



	Vtq o gvc o qn"	8027 o i"	34032 o i"	3:037 o i"	46042 o i"	37095 o i"	42079 o i"
	J { ftqe jnqtke"cekf"	C f g s w c v g" f q u g"					
	Uqfkw o"j { ftqzkgf"	C f g s w c v g" f q u g"					

### 3.2 Product Description

Dtcpf"pc o g"	Rtq J cpeg"kpvtcxgpqwu"klplgevkqp"				Rtq J cpeg"kpvtcxgpqwu" u { tkpi g"	
	7 o N"	32 o N"	37 o N"	42 o N"	35 o N"	39 o N"
Fguetkrvkqp"	Eqnqtnguu"cpf"engct"uqnwvkqp"					
r J"	807"/":02"					
Qu o qvke"rtguuwtg"tcvkq" " *tcvkq"tgncvkg"vq"kuqvqpk"uqfkw o" e j n q t k f g"uqnwvkqp+"	C r r t q z k o c v g n { " 4"					
Xluequkv { " * 59 . " o R c · u +"	305"					

### 4. INDICATIONS

Eqpvtcu"gpj cpeg o gpv"kp" o c i p g v k e" t g u q p c p e g" k o c i k p i " \* O T k + " q h" h q m q y k p i " n g u k a p < " O D t c k p" c p f" u r k p c n" e q t f" O V t w p m" c p f" g z v t g o k v k g u"

### 5. PRECAUTIONS CONCERNING INDICATIONS

V j g" p g e g u k v { " q h" g z c o k p c v k q p u" w u k p i" i c f q n k p k w o / d c u g f" e q p v t c u v" c i g p v u" u j q w n f" d g" e c t g h w n n { " g x c n w c v g f" d g e c w u g" v j g t g" j c x g" d g g p" t g r q t v u" q h" j k i j" u k i p c n" k p" v j g" d t c k p" u g e v k q p u" k p e n w f k p i" f g p v c v g" p w e n g w u" q h" e g t g d g n n w o" c p f" i n q d w u" r c m k f w u" q p" w p g p j c p e g f" V 3 / y g k i j v g f" O T" k o c i g u" c p f" f g v g e v k a p" q h" i c f q n k p k w o" k p" c w w q r u k g f" d t c k p" v k u u w g u" k p" r c v k g p v u" y j q" t g e g k x g f" o w n w r n g" f q u g u" q h" i c f q n k p k w o / d c u g f" e q p v t c u v" c i g p v u 0"

### 6. DOSAGE AND ADMINISTRATION

#### <General (except kidney imaging)>

V j g" w u w c n" f q u g" k p" c f w n v" r c v k g p v u" k u" 204" o N l m i" c f o k p k u v g t g f" d { " k p v t c x g p q w u" k l p l g e v k a p 0" k p" r c v k g p v u" y k v j" u w u r k e k a p" q h" j c x k p i" o g v c u v c u g u" v q" d t c k p" c f f k v k a p c n" f q u g" q h" 204" o N l m i" e c p" d g" c f o k p k u v g t g f" y k v j k p" 52" o k p w v g u" c h v g t" c f o k p k u v t c v k a p" q h" v j g" k p k v k c n" f q u g" q h" 204" o N l m i" . k p" e c u g" q h" p q" v w o q t" k u" f g v g e v g f" q t" k o c i k p i" g h h k e c e { " k u" k p u w h h k e k g p v" g x g p" k h" c" v w o q t" k u" f g v g e v g f 0"

#### <Kidney imaging>

V j g" f q u g" k p" c f w n v" r c v k g p v u" k u" 203" o N l m i" c f o k p k u v g t g f" d { " k p v t c x g p q w u" k l p l g e v k a p 0"

