /43=U'cr r'qtq. 'Lcr cp'0'                  Ugg"Cr r'g'p'f'kz"380030'</p>
<p><b>Study Period:</b></p>	<p>28'P qx"422: "v"33'Cr t"4233"</p>
<p><b>Phase of Development:</b></p>	<p>Rj'cug"4"</p>
<p><b>Objectives:</b></p>	<p><b>Primary Objective</b>                  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'g'uk'uc'p'v'                  f k'htg'p'v'k'v'g'f 'v'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'&lt;                  • 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'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'tu' *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'  <b>Secondary Objectives</b>                  Kp" uwdlgeu" y kj " O VE" qt "tcf k'q'k'f'k'p'g" *353 K/t'g'ht'cev'qt { l'g'uk'uc'p'v' F VE." v'j'g'uge'q'p'f'c't { "                  q'd'l'g'e'v'x'g'u'y'g't'g'v'q'&lt;                  • 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'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'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' ]E'T_ "r'c't'v'c'n't'g'ur'q'p'ug' ]R'T_ "q't' 'u'c'd'r'g'f'k'ug'c'ug' ]U'F_+"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'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'u'k'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'h'g'e'v' "c'p'f' "v'q'r'g't'c'd'k'k'v'f' "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'c'p'ur'q't'v'g'tu' "r'q'u'k'd'n'f' "k'p'x'q'k'g'f' "k'p" "x'c't'k'c'd'k'k'v'f' "q'h'ng'p'x'c'v'k'p'd" R'M' "r'c't'c'o'g'v'g'tu' "d { "                  i'g'p'q'v'f'r'k'p'i "u'w'd'l'g'e'v'u'i'g'p'q'o'k'e'F'P'C' "w'ul'p'i "v'j'g'C'h'h' { o'g'v't'k'z'F'O'G'V' "c't't'c' { "                  • F'g'v't'o'k'p'g'v'j'g'g'd'k'q'ej'g'o'l'c'e'd'i't'g'ur'q'p'ug' "w'ul'p'i "w'o'q't' "o'c't'ng'tu' *g'k'j'g't'v'j' { t'q'i'q'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' ]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'g' "u'w'f' { "                  v't'g'c'v'o'g'p'v'+"                  • K'p'x'g'u'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'tu'y'k'j' "g'h'h'e'c'e { &lt;                  É U'g't'w'o' "r't'q'v'g'q'o'g'g'z'r't'g'u'k'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' ]E'c'h_+"                  É U'g't'w'o' "d'k'q'o'c't'ng'tu' "q'h' "c'r'q'r'v'q'u'k'u' *e'c'ur'c'ug' "5'9' ]E'c'ur' "5'9_ "e { v'q'ej' "t'q'o'g' "e'                  ]E { v'q'E_ "c'p'f' "O'52' "p'g'q'c'p'w'i'g'p' ]O'52_±</p>
<p><b>Methodology:</b></p>	<p>V'j'k'u' "y'c'u'c' "R'j' "c'ug' "4. "o'w'n'k'e'g'p'v't. "q'r'g'p' "n'd'g'n' "u'k'p'i'ng'c'to' "u'w'f' { . "u'w'c'v'k'ht'g'f' "d { "j'k'u'q'q'i' { "                  *F'VE' "q't' "O'VE+0'""                  V'j'k'u' "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'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>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"hwpevqpp0</p> <p>f0 etgcwlpkg'engctpeg"&gt;"82"o Nlo kp'r gt"vj g"Eqenetqhw'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' Cuqekvqpp" ]P [ J C_ " Ercau'KK" wpuvdrng" cpi kpc" qt" o { qectf'kcn' kphctevqpp'y kj kp"8"o qpj u'qhi'uwf { 'uvtv"qt"ugtqwu'ectf kee'cttj { vj o kc+"</p> <p>60' Cevxg"j go qr v'uku"dtki j v'tgf "dmqf "qh'cv'rgcu" " v'gcur qqpp+"lp"vj g"4: "f c{u'r tkqt" v'uwf { "gpv { "</p> <p>70' Drggf kpi "qt"vj tqo dqve"l kuqtf gtu'qt"vug"qh'cp'leqci wcpw."uwej "cu'y cthctkp."y kj "c"vj gtr gwle"lpvgtpcvqpcr'pqt o 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" ugxgtg'hwpeqpv'qngf "lpvgtewt'gpv'kmpguu'qt"lphgevkpp"</p> <p>90' Qti cp'cmqi tchm'tgs wtkpi "lo o wpuwr r tguukxg"tgcvo gpv"</p> <p>: 0' Rtkqt"o crki pcpv { "qvj gt"vj cp'pqpo grrpgo c"unkp"ecpegt"qt"egt xlecn'ectekpgo c"lp"ukw"wpguu"vj g'r tkqt"o crki pcpv { "y cu'f kci pqugf "cpf "f ghkpkxgn' "tgcvgf "≥7" { gctu r tgxkqwn' "y kj "pq"uwdugs wgpv'gxkf gpeg"qh'tgewt'gpeg"</p> <p>; 0' Dtcip"qt"nrg vqo gplki gcn' *egpvtcn'pgtxqwu"u{ungo " ]EPU_+" o gvcucugu0"Uwdlgevu" y kj "ucdrng"qt"r tgxkqwn' "ktcf kcvf "dtclp"o gvcucugu'y gtg'cnq"gzemf gf 0"</p> <p>320' O ctngf "dcugrpg" r tqnqi cvkqp"qh" S VIS Ve" lpvgtxcr' "S Ve" lpvgtxcr' ≥722" o uge+" wukpi "vj g" Hkf gtelek"o gvj qf "S Ve"? "S VIT<sup>265</sup> "+"ht" S Ve"cpv'uku"</p> <p>330' I tgcvgt"vj cp"3- " r tqvklpwtk" qp"wtkpg" f kr ukem'vukpi "qt"@52"o i lf N0"Uwdlgevu" y kj " r tqvklpwtk"@3- "qp"wkpg" f kr ukem'vukpi "y qwrf "j cxg"wpf gti ppg"46/j qvt" wtkg"eqmgevkpp"ht"s wcpv'cvxg"cuuguu gpv'qh'r tqvklpwtk0"Uwdlgevu"y kj "46/j qvt" r tqvklp"≥3"i 46"j qwtu'y gtg'lpgrki kdng0"</p> <p>340' J kvqt { "qh'i cutqkpvukpcr'no crduqtr vkpp"qt"j cxkpi "wpf gti ppg"uwti gt { "tgs wtkpi" i cutqkpvukpcr'ncpuqo qugu"y kj kp"6"y ggmi"qh'uvtv'kpi "v j gtr { "qt"vj qug"y j q" j cxg"pqv'tgeqxtgf"ht qo "o clqt"uwti gt { "y kj kp"6"y ggmi"qh'uvtv'kpi "vj gtr { "</p> <p>350' Y qo gp"y j q"y gtg"r tgi pcpv'qt"dtgcuv'ggf kpi =y qo gp"qh'ej krf dgctkpi "r qvqpv'kcn' y kj "c"r qukkxg"r tgi pcpv { "vuv'cv'r tgv'gvo gpv'qt"pq"r tgi pcpv { "vun0"Y qo gp"qh' ej krf dgctkpi "r qvqpv'kcn'wpguu"3+"uwti kcm' "uvtkpg"qt" *4+"wukpi "cf gs wcvg"o gcuwt gu' qh'eqpv'cegr vkpp" *kpenf kpi "y q"ht o u"qh'e'qpv'cegr vkpp."ppg"qh'y j lej "o wuv'dg'c' dcttkt"o gvj qf "+"lp"vj g"qr klpq"qh"vj g"lpxgunki cvqt0"Rgtko gpar cwucn'y qo gp"o wuv' j cxg" dggp" co gpqttj gle" hqt" cv' rgcu" 34"o qpj u" vq" dg'e qpukf gtgf" qh' papej krf dgctkpi "r qvqpv'kcn' "Hgtv'rg" o crgu"y kj "hgo crg" r ctv'pvtu"y j q"y gtg'pqv' y krpki "vq"vug" eqpv'cegr vkpp"qt"y j qug'hgo crg" r ctv'pvtu'y gtg'pqv'wukpi "cf gs wcvg" eqpv'cegr v'xg'r tqvgevkpp"y gtg'gzemf gf 0"</p> <p>360' Qvj gt"uki plkecpv'f kugcug"qt" f kuqtf gt"vj cv"lp"vj g"lpxgunki cvqt0"qr klpq."y qwrf "gzemf g"vj g"uwdlgev'ht qo "vj g'uwf { "</p> <p>370' Rtgxkqwu'rgpxcv'kpld"vj gtr { "</p> <p>380' Rtgxkqwu"tgcvo gpv' y kj "cp" lpxgunki cvkpcr' f twi . "y kj "vj g"gzegr vkpp"qh"vj qug" kf gpv'htgf "lp" kpenukqp" Etkgtkqp" %0." y kj kp"vj g"52" f c{u'r tkqt"vq"vj g"uvtv'q h' rgpxcv'kpld"cf o kplutcvkpp"</p> <p>390' J kvqt { "qh'creqj qruo . "f twi "cf f'kvkpp."r u{ej kv'le"qt"r u{ej qnqi kcn'eqpf kkpq."qt" uqekcn'ukwcvkpp"y j lej . "lp"vj g"qr klpq"qh"vj g"lpxgunki cvqt."y qwrf "lo r ckt"uwf { " eqo r rkepeg"</p> <p>3: 0' Ngi cnlpecr cekf 0</p>
<p><b>Test Treatment, Dose, Mode of Administration, and Batch Numbers:</b></p>	<p>Ngpxcv'kpld"y cu'cf o kplngt'gf "lp"y q" f quci gu" f wtkpi "vj ku'uwf { 0" Ceeqtf kpi "vq"vj g"qt ki kpcr' r tqv'eqn"vj g" f quci g"y cu"ppg"32"o i "vcdng"y keg" f ckn' " *DKF +0"V y q"uwdlgevu"y gtg'v'gcvf" y kj "vj ku' f quci g0"Vj g" f quci g"y cu'ej cpi gf "vq"46"o i "qpeg" f ckn' " *S F +y j lej "eqpukv'gf"qh' v'q"32"o i "vcdngw'cpf"qpg"6"o i "vcdngv" *Co gpf o gpv'23+0"C"vqwn'qh'337"uwdlgevu"y gtg' v'gcvf" y kj "vj ku' f quci g0" "Ngpxcv'kpld"y cu' ugh'cf o kplngt'gf " qtcml" d { "uwdlgevu0"Ugg" Vcdng"4"ht"dcvej "pwo dgtu0</p>

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<b>Reference Therapy, Dose, Mode of Administration, and Batch Numbers:"</b>	P qv'cr r ñecdrğ
<b>Duration of Treatment:</b>	Uwdlgeu'y gtg"vtgcvgf "kp'v j g" Vtgcvo gpv' Rgtkqf "qh' vj g" Vtgcvo gpv' Rj cug" cpf " Gz vğpukqp Rj cug0" Vj g" uwdlgev' eqpłkpwgf "uwf { "vtgcvo gpv'wpłk'f kugcug" r tqi tguukqp. "f gxgrqr o gpv'qh' wpceegr vcdrg" vqzlek{. "f gcvj . "uwdlgeu' y kj f tcy cñ' qh' e qpugpv' ltqo " r ctvlekr cvkqp" kp" vj g" uwf { . "qt' uwdlgeu' ej qleg' vq' uqr " uwf { "vtgcvo gpv0
<b>Criteria for Evaluation:</b>	<p><b>Efficacy:</b></p> <p><b>Tumor Assessments for Response Assessment:</b></p> <p><b>Tumor Assessments for Subjects with DTC:</b>  Rtgtgcvo gpv' wo qt "cuuguo gpw' wulpi "EV" qh' vj g" pğemlej guvkdf qo gp' l r grklu" cpf " qv' gt" ctgcu' qh' npqy p' f kugcug' qt' pgy n' "uwur gevğ f "f kugcug" y gtg" vj j c xg" dggp" r gt hqto gf "y kj kp" 6" y ggmu' r tkqt" vj j g" hktuv' f qug' qh' rğp xcvłkd" cf o kłkntcvkqp. "r tğtgcvo gpv' wo qt "cuuguo gpw' wulpi "EV" qh' vj g" pğemlej guvkdf qo gp' l r grklu" cpf " qv' gt" ctgcu' qh' vj j g" ddf { "o c { "j c xg" dggp" f qpg" y kj "O TKłpugcf "qh' E V. "dw' gxcnvcvqp" qh' vj j g" ej guv' y gtg" vj j c xg" dggp" f qpg" y kj "EV0" E V" uecpu" y gtg" r gthqto gf "y kj "qtcr' cpf" kqf kpcvğf "kx0' eqpłcv' cpf "O TKuecpu" y kj "kx0' i cf qñkpw "ej grvğ" wprguu' vj gtg" y cu' c" o gf lecn' eqpłcv' kpcvğf "v' eqpłcv' 0"</p> <p>Hqmny /wr " wo qt "cuuguo gpw' qh' vj g" pğemlej guvkdf qo gp' cpf " qv' gt" ctgcu' qh' npqy p' f kugcug' cv' Rtgtgcvo gpv' qt' pgy n' "uwur gevğ f "f kugcug" y gtg" vj j c xg" dggp" r gt hqto gf "qpeg' gxgt { "qv' gt" e { eng' dgy ggp" F c { u' 43" cpf " 4: "qt' uqpgt "h' vj j g" y cu' gxf gpeg' qh' r tqi tguukqp" f kugcug" cpf " vj qwf " j c xg" wklk' gf " vj j g" uco g" o g' y qf qm' i { "EV" qt " O TK" cpf " uecp' ces wklkqp" vğej pls wgu' "łpen' łpi " wug" qt " pqpwug" qh' kx0' eqpłcv' cu' y gtg' w ugf " hqt" vj j g" Rtgtgcvo gpv' cuuguo gpw' 0" C" ej guv' z/ t c { "qt' ungrv' n' z/ t c { "v' j cv' erçtn' "f go pu' tcvğf " c' pgy " o g' cv' v' le' r' gukqp" o c { "j c xg" dggp" wugf "v' j f qewo gpv' r tqi tguukqp" kp' r' kw' qh' vj j g" EV" qt " O TK" uecpu' 0"</p> <p>Vwo qt "cuuguo gpv' cv' vj j g" Hłpcn' Xkuk' y cu' qpn' "p geguuct { "h' p' qv' f qpg" y kj kp" 6" y ggmu' qh' r' cu' v' wo qt "cuuguo gpv' 0"</p> <p>EV" cpf " O TK" ces wklkqp" i wkl' gr' pgu' hqt "uwdlgeu' y kj "F VE" y gtg' f g' v' k' gf "kp" vj j g" Vğej plecn' Ukg" O cpw' n' r' tqxk' gf " vj j g" g' cej " uksg" d { " vj j g" ko ci łpi "ETQ" f' guki pcvğf " d { " vj j g" ur' qpuqt" vj j g" r gthqto " vj j g" łpf gr' p' gp' v' t' gx' lgy "qh' vj j g" wo qt "cuuguo gpv' 0"</p> <p><b>Tumor Assessments for Subjects with MTC:</b>  Y kj kp" 6" y ggmu' r tkqt "v' j j g" hktuv' f qug' qh' rğp' xcvłkd" cf o kłkntcvkqp. "r tğtgcvo gpv' wo qt "cuuguo gpw' wulpi "EV" qh' vj j g" pğemlej guv' l r grklu" cpf " qv' gt" ctgcu' qh' npqy p' f kugcug' qt' pgy n' "uwur gevğ f "f kugcug" y gtg" vj j c xg" dggp" r gt hqto gf "qpeg' gxgt { "qv' gt" e { eng' dgy