### 8. IMPORTANT PRECAUTIONS

- 8.1** Ugtkqwu"cfxgtug"tgevkqpu"uwej"cu"ujqem"cpf"cpcri{jnczku"oc{"qeewt"0Hqt"cf o k p k u v g t k p i" v j k u" f t w i" . o c m g" u w t g" c r r t q r t k c v g" g o g t i g p e { " o g c u w t g u" u j q w n f" d g" k o o g f k c v g n { " c x c k n c d n g 0" E q p v k p w q w u n { " o q p k v q t" r c v k g p v u" e q p f k v k a p" e c t g h w n n { " g x g p" c h v g t" c f o k p k u v t c v k a p" d g e c w u g" f g n c { g f" c f x g t u g" t g e v k q p u" \* u e j" c u" r { t g z k c" . t c u j" . p c w u g c" . d n q q f" r t g u u w t g" f g e t g c u g f" . f { u r p a g c" . g v e 0 + " y j k e j" o c { " q e e w t" h t q o" q p g" j q w t" v q" u g x g t c n" f c { u" c h v g t" h t q o" v j g" k p k v k c v k a p" q h" c f o k p k u v t c v k a p" j c x g" d g g p" t g r q t v g f" k p" q v j g t" i c f q n k p k w o / d c u g f" e q p v t c u v" c i g p v u 0" V c m g" c r r t q r t k c v g" o g c u w t g u" u e j" c u" k p u v t w e v k p i" r c v k g p v u" v q" k o o g f k c v g n { " e a p v c e v" v j g" c w g p f k p i" r j { u k e c p u" q t" q v j g t" j g c n v j e c t g" r t q h u a k q p c n u" k h" c p { " q h" v j g" c h a t g o g p v k a p g f" u { o r v q o u" q e e w t 0" } u g g" 330303\_
- 8.2** Rcvkqpvu"ujqwnf" dg" ectghwnn{" kpvgtxkg ygf" hqewukpi" qp" cngtike" rtgfkurqukvkqpu" uwej" cu" dtapejken" cuvjo c" dghqtg" cfo k p k u v g t k p i" v j k u" f t w i 0" } u g g" ; 0304\_ ; 0306 / ; 0308\_
- 8.3** Eqpvtcu"gpj cpegf"ghhgev"ku"uwucn{"eqpvkpwgf"ht"cdqvw"67" o k p w v g u" h t q o" k o o g f k c v g n { " c h v g t" c f o k p k u v t c v k a p" q h" v j k u" f t w i 0" F q" p q v" c f o k p k u v g t" c p { " c f f k v k a p c n" f q u g" y k v j q w v" c" u r g e k h k e" t g c u a p" y j k n g" v j g" g h h g e v" k u" e q p v k p w g f" d g e c w u g" c p" c f f k v k a p c n" f q u g" f q u" p q v" c n y c { u" k o r t q x g" v j g" g h h g e v" \* g z e g r v" r c v k g p v u" y k v j" u w u r k e k a p" q h" j c x k p i" o g v c u v c u g u" v q" d t c k p + 0" V j g" f g e k u k a p" v q" i k x g" c f f k v k a p c n" f q u g" v q" r c v k g p v u" y k v j" u w u r k e k a p" q h" j c x k p i" o g v c u v c u g u" v q" d t c k p" u j q w n f" d g" d c u g f" q p" v j g" t g u w n v u" q h" v j g" k p k v k c n" f q u g 0" } u g g" 390305\_

## 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

### 9.1 Patients with Complication or History of Diseases, etc.

#### 9.1.1 Patients with an extremely poor general condition

Fq"pqv"cf o kpkuvgt"vjku"ftwi"wpnguu"kv"ku"fgg o gf"wpexqkfc dng"hqt"fkci pqku0" "

#### 9.1.2 Patients with bronchial asthma

Fq"pqv"cf o kpkuvgt"vjku"ftwi"wpnguu"kv"ku"fgg o gf"wpexqkfc dng"hqt"fkci pqku0"Cp cr j {nczku" o c {"qeewt0" "  
kv"jcu"dggp"tgrqvtgf"vjcv"qvjgt"icfqnkpkw o /dcugf"eqpvtcu"ci gpvu"hqt"OTK"\*icfqr gpgvcvg"fkoginw o kpg+" o c {"ecwug"ugtkqu"  
cfxgtug"tgcevkqu"uwej"cu"ujqem"qt"cp cr j {nczku"kp"rcvkgpvu"ykvj"dtqpejkcncuvj o c"cv" c"jki jgt"htgswgpe {"vjcp"kp"qvjgt"  
rcvkgpvu0"jugg":04."330303\_"

#### 9.1.3 Patients experienced adverse reactions (excluding serious adverse reactions) at the initial dose and need to be given additional dose

Fq"pqv"cf o kpkuvgt"vjku"ftwi"wpnguu"kv"ku"fgg o gf"wpexqkfc dng"hqt"fkci pqku0"

#### 9.1.4 Patients with allergic predispositions such as allergic rhinitis, rash or urticaria, etc.

]ugg":04\_

#### 9.1.5 Patients whose parents or siblings have allergic predisposition, such as bronchial asthma, allergic rhinitis, rash or urticaria, etc.

]ugg":04\_

#### 9.1.6 Patients with a history of drug hypersensitivity

]ugg":04\_"

#### 9.1.7 Patients with convulsion or epilepsy including a history, or with predisposition to them

Eqpxwnukqp" o c {"qeewt0"jugg"330304\_" "

## 9.2 Patients with Renal Impairment

### 9.2.1 Patients with serious renal impairment

Fq"pqv"cf o kpkuvgt"vjku"ftwi"wpnguu"kv"ku"fgg o gf"wpexqkfc dng"hqt"fkci pqku0"  
Ukpeg" vjku" ftwi" ku" gzetgygf" o ckpn {"vj tqw i j" vjg" mkfpg {u. vjg" gzetgykqp" o c {"dg" fgnc {gf" cpf" tgpcn" hwpevkqp" o c {"dg"  
c i i texcvgf0"jugg"304."330305\_" "

### 9.2.2 Patients with end-stage renal impairment on long-term dialysis, chronic renal impairment with eGFR (estimated glomerular filtration rate) of less than 30 mL/min/1.73m<sup>2</sup>, or acute renal impairment (except patients with serious renal impairment)