ggp" F c { u' 43" cpf " 4: "qt' uqpgt "h' vj j g" y cu' gxf gpeg' qh' r tqi tguukqp" f kugcug" cpf " vj qwf " j c xg" wugf "v' j j g" uco g" o g' y qf qm' i { "EV" qt " O TK" cpf " uecp' ces wklkqp" vğej pls wgu' "łpen' łpi " wug" qt " pqpwug" qh' kx0' eqpłcv' cu' y gtg' w ugf " hqt" vj j g" r tğtgcvo gpv' cuuguo gpw' 0" Cu' cv' Rtgtgcvo gpv' vj j g' c' df qo gp" o wu' j c xg" dggp" gxcnvcvğf " wulpi " g' kj gt" O TK y kj " cpf " y kj qw' eqpłcv' qt "EV" qh' vj j g" cdf qo gp" y kj "v' k' r' j c u g" ko ci łpi "qh' vj j g" r' cu' v' j j g" j c xg" dggp" p' qe' eqpłcv' EV" qh' vj j g" r' kx' gt " hqmny gf " d { " kx" eqpłcv' łp' l' g' v' k' p' cpf " ct' v' t' k' n' r' j c u g" ko ci łpi "qh' vj j g" r' kx' gt. " hqmny gf " ko o gf k' v' n' d { "EV" qh' vj j g" pğem' ej guv' cdf qo gp' cpf " r' grklu' 0" k' cf f' k' k' qp" v' q' uecpu' qh' vj j g" cdf qo gp. "uecpu' qh' vj j g" pğem' r' grklu' cpf " qv' gt" ctgcu' qh' f' kugcug" o c { "j c xg" dggp" f qpg" y kj "O TKłpugcf "qh' E V. "dw' vj j g" ej guv' gxcnvcvqp" y cu' v' j j g" c xg" dggp" f qpg" y kj "EV0" E V" uecpu" y gtg" vj j c xg" dggp" r gthqto gf "y kj "qtcr' cpf" kqf kpcvğf "kx0' eqpłcv' cpf "O TKuecpu" y kj "kx0' i cf qñkpw "ej grvğ" eqpłcv' wprguu' vj gtg" y cu' c" o gf lecn' eqpłcv' kpcvğf "v' eqpłcv' 0"</p> <p>Hqmny /wr " wo qt "cuuguo gpw' qh' vj j g" pğemlej guvkdf qo gp' cpf " qv' gt" ctgcu' qh' npqy p' f kugcug' cv' Rtgtgcvo gpv' qt' pgy n' "uwur gevğ f "f kugcug" y gtg" vj j c xg" dggp" r gt hqto gf "qpeg' gxgt { "qv' gt" e { eng' dgy ggp" F c { u' 43" cpf " 4: "qt' uqpgt "h' vj j g" y cu' gxf gpeg' qh' r tqi tguukqp" f kugcug" cpf " vj qwf " j c xg" wugf "v' j j g" uco g" o g' y qf qm' i { "EV" qt " O TK" cpf " uecp' ces wklkqp" vğej pls wgu' "łpen' łpi " wug" qt " pqpwug" qh' kx0' eqpłcv' cu' y gtg' w ugf " hqt" vj j g" r tğtgcvo gpv' cuuguo gpw' 0" Cu' cv' Rtgtgcvo gpv' vj j g' c' df qo gp" o wu' j c xg" dggp" gxcnvcvğf " wulpi " g' kj gt" O TK y kj " cpf " y kj qw' eqpłcv' qt "EV" qh' vj j g" cdf qo gp" y kj "v' k' r' j c u g" ko ci łpi "qh' vj j 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 tguukq'lp'hgw'qh'vj g'EV'qt'O TKuecpu0"</p> <p>Vvo qt'cuuguu gpv'cv'vj g'Hkpcn'Xkuk'y cu'qpn{ 'p geguuct { 'h'pqv'f ppg'y kj lp'6'y ggmi'qh'vj g ruv'wo qt'cuuguu gpv0</p> <p>EV'cpf "O TKces wukq'p'i wkf grkpgu'hqt'uwdlgeu'y kj "O VE'y gtg'f gvckgf "lp'vj g'Vej plecni Ukg'O cpwcn'r tqxkf gf "vq" gcej "ukg'd { "vj g" lo ci lpi "ETQ'f guki pcvxf "d { "vj g"ur qpuqt"vq" r gthqto "vj g'lpf gr gpf gpv'tgxkgy "qh'vj g'wo qt'cuuguu gpv0</p> <p><b>For All Subjects:</b></p> <p>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 "k0'0'cpf "qtcn'eqpvtcu0"Kk0'0'eqpvtcu'y cu'eqpvtckpf lecvgf . "vj g'ej guv'gxcnvcv'kq'p' y cu'r gthqto gf "y kj "pqpeqvtcu'EV'cpf "vj g'cdf qo gp lr grkku'gxcnvcv'kq'p'f ppg'y kj "O TK' Dtclp"uecpu. "y j gtg'tgs wktgf . "y gtg'r gthqto gf "y kj "k0'0'eqpvtcu'wukpi "gkj gt'O TK*y kj " i cf qnkpw "ej grv'eqpvtcu'wrguu'vj gtg'y cu'c'eqpvtckpf lec'vq'vj ku'v' r g'qh'eqpvtcu'qt' EV0'Nqy 'f qug'EV'uecpu" hqo "c'eqo dlpcv'kq'p'RGV/EV'uecppgt" y gtg'pqv'ceeg r vdrng0' Wntcuw'p'f "cpf "hwqtkp/3: /4/hwqtk/4/f gqz{/F/i meqg/r quktq'p' go kukq'p' vqo qi tcr j { " *HI /RGV+ "y gtg'pqv'vq" j cxg" dggp" wugf "hqt" tcf kqi tcr j le" wo qt'cuuguu gpv0' K'y cu' tgeqo o gpf gf "vj cv' ur kcnlo wnkf gvgevt "EV" dg" r gthqto gf "y kj "c" ≤ "7" o o "eqpvi wqwu' tgeqvt'w'kq'p'cni qtkj o 0'K'dqf { 'O TKuecpu'y gtg'r gthqto gf . "vj g' { 'y gtg'tgeqo o gpf gf "vq' dg" f ppg" y kj "eqpvi wqwu' urlegu'q h' ≤ "7" o o 0' K'lwde wcpqgw" o cuugu' qt' "pqf gu" y gtg' r cr cdrng "g0 0'dwn{ + "cpf "y gtg'cuuguudrg"d { "dqj "eriplecni'cpf "tcf kqi tcr j le" vej pls wgu. " yj g'tcf kqi tcr j le" *EV'qt'O TK' vej pls w' y cu'vq" j cxg" dggp" wugf "hqt" vj g'cuuguu gpv'qh' vti gv' cpf "pqpvti gv'ngukpu0' Cuuguu gpv' y cu'r gthqto gf "cv' vj g'ukg" d { "cr r tqr tkvgn' s wcnk'gf "r gtuqppgn" tcf kqmi ku'lp'eqplw'v'kq'p' y kj "eriplecni'kpxguki cvqt'+cpf "tguwmu'y gtg' tgeqtf gf "qp'vj g'cr r tqr tkv'g'ETHr ci g*u0</p> <p>"</p> <p><b>Target and Nontarget Lesions:</b></p> <p><b>Measurable Disease:</b></p> <p>Ceeqtf lpi "v'vj g' qtki lpcn' TGEKUV'cpf " o qf kkgf "TGEKUV."o gcuwcdrg" f kugcug'y cu' f ghkpf "d { "vj g'r tgupeg'qh'cv'ngcu'v'qpg'o gcuwcdrg'ngukp0"C"o gcuwcdrg'ngukp'ku'qpg'vj cv' eqwf "dg'ceewtcvgn' "o gcuwgf "lp'cv'ngcu'v'qpg'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 { "eriplecni' o gcuwtgo gpv0' Hqt"vj ku'tlcn'cm'uwdlgeu'y gtg'tgs wktgf "vq" j cxg'cv'ngcu'v'qpg'ngukp"&gt;30"eo "lp'NF" hqt' pqrni o r j "pqf gu'cpf "&gt;40"eo "lp'NF" hqt'ni o r j "pqf gu'vj cv'y gtg'ugtkcm' { "cpf "ceewtcvgn' o gcuwcdrg'ceeqtf lpi "vq" o qf kkgf "TGEKUV" wukpi "gkj gt'EV'qt'O TK' "Ngukpu"vj cv'j cf' tgeglxgf "GDTV" o wuv'j cxg'uj qy p' gxf gpeg' qh'r tqi tguukg' f kugcug' dcugf "qp" o qf kkgf "TGEKUV"vq'dg'f ggo gf "c'v'cti gv'ngukp0'K'c'ngukp'y cu'cuuguudrg"d { "dqj "tcf kqmi lecn'cpf' eriplecni'vej pls wgu. "tcf kqmi lecn'vej pls wgu" y gtg'vq" j cxg" dggp'wugf 0'K'vj g'o gcuwcdrg' ngukp'y cu'c'h' o r j "pqf g."k'v' wuv'j cxg'o gcuwgf "cv'ngcu'42"o o "lp'NF 0'K'c'ukpi ng'ngukp' y cu'kf gpv'kkgf "cu'vj g'v'cti gv'ngukp. "c'e' { vqmi lecn'qt" j kqmi lecn'eqpht'o cv'kq'p'qh'vj { tqkf' ectekpqo c'y cu'tgs wktgf 0</p> <p>Vcti gv'ngukpu" y gtg'ugrevgf "q p"vj g' dcuku'qh' vj gkt' uk' g'NF + "cpf " vj gkt' uwkcdkks { "hqt' ceewtcv' tgr gv'gf "o gcuwtgo gpv0' Cni' o gcuwcdrg'ngukpu"wr "vq" c'o czko wo "qh'7"ngukpu' r gt' qti cp' lukg'cpf "32"ngukpu'lp'v'cn'vj cv'y gtg'tgr tgupeg'v'k'g'qh'cni'kpxqk'gf "qti cpulukgu' y gtg'kf gpv'kkgf . "o gcuwgf . "cpf "tgeqtf gf "cu'v'cti gv'ngukpu'qp'vj g'cr r tqr tkv'g' dcugrkpg'ETH' Vj g'uco g'ngukpu'y gtg'o gcuwgf "cpf "tgeqtf gf "cv'cn'hmjy /w "ko g'r qkpw0"</p> <p>Cm'qj gt' ngukpulukgu'qh'f kugcug'y gtg'kf gpv'kkgf "cu'pqpvti gv'f kugcug."tgeqtf gf "qp"vj g' dcugrkpg' ETH'cpf " cuugu'f " cv'cn'hmjy /w " ko g' r qkpw" cu' opq" ej cpi glwcdrg.ö' öcdugpvlf kucr r gctgf .ö' öwpgs w'xqecni' y qtuglpi .ö"qt' öqj gt' *ur gekh' +0" C p { "pgy "ngukpu' f gv'evgf "tcf kqi tcr j lecm' y gtg'tgeqtf gf "qp'vj g'cr r tqr tkv'g'pqpvti gv'ngukp'ETHr ci g0</p> <p><b>Clinically Evaluable Disease:</b></p> <p>Eriplecni' "gxcnvcv'ngukpulukgu'qh'f kugcug"*wej "cu'r ngwcn'gh'wukq'p."cuekgu."ewcpgqwu'</p>
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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"opq'ej c pi g luvdrq.ö"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' "gxcnwdrg'ngukpu'y cu'tgeqtf gf "qp'v'j g'r quwtgcvo gpv'ETHO"

**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"eqphkto cvqt { "v'o g'r q'k'p'v'k'p'c'm'iuwdlgeu'y kj "ET" cpf "RT0"HF I "RGV" y cu'p'q'v'c'p'ceeg r v'cdrg'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 qp'c'v'g"dqpg"uecp0" Y j qrg"dqf { "O TKo c { "j cxg"dg'p'p'wugf "cu'c'p' "cngt'p'c'v'g"vq' dqpg"uecpu'cv'r tgv'gvo gpv'cpf "h'qmy /w "k'h'wugf "epuk'v'p'v'k' "cet'qu'u'c'n'n'g'v'k'w'gf "v'o g' r q'k'p'v'0"Dqpg"uecpu'y gtg"v'wugf "v'f'g'v'ev'p'gy "dqf { "ngukpu0"K'c'p'gy "ngukp"cr r gctgf "qp"c' h'qmy /w "dqpg"uecp. "k'y cu'tgeqo o g'p'f'gf "v'j cv'z/tc{ . "E.V. "qt "O TKdg"v'wugf "v'j g'eqphkto "v'j g' o c'k'i p'c'p'v'p'c'w'g'q'h'v'j g'p'gy "t'c'eg't'w'v'c'ng0"

**Evaluation of Tumor Response:**  
Vvo qt" t'g'ur qpug" y cu'g'x' c'w'c'v'gf " cv'v'j g" uk'g'd { " s'w'c'n'k'k'g'f " r gtu'q'p'p'g'i " \*c" t'c'f' k'q'q'i k'u'v' k'p' eqpl'w'p'v'k'p'p"y kj "vj g'erlplecn'k'p'x'g'v'k'i cvqt+'w'ul'p'i "o qf k'k'g'f "TGEKUV0" Cp" K'K" qh"wo qt" t'g'ur qpug'u'y cu'c'n'q'r gthqto gf "d { "E'q't'g'r'c'd'R'c't'v'p'g'u0" T'g'ur qpug'u'y g'g'cu'gu'ug'f "c'ee'q't'f' k'p'i "v'q" o qf k'k'g'f "TGEKUV. "f' g'v'c'k'g'f "k'p'c'p'k'p'f' g'r g'p'f' g'p'v'k'o c'i k'p'i "T'g'x'g'y "E'j c't'v'g't. "y j k'ej "y cu'k'u'w'g'f r tkqt"vq"v'j g'u'c't'v'q'h'v'j g'k'p'f' g'r g'p'f' g'p'v'g'x'g'y 0"K'p'x'g'v'k'i cvqtu'y gtg't'g's wktgf "v'q'r t'q'x'k'f' g'eq'r k'g'u' \*r t'g'h't'c'd'n' "k'p'f' k'i k'c'n'h'q'to cv'q'h'l'o c'i g'u'h'q't "wo qt "cu'gu'guo gpv'"E.V. "O TK'dqpg"uecpu+"v'q" c' e'g'p't'c'n'f'c'k'k'v'0"C"o c'p'w'n'f' g'v'c'k'k'p'i "t'geqo o g'p'f'gf "u'ec'p'k'p'i "r c't'c'o g'v'g'u. "k'o c'i g'j" c'p'f' r'k'p'i . c'p'f' "u'j k'r r k'p'i "y cu'r t'q'x'k'f' g'f "v'j g'c'ej "u'k'g0"Vj k'u'f' q'ewo gpv'k'u'h'q'c'v'gf "k'p'v'j g'v't'k'n'o cv'g't' "h'k'g0 Vj g'K'K" "g'x'c'n'w'c'k'p'p"y cu'w'ug'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'k'c'c' { "cu'gu'guo gpv'q'h'v'j g' u'w'f { 0"

K'p'q't'f' g't' "h'q't"v'j g'UF "f' g'v'k'i p'c'v'k'p'v'q"dg'i k'x'g'p' "h'q't"dg'u'v'q'x'g't'c'n't'g'ur qpug"\*DQT+ "cv'ng'c'v'p'p'g' r quwtgcvo gpv'o gcuwtgo gpv'o w'v'v'j cxg'o g'v'v'j g'UF "e't'k'g't'c'c"o k'p'k'o w'o "q'h'9"y ggmu'c'h'g't' hktuv'w'w'f { "f' t'w'i "c'f' o k'p'k'v'c'k'p'0"C"ET"qt "RT"cu'gu'ug'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'vo gpv'y kj q'w'c'eq'p'h'to c'v'k'p'q'h'RT"qt "ET"cv'ng'c'v'6"y ggmu'h'v'g't'd { "h'qmy /w "uecpu. dw'v'j cxk'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'cu'gu'guo gpv."y cu'eq'p'k'f' g'f "UF "h'q't"v'j g'd'g'u'v' t'g'ur qpug0"J q'y g'x'g't. "ET"qt "RT"cu'gu'ug'f "rguu'v'j cp"9"y ggmu'c'h'g't' u'c't'v'q'h'v'g'vo 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'v' cu'eq'p'k'f' g'f "r t'q'i t'g'u'k'x'g'f' k'g'c'g'v' h'q't"v'j g'd'g'u'v' t'g'ur qpug0"

Eq'p'h'to gf "t'g'ur qpugu"\*ET"qt "RT+"y g't'g'f' g'v'g'to k'p'g'f "c'v'c't'g'r g'c'v'wo qt "g'x'c'n'w'c'k'p'p'cv'ng'c'v'6" y ggmu'c'h'g't' d'g'k'p'i "hktuv'q'd'ug't'x'g'f "d { "g'k'j g't'v'j g"l'p'x'g'v'k'i cvqt"qt "K'K" y j q"o c'f' g'v'j g"l'p'k'k'c'n' cu'gu'guo gpv0"Vj g'p'g'z'v'g'x'c'n'w'c'k'p'p' "h'q't"r q'v'p'v'c'n'eq'p'h'to c'v'k'p'q'h'v'j g'hktuv'RT"qt "ET"eq'w'f " j cxg"y c'k'g'f "w'p'v'k'v'j g'p'g'z'v't'g'i w'c't'n' "u'ej g'f' w'g'f "wo qt "cu'gu'guo gpv0"Vvo qt "cu'gu'guo 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 kj k'p'6"y ggmu'q'h'v'j g'nc'u'v'g'vo gpv'e { erg0 C"ej g'u'v'z/tc { "q't' u'ng'g'v'c'n'z/tc { "v'j cv'eng'c't'n' "f' go q'p'u't'c'v'gf "c'p'gy "o g'v'c'v'c'v'e'ng'uk'p'o c { "j cxg' d'g'g'p'w'ug'f "v'j f' q'ewo gpv'r t'q'i t'g'u'k'p. "k'p'k'g'w'q'h'v'j g'EV"qt "O TK'ue'c'p'u0"

**Tumor Assessments if Subjects Discontinued from Study Treatment Without Progressive Disease:**  
K'i' u'w'd'g'eu'f' k'ue'q'p'v'k'p'w'g'f "h'q'to "u'w'f { "t'g'vo gpv'y kj q'w'r t'q'i t'g'u'k'x'g'f' k'g'c'g'v' c'p'f "f' k'f" p'q'v' y kj f' t'c'y "eq'p'g'p'v'wo qt "cu'gu'guo gpv'u'y g't'g'r g't'g'q'to gf "cv'v'j g'H'p'c'n'X'k'k'v"y kj k'p'52" f' c { u'q'h' v'j g'nc'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't'g'q'to gf "y kj k'p'v'j g'r t'g'x'k'q'w'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'nc'u'v'wo qt "cu'gu'guo gpv'w'p'v'k'v'r t'q'i t'g'u'k'x'g'f' k'g'c'g'v' 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"

**Pharmacokinetics:**  
Ng'p'x'c'v'p'k'd" r'nc'u'c" eq'p'g'p't'c'v'k'p'p' f'c'v'c'y g't'g' "eq'm'g'ev'g'f' c'p'f' "d'g'ec'w'ug" q'h'v'j g'ur c't'ug" RM' u'c'o r'k'p'i "v'o g'u. "y cu'r q'q' r'g'f" y kj "vj g'k'p'v'g'p'k'x'g" RM'f'c'v'c "h'q'to "v'j t'g'g'r t'g'x'k'q'w" Rj c'ug"3" u'w'f' k'g'u'k'p' u'w'd'g'eu'y kj "u'q'k'f" "wo q'tu"\*G92: 2/G266/323. "G92: 2/C223/324. "c'p'f' "G92: 2/

"

	<p>I2: 3/325+'hqt'RM'o qf grif gxmqr o gpw0"</p> <p>Hqt'y j g'y q'uwdlgeu'y j q'y gtg'tgcvgf'y kj "rgpxcxlkd"32"o i "DIF ."c'vqcn'qh'33"RM'dmqqf "uco r rgu'y gtg'qdvckpfg'r gt'uwdlge0"Uco r rgu'y gtg'qdvckpfg'qp"E {erg'3'F c {u'3'cpf "4'cpf "qp"E {erg'4'F c { "30"Hqt'y j g'tgo clkpi "337"uwdlgeu'y j q'tgegkxgf "rgpxcxlkd"46"o i "S F ."c'vqcn'qh'plkg"RM'd mqqf "uco r rgu'y gtg'qdvckpfg'r gt'uwdlge0"Uco r rgu'y gtg'qdvckpfg'qp"E {erg'3'F c {u'3'cpf ". .E {erg'4'F c { "3."cpf "E {erg'5'F c { "30"</p> <p><b>Pharmacokinetic/Pharmacodynamic (PK/PD):</b></p> <p>Cpcn'ugu'y gtg'eqpf wevgf "d { "o qf grkpi "vq" gZR nqtg" gZR quwtg0tgur qpug"tgrvckpuij kr u" hqt' uchgv { "cpf "ghlece { 0"</p> <p><b>Pharmacodynamics:</b></p> <p>Vj g" r rppgf "RF "cuuguuo gpwu' kpenwf gf "vj g" hqmjy kpi "ugtwo "dkqo ctngtu&lt;" 3+" vj { tqkf "hmpvckp" vguu' kpenwf kpi "htgg" V6" c pf "VUJ = 4+vj { tqi mdrwkp "F VE "uwdlgeu" qpnf = 5+ ecvckp"cpf "EGC "O VE "uwdlgeu" qpnf = 6+ dkqo ctngtu"qh' cr qr vaku "Ecur "5 19." E {vqE." cpf "O 52 = 7+ r tqvgo g" ECH' dkqo ctngtu"qh' cpi kji gple li tqy vj "hcvqtu." kpenwf kpi ej go qnkpg. "gpf qj grkwo "hmpvckp." cpf "kpvgrvwnkplko o wpg" tgur qpug= Rj cto ceqf { pco ke' cpf "wo qt' t'gur qpug' tgrvckpuij kr u'y gtg' gZR nqtg 0"</p> <p>"</p> <p><b>Pharmacogenomics:</b></p> <p>Vj g" r rppgf " r j cto ceqi gpqo ke" *RI +cuuguuo gpwu' kpenwf gf " vj g" hqmjy kpi &lt;" 3 + " wo qt' o wcvkpu"uqo cvk "F P C"ugs wpeg'xctkcpw+lp" BRAF, H-, K- "cpf "N-Ras," cpf "RET/PTC1, 2," cpf "3" cuuguugf " lp" hqto cirk/hkzgf " r ctchkp/go dgf f gf " *HRG+ " wo qt' "kuuwg'cp f " 4+ i gto rkp" F P C "ugs wpeg'xctkcpw"lp" i gpgu"lpxqkxgf "lp" C F O G "cu'y gni'cu" RET" cpf "F P C" xctkcpw" pget " FOXE1 " *rs965513+ " cpf " NKX2-1 " *rs944289+ " cuuguugf " hqto " uwdlgev' dmqqf "uco r rgu0" Rj cto ceqi gpqo ke" cpf "v wo qt' t'gur qpug" tgrvckpuij kr u' y gtg' r rppgf " vq" dg' gZR nqtg 0"</p> <p><b>Safety:</b></p> <p>Uchgv "cuuguuo gpwu'eqpukvgf "qh"o qpkqtkpi "cpf "tgeqtf kpi "cm'cf xgtug" gxgpw" *CGu+ "cpf " ugtkqwu" cf xgtug" gxgpw" *UCGu= " eqpeqo kcpv" o gf kcvkpu." tgi wct " o qpkqtkpi " qh' j go cvqmi { ." dmqqf " ej go kut { ." cpf "wtkpg" xcwgu= r gtlkf ke" o gcuwtgo gpv' qh'xkcn' uki pu. GEQI " r gthqto cpeg" ucwuw. P [ J C " cuuguuo gpwu." grgevtqectf kji tco u" *GEI u+ gej qectf kji tco u= cpf " r gthqto cpeg'qh'r j { ulecn'gzco kpcvku0"</p>
<b>Bioanalytical Methods:</b>	<p>Rruo c" eqpepvtcvkpu" qh'r ctgvp' f twi " y gtg' s wcpvklgf " d { " rls wlf " ej tqo cvqi tcr j { lo cuu' ur gevto gvt { lo cuu' ur gevto gvt { " *NE IO UIO U+ " o gj qf qmji { " wukpi " c" r t'gxkqwu" { "xcikf cvgf " cuuc { 0"</p>
<b>Statistical Methods:</b>	<p>F cvc" qdvckpfg' "wr "vq" vj g' f cvc' ewqhh' f cvg' qh' 33" Cr t " 4233" ctg' kpenwf gf "lp" vj ku' tgr qt v0" kpi' cf f ksqp. " f cvc" hqt' cuuguuo gpvlgxgpw" y kj " c' utcvf' cvg" r tktq" vq" vj g' ewqhh' f cvg' vj cv' eqpvkpwgf " chgt' vj g' ewqhh' f cvg" ctg' cnuq " kpenwf gf " *g0 0" CG. e qpeqo kcpv" o gf kcvkpp. r tqegf wtg. "cpf "uwwf { "tgcvo gpv0" Hwt j gto qtg. "uwxkcnf cvc" eqngvgf "chgt' vj g' ewqhh' f cvg" ctg' cnuq' kpenwf gf "lp" qt' gt "vq" qdvckp' uwdlgeu' uwxkcn' uxcwu' cv' vj g' ewqhh' f cvg0"</p> <p>Vj g' kpvv' vq " Vtgc v' *KV+ Rqr wcvkpp' kpenwf gf "cm' uwdlgeu'y j q' tgegkxgf "cv' r' gcu' v' qpg' f qug' qh' vj g' uwwf { "f twi "cpf "y cu' vj g" r tlo ct { "cpcn' uku' ugv' wugf "hqt' ghlece { " cpcn' ugu0" Vj g' Ghlece { "Gxcncdrj" Rqr wcvkpp' kpenwf gf "cm' uwdlgeu'y j q' tgegkxgf "cv' r' gcu' v' qpg' f qug' qh' vj g' uwwf { "tgcvo gpv." j cf "c' dcugnkp" cpf "cv' r' gcu' v' qpg' r quwtgcvo gpv' wo qt' t'gur qpug' gxcncvckp. cpf "hwtkngf "kpenwkpp' etkgtk' "3. "4. "5. "cpf "60" Vj g' Uchgv' "Rqr wcvkpp' kpenwf gf "cm' 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 quwtgcvo gpv' uchgv' cuuguuo gpv' cpf "y cu' vj g" r tlo ct { "cpcn' uku' ugv' hqt' "cm' uchgv' f cvc0" Vj g' uchgv' "cpcn' ugu'y gtg' eqpf wevgf "d { " utcw0 " *F VE " cpf " O VE + ugr ctcvgn' "cp f " y kj " vj g' y q' utcv " eqo dlpf 0" kpi' cf f ksqp. " vj g' y q' " F VE " uwdlgeu' gptqmgf " wpf gt " vj g' qtki kpcn' r tqvqen' y kj " kpkcn' DIF " f qukpi " y gtg' cpcn'   gf " ugr ctcvgn' " cu' c' i tqwr . "cn uq " vqi gj gt " y kj " cm' vj g' uwdlgeu' cu' vj g' qxgtcn' uwo o ct { "hqt' vj g' uwwf { 0"</p>



"

	<p>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"lcttj gc. hcvk wg."f getgcugf "cr r gvkg."pcwgc."cpf "y gli j v'f getgcug."cpf "rdqtcvqt {"r ctco gygtu"r hqt" j go cvqmi {&lt;"j go cvqetk."j go qi mdlp."y j kg"drqf "egm."pgwtqr j kn"cpf "r rvgv'eqwpu="hqt" dkqej go kvw {&lt;" cmvklpg" r j qur j cvug." dklwdlp." crvklpg" co kpvtpuhgtcug." cur ctvcg co kpvtpuhgtcug."ugt wo "cndwo kp."ugt wo "etgcvklpg."cpf "vqcnr tqvklp-0"</p> <p>Tgrvklpuj kr u'y gtg"gzr mtgf "dgv ggp"ngpxcvklpd"gzr quwtg"cpf "yj g"hmny kpi "dkqo ctngtu" dkqej go kecn'o ctngtu"*j { tqi mdwlp"hqt"yj g'F VE"eqj qtv."ecrekqkp"cpf "EGC"hqt"yj g'O VE" eqj qtv." cpf " y { tqf " hwpvklp" vguvt guw nu" *ftgg"V6 " cpf " htgg"VUJ " hqt" cniwd 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." kpvtrgwklp"lko o wpg'tgur qpug"hcvtu."cpf "qj gt"hcvtu0"</p> <p>Uchgv" f cvc."kpenwf kpi "CG"cpf "rdqtcvqt {"xcnmu."r tlqt"cpf "eqpeo 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" ucvkukou" *p."o gcp."o gf kcp." ucpf ctf " f gxlvklp." tci g+"hqt" eqvklpwqwu"o gcuwgu." cpf kpek gpeg"eqwpu"*pwo dgt"cpf "r gtegpv"hqt"ecvgi qtlecn'xctkcdrgu0"</p>
<p><b>Results:</b></p>	<p><b>Analysis Sets</b></p> <p>Vj g"KVVRqr wvklp"cpf "yj g"Uchgv"Rqr wvklp"y gtg"yj g'uco g'lp"yj ku"uwf {&lt;"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 -"c pf "7; "uwdlgeu"lp"yj g'O VE"eqj qtv" f qugf "46"o i "S F 0"V j g"GHlece {"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"KVVR"qr wvklp."t gur gevkgf +0'</p> <p><b>Subject Disposition"</b></p> <ul style="list-style-type: none"> <li>• 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 "htqo " yj g' tgcvo gpv'lp"yj g'Vtgcvo gpv' Rj cug0" Ukvggp" uwdlgeu" *4; ' +lp" yj g' S F " f qulpi i tqw " f kueqpvklpwgf " f wg" vq" f kugcug" r tqi tguukqp0" C "vqcn'qh"37" uwdlgeu" *49" +lp" yj g' S F " f qulpi " i tqw " f kueqpvklpwgf " f wg" vq" CGu" 36" *47" +y kj " CG* u" cu" yj g' r tko ct { " tgcup" hqt" f kueqpvklpwgf" cpf " 3" uwdlgev" y kj " uwdlgev" ej qlkg" cu" yj g' r tko ct { " tgcup" hqt" f kueqpvklpwgf" cpf " y kj " cp" CG" cu" yj g' ugeqpf ct { " tgcup0 Qpg" cf f kkpcri" 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 kueqpvklpwgf" 0"</li> <li>• 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 " htqo " 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 kueqpvklpwgf" *kpenwf kpi " 3" uwdlgev" y kj " dqj " yj g' r tko ct { " cpf " oqvj gt o' tgcup" ]lp" cf f kkp" vq" yj g' r tko ct { " tgcup_ " hqt" f kueqpvklpwgf" pqv" cu" dglpi " f wg" vq" CGu" + cpf " 3" uwdlgev" y kj " uwdlgev" ej qlkg" cu" yj g' r tko ct { " tgcup" hqt" f kueqpvklpwgf" cpf " y kj " cp" CG" cu" yj g' ugeqpf ct { " tgcup0" Qpg" cf f kkpcri" uwdlgev" f kueqpvklpwgf " f wg" vq" uwdlgev" ej qlkg" cu" yj g' r tko ct { " tgcup" hqt" f kueqpvklpwgf" 0'</li> <li>• 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" uknlt gegklpi " tgcvo gpv' lp" yj g' Gzvgpukqp" Rj cug0'</li> </ul> <p><b>Exposure</b></p> <ul style="list-style-type: none"> <li>• Hqt" yj g' F VE" eqj qtv" yj g' o gf kcp" f wcvklp" y cu" 5; 50" f c { u" *tci g&lt;" 42" 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; .</li> </ul>

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	<p>tgur gevkgñ(0"</p> <ul style="list-style-type: none"> <li>• Hqt"vj g"O VE"eqj qtv"vj g"o gf kcp"f wcvkqp"y cu"4860"f c{u"*tpci g&lt;"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 gevkgñ(0"</li> </ul> <p><b>Efficacy</b></p> <ul style="list-style-type: none"> <li>• 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"0"Vj g"QTT"y cu"72" "kp"vj g"VE"eqj qtv"cpf"58" "kp"vj g"O VE"eqj qtv"0"</li> <li>• Ugeqpf ct{ "ghhece{ "tgumu"ht"vj g"VE"eqj q t"v'y gtg"cu"hmjy u0"Cv'c'o kpk wo "hmjy /w"r gtlqf "qh"36"o qpj u."vj g"o gf kcp"gwko 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 gkgt"cpch"uku"eqwf "pqv"dg"tgrkdn{ gwko cvg"0"Vj g"qxgtcm"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"hmjy /w"ko 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"ko 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"</li> <li>• Ugeqpf ct{ "ghhece{ "tgumu"ht"vj g"O VE"e qj qtv"y gtg"cu"hmjy u0"Cv'c'o kpk wo "hmjy /w"r gtlqf "qh": "o qpj u."vj g"o gf kcp"gwko 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 gkgt"cpch"uku"eqwf "pqv"dg"tgrkdn{ "gwko cvg"0"Vj g"qxgtcm" uwtxkcn"tcvg"y cu"98" "cv"34"o qpj u"cpf"y cu"pqv"gwko cdng"cv3: "cpf"46"o qpj u0" Vj g"o gf kcp"hmjy /w"ko 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"ko g"vq" tgur qpug"ht" uwdlgeu"y kj "eqpkto gf "c"DQT"qh"ET" qt"RT"kp"v j g"Ghhece{ " Gxcncdng"Rqr wcvkqp"*p?3; +y cu"50"o qpj u0"</li> <li>• 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"uko 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 gevkgñ(0"</li> <li>• Ugeqpf ct{ "ghhece{ "gpfr qkpw"y gtg"cuq"dcugf "qp"vj g"kpwxuki cvqtu0"cuuguo gpw'd{ Vj g"ugeqpf ct{ "ghhece{ "gpfr qkpw"uj qy gf "pq"o clqt"fhgt gpegu"dcugf "qp"vj g"y q" uqwtegu"qh"cuuguo gpw'd{</li> </ul> <p><b>Pharmacokinetics/Pharmacodynamics</b></p> <ul style="list-style-type: none"> <li>• Vj g"RM"qh"ngpxcvkpd"kp"vj g"eqo dkgf "VE"cpf"O VE"eqj qtv"y gtg"uko 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 { "ucvg"WE"eqwf "dg"qdugtxgf"y kj "QTT"cpf"RHU"</li> </ul> <p><b>Safety</b></p> <ul style="list-style-type: none"> <li>• Cm' uwdlgeu"kp"dqj "eqj qtv" gzr gtlkpegf "cv'hcuv"qpg"v tgcvo gpvgo gti gpv"CG" *VCGG-" cpf" cv' ngcu"qpg"VCGG"tg r qtvgf" cu"tgcvo gpv"tgrcvgf 0"Vj g" o quv htgs wgpw{ "tgr qtv"VCGG"*62" "qh"uwdlgeu"kp"gkj gt" eqj qtv"y gtg"lctj gc." j {r gtvgpukp."r tqvklpwlk."h"ki wg."y gli j v'f getgcugf."f getgcugf"cr r gvkq."pcwugc." j gcf cej g."eqw j ."cpf" f {ur j qpk0"</li> <li>• Vqzlekkgu"y gtg"o cpci gf" d{ "uwf { "f twi" "kpvtw"v kcp" cpf" uwdugs wgpv" f qug" tgf wcvkqp"v"tgf weg"vj g"pgeguks{ "ht"uwf { "f twi"y kj f tcy cto"VCGG"hgcf lpi"vq" uwf { "f twi"y kj f tcy cni"qeewtgf "kp"37"uwdlgeu"*48" +kp"vj g"VE"eqj qtv"cpf"kp" 36"uwdlgeu"*46" +kp"vj g"O VE"eqj qtv"</li> </ul>
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	<ul style="list-style-type: none"> <li>• VGCu"qh'ur gekni'kpvtguv'kpenmf gf "j { r gt vgpukqp"cpf "r tqvklpwk."y j lej "ctg"CGu npqy p"vq"dg"cuuqekvxf "y kj "tgcvo gpv'y kj "ngpxcvkpld"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 " kpvttr 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 cni'htqo "y j g'uwf { "tgcvo gpv'f wg"vq"j { r gt vgpukqp qeewtgf "kp"qpg"uwlgev'gcej "kp"y j g'F VE" cpf "O VE"eqj qtv0" Rt qvklpwk"rgf "vq" uwf { "f twi "y kj f tcy cni'kp"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 "kp"y q"uwlgeu'lp"y j g'F VE"eqj qtv' cpf "kp"qpg"uwlgev'lp"y j g'O VE"eqj qtv0"Rt qvklpwk."cu'cp"UCG."qeewtgf "kp"qpg' uwlgev'lp"y j g'F VE"eqj qtv'cpf "pqv'lp"cp { "uwlgev'lp"y j g'O VE"eqj qtv0"</li> <li>• Kp"y j g'F VE"eqj qtv."y j g'o quv'htgs wgpw' "tgr qtvf "I tcf g"5"VGCu"qeewtkpi "kp" 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"VGCu"qeewtgf &lt;"j { r qecre go kc."j { r gtnre go kc. cdcuk."cpf "cewg"o { qectf ker'kphctevkq"qpg"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" VGCu"qeewtkpi "kp"cr r tqzko cvgn' "32" "qh'uwlgeu"qh'uwlgeu"y cu'f kcttj gc0 Hxg"I tcf g"6"VGCu"qeewtgf &lt;"co { rug"ketgcugf . "nr cug"ketgcugf . "r pgwo qpk cur kcvkq. "gzhqkcvkxg'tcu'j . "cpf "ceekf gpv'ni'qxtgf qug"qpg"tgr qtv'gcej +0"</li> <li>• UCGu"dqy "hcvn'cpf "paphcvn"qeewtgf "kp"4: "uwlgeu"*6: " +lp"y j g'F VE"eqj qtv' cpf "kp"52"uwlgeu"*73" +lp"y j g'O VE"eqj qtv0"UCGu'y j lej "qeewtgf "kp"cv'ngcu' y q" uwlgeu" y gtg" cu' hmqy u&lt; "kp" dqy " eqj qtv." r wv qpct { " go dqruo " cpf f gj { f tcvkq=" qpn' " kp" y j g'F VE" eqj qtv." ny gt" cdf qo kpcn' r clk." j { r qvgpukqp. j { r gt vgpukqp."cpf "ectf kce"tckntg="cpf "qpn' "kp"y j g'O VE"eqj qtv."cdf qo kpcn' r clk. npi "kphgevkq."f getgcugf "cr r gvkg."cpf "r tgo cwtg'o gpqr cvwg0"</li> <li>• F gcj .f wtkpi "tgcvo gpv'qt'y kj lp"52"fc { u'qh'y g'rcuv'f qug'qh'uwf { "f twi ."qeewtgf "kp"cv'ngcu'qh'ugxgp"uwlgeu'lp"y ku'uwf { &lt;"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."qpg"lp"y j g'F VE"eqj qtv'cpf "qpg"lp"y j g'O VE"eqj qtv. y gtg"tgr qtvf "f wg"vq"erikplecni' r tqi tguukqp"qh'f kugcug0"Hxg" f gcj u'y gtg"tgr qtvf cu'cp"qweqo g'qh'cp"UCG&lt;"y q "kp"y j g'F VE"eqj qtv'cpf "y tgg"lp"y j g'O VE"eqj qtv0 Y kj "y j g'gxncv'kq"qh'y j g'kphqto cvkq"cxckndrg"ht' y j g'g'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"ectqkf ctvt { "j go qttj ci g'y j lej "y cu'tgrvxf "vq"necni'kphco o cvkq"qh'y j g'xguun'htqo "c r tgxkqwu"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'rcuv'f qug' qh'uwf { "f twi ."ulz"y gtg"cuuqekvxf "y kj "r tqi tguukqp"qh'f kugcug."cpf "qpg"y cu'y j g' qweqo g'qh'cp"UCG0</li> <li>• P q"erikplecni' "ko r qtvcv'ej cpi gu'lp"o gcp"j go cvqni { "cpf "dkqej go knt { "xcnvgu' htqo "dcugrkpg"vq"y j g'gpf "qh'y j g'xctkqwu'e { ergu'y gtg"qdugtxgf 0" T guwmu'htq'o gcp" r nvgv'cpf "pgwtqr j k'eqwpu'uj qy "c'u nki j v'f getgcukpi "vtgpf ."dw'y gtg'y kj kp pqto cn'tepi g'htq'gcej " r ctco gvt0"Vj gug"tguwmu'y gtg"uggp"kp"dqy "F VE"cpf "O VE"eqj qtv0"Vj g'uj kn'cpcn'uku'htq'EVECG'i tcf gu'tgxgcrf "pq"uj kn'qh'erikplecni' eqpegt'htq'j go cvqni { "qt'erikplecni'ej go knt { "r ctco gvtu'htqo "dcugrkpg"vq"y j g'gpf qh'gcej "e { erg0"ketgcugu'lp"r tqvklpwk"y j g'v'kpg'y gtg"qdugtxgf "qxtg"ko g'y j lej "ku' eqpukngpv'y kj "y j qeewt gpeg'qh'r tqvklpwk"tgr qtvf "cu"VGCu0"</li> <li>• Eriplecni' "ko r qtvcv'ej cpi gu'lp"o gcp" xkcn'uki pu'htqo "dcugrkpg"vq"y j g'gpf r qkpu' cv'xctkqwu' xkuku"y gtg" qdugtxgf 0" Dnqf " r tguwtg"ej cpi gu' qeewtgf "cpf "y gtg' tgr qtvf" cu' VGCu" kn' f ggo gf " erikplecni' " ko r qtvcv' d { " y j g' lpxguki cvqt0 Ngpxcvkpld"tgcvo gpv'y cu'eqttgrvxf "y kj "cp"ketgcug"lp"dnqf "r tguwtg0"O quv'qh' y j g' ketgcugu"lp" dnqf " r tguwtg" qeewtgf " f wtkpi " y j g' htu'v' e { erg0" Chgt " y j g'</li> </ul>
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	<p>lpetgcug."f qy py ctf "tgpf u"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"> <li>• P q"eriplecni { "tgrxcpv"hpfi lpi u"lqt"ej cpi gu"lp"GEI u"qt"gej qectf kqi tco u"y gtg" qdugtxgf 0"</li> </ul>
<p><b>Conclusions:</b></p>	<p>Kp" vj ku" Rj cug" 4" uwf { " lp" uwdlgeu" y kj " gkj gt" O VE"qt " F VE" Kif kpg/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"ht" y q" uwdlgeu" y j q" y gtg" tgcvgf "cv" vj g" f qug"qh"32" o i "DKF ."cu" r nppgf "lp" vj g" qtki kpcn" r tqvqeqr0" Uwdlgeu" eqpvkpwgf " tgcvo gpv" wvkn" f kugcug" r tqi tguukqp." f gxmqr o gpv"qh" wpccegr vcdng" vqzkek { . 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&lt;"42" vq"75: " f c { u" lqt" vj g" F VE" eqj qtv" cpf "4860" f c { u" t cpi g&lt;"35" vq"769" f c { u" lqt" vj g" O VE" eqj qtv0" C vj g" vko g"qh" f cv" ewqhl" lqt" vj ku" EUT" *33" Cr t"4233+ "74" uwdlgeu" *45" lp" vj g" F VE" eqj qtv" cpf "4; "lp" vj g" O VE" eqj qtv" y gtg" vknit" gegkxkpi " tgcvo gpv" lp" vj g" Czvgpukp" Rj cug0'</p> <p>Vj g" RM"qh" rgpxcvkpld" lp" vj g" F VE" cpf "O VE" eqj qtv" y gtg" uko kct" vq" vj cv" qdugtxgf "lp" vj g" Rj cug"3" uwf lgu0" P q" f kgev" tgrcvkqpuj kr "qh" rgpxcvkpld" gzr quw" g" uvgf { " uvcg" C WE" + eqwf " dg" qdugtxgf " y kj " QTT" cpf "RHU0'</p> <p>Ngpxcvkpld" u" j qy gf " o gcpkpi hni" cpvkw o qt "cevxxk { "lp" dqj " vj g" F VE" cpf "O VE" j knqni lecn" eqj qtv0" Vj g" r tko ct { " gpf r qkp" v"qh" vj g" uwf { . "QTT" dcugf " qp" vj g" cuugu o gpv" d { " vj g" KKT . y cu"72' "lp" vj g" F VE" eqj qtv" cpf "58' "kp" vj g" O VE" eqj qtv0" Uge qpf ct { " ghlece { " tguwnu" u" j qy gf " vj g" QTT. "dcugf " qp" cuugu o gpv" d { " vj g" lpxgunki cvqtu. y cu"75' "lp" vj g" F VE" eqj qtv" cpf "6; ' "lp" vj g" O VE" eqj qtv0" F khtgpegu" dgwy ggp" vj g" tguwnu" qdvkpgf " d { " vj g" KKT" cpf " vj g" lpxgunki cvqtu" y gtg" gzr gev" f . "cpf " qxgtcm" vj g" tguwnu" ctg" lp" eqpe qtf cpeg0" Qv j gt" ugeqpf ct { " ghlece { " gpf r qkpw. lpenwf lpi " F ET. " EDT. " cpf " RHU. " cnuq" u" j qy g f " cpvkw o qt "cevxxk { "qh" rgpxcvkpld0" Hqt" vj g" F VE" eqj qtv" y kj " c" hqmjy /w" vko g"qh"36" o qpj u. " vj g" o gf lcp" guko cvg" qh" RHU" y cu"3408" o qpj u. " cpf " lqt" vj g" O VE" eqj qtv" y kj " c" hqmjy /w" vko g"qh". 0" o qpj u. " vj g" o gf lcp" guko cvg" qh" RHU" y cu", 0" o qpj u0" Hqt" vj g" F VE" eqj qtv" y kj " c" v"34" o qpj u" cpf " y cu" o gf lcp" hqmjy /w" vko g"qh"3808" o qpj u. " vj g" qxgtcm" uwtxkcn" tcv" y cu": 8' "cv"34" o qpj u" cpf " y cu" o gf lcp" hqmjy /w" vko g"qh"3308" o qpj u. " vj g" qxgtcm" uwtxkcn" tcv" 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 hni" cpvkw o qt "cevxxk { " y cu" cnuq" qdugtxgf "lp" uwd lgeu" y j q" j cf " r tgxkqwn { " dggp" tgcvgf " y kvj " qj gt" r tkt" XGI H" vti gvgf " ci gpv0" Vj g" ghlece { " f cvc " qdugtxgf "lp" vj ku" uwf { " eqo r ctg" hcxqtcni" y kj " r wdkuj gf " f cvc" lqt" qj gt" cpv" XGI H" ci gpv0' Kp" vj ku" uwf { . " rgpxcvkpld" j cf " cp" ceegr vcdng" uchgv { " r tqhkg" lqt" u" wdlgeu" y kj " tghtcevt { " vj { tqkf " epegt0" P q" pgy " uchgv { " eqpegtpu" y gtg" qdugtxgf 0" Cu" r tgxkqwn { " uggp" kp" qj gt" uwf lgu. " j { r gtvgpukp" cpf " r tqvkwk" y gtg" uchgv { " eqpegtpu" y kj " rgpxcvkpld. " cu" y kj " qj gt" f twi u" vj cv" chgev" vj g" XGI H" uki pcrkpi " r cvj y c { 0' D qj " j { r gtvgpukp" cpf " r tqvkwk" f gxmqr gf " gctn { "lp" vj g" eqwtug" qh" uwf { " f twi " cf o kplntcvkqp0" Kp" i gpgtch" j { r gtvgpukp" y cu" y gni" eqpv" qmgf " 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" vj cv" r tqo kulpi " cpvkw o qt "cevxxk { " cpf " cp" ceegr vcdng" uchgv { " r tqhkg" ecp" dg" cej lxxgf " wukpi " vj g" f qulpi " r ncp. " y j lej " lpkkcvu" vj gter { " cv" vj g" o czko wo " vqngtcev" f qug" *O VF + " vq" lpf weg" vj g" dguv" qxgtcm" wo qt " tgr qpug" cpf " vj gp" lpf kxf wcn { gu" vj g" f qug" dcugf " qp" qdugtxgf " uchgv { " r ctco gvgu. " wukpi " r nppgf " f qug" tgf wevkqpu" qh" rgpxcvkpld0" Vj ku" f qulpi " r ncp" y knidg" gxcnvcgf " hmt vj gt "lp" uwdugs wgpv" cpf " rcti gt" uwf lgu0" Vj g" ghlece { " cpf " uchgv { " qh" rgpxcvkpld" ku" ewt gpv { " dgkpi " vguvf " lp" c" Rj cug"5" vknit" lp" uwdlgeu" y kj " F VE0"</p>
<p><b>Date of Report:</b></p>	<p>27/HGD/4236</p>