Kv"ku"fguktcdng"vq"cxqkf"cf o kpkuvtcvkqp"qh"vjku"ftwi"cpf"uwduvkvwvg"qvjgt"gzc o kpcvkqp0"  
Tkum"qh"qeewt"tpeg"qh"pgrj tqi gpk"u {uvgo ke"hkdtquku"fwg"vq"icfqnkpkw o /dcugf"eqpvtcu"ci gpvu"jcu"dggp"tgrqvtgf"vq"dg"  
kpetgcugf0"jugg"304."330305\_" "

### 9.2.3 Patients with renal impairment or suspicion of having impaired renal function (except patients with serious renal impairment)

Vjku"ftwi"ujqwnf"dg"cf o kpkuvgtgf"ykvj"ecwvkqp"chvgt"ectghwn {"cuuguukpi"vjg"rcvkgpvu"tgpcn"hwpevkqp0"jugg"304."330305\_"

## 9.5 Pregnant Women

Cf o kpkuvtcvkqp"qh"vjku"ftwi"vq"yqogp"yjqctg"qt" o c {"dg"rtgipcpv"ujqwnf"dg"nk o kvgf"vq"vjg"ecug"kp"yjkj"vjg"fkci pqkuve"  
dgpghk"ku"eqpukfgtgf"vq"uwtrcuu"vjg"tkum0"

## 9.6 Breast-feeding Women

Fkci pqkuve" dgpghk" wukpi" vjku" ftwi" cpf" vjg" dgpghk" qh" dtgcuv" o knm" pwvtkgpvu" ujqwnf" dg" ygki jgf" hqt" eqpukfgtcvkqp" qh"  
eqpvkpwkpi"qt"fkueqpvkpwkpi"dtgcuvhggfkipi0" "  
Gzetgykqp"qh"vjku"ftwi"kpqv"dtgcuv" o knm"jcu"dggp"tgrqvtgf"kp"cpk o cn"uwvfkgu"\*tcvu."kpvtxgpgqu"cf o kpkuvtcvkqp+0"

## 9.7 Pediatric Use

Pq"enkpkcn"uvwf {"jcu"dggp"eqpfwevgf"kp"rgfkvtke"rcvkgpvu0" "

## 9.8 Geriatric Use

Vjku"ftwi"ujqwnf"dg"cf o kpkuvgtgf"vq"vjg"gnfgtn {"rcvkgpvu"ykvj"ectghwn" o qpkvqtkpi0"  
Vjg"gnfgtn {"jcxg"tgfwegf"rj {ukqnqikecn"eqpfvkqp"kp"igpgtcn0"  
"

## 11. ADVERSE REACTIONS

Hqnnqy kpi" cfxgtug"tgcevkqu" o c {"qeewt0" Oqpkvqt"rcvkgpvu0"eqpfvkqp"ectghwn {"cpf"vcmg"cr rtrtkcvg" o gcuwtgu"uwej"cu"

fkieqpvkpwkpi"vjg"cf o kpkuvtkvqkq"kh"cp{"cdpqt o cnkvku"ctg"qdugtvgf0" "

**11.1 Clinically Significant Adverse Reactions**

**11.1.1 Shock and anaphylaxis**\*htgswgpe{"wmpqy p"ht"dqvj+" "

Ujqem" o c{"qeewt."cpf"dg"ceeq o rcpkfg" d{"cpcrj j{nczku" ykvj"u{ o rvqou"qh"uwej"cu" f{urpqc."u{peqrg."uwrqt."nquu"qh" eqpuekqwupguu."tgrktcvqt{"cttguv."ectfke"cttguv."igpgtck|gf"hnwujkpi."cpikqgfg o c."cpf"wtvkectk0"jugg":03.";0304\_"

**11.1.2 Seizure**\*htgswgpe{"nguu"vjcp"203 ' + "

Vcmg"cr rtrtkcvg" o gcuwtgu"uwej"cu"cf o kpkuvtkpi" dctdkwtke"cekf"fgtkxcvkxgu" kpenwfkpi" rjgpqcdctdkvcn"qt" fkc|grc o0" jugg";0309\_"

**11.1.3 Nephrogenic systemic fibrosis (NSF)** \*htgswgpe{"wmpqy p+" "

Vjg"qeewttgpeg"qh"PUH"jcu"dggp"tgrfvtvgf"chvgt"cf o kpkuvtkvqkq"qh"vjku"ftwi"vq"rcvkgpvu" ykvj"ugtkqwu"tgpcn"ko rckt o gpv"kp" qvjgt"eqwptkku0"Ectghwn" o qpkvktkpi"ujqwnf"dg"eqpvkpwgf"chvgt"cf o kpkuvtkvqkq"qh"vjku"ftwi"cpf"ykvj"rctvkewnct"cvwgpvkqkq"vq" vjg"qeewttgpeg"qh"cdpqt o cnkvku"uwej"cu"vej{"umkp."uygnkpi."jctfgpkpi"qh"umkp."lqkp"uvkhpguu."cpf" o wuewnct"ygcmpguu0" jugg"304.";0403;/0405\_" "

**11.2 Other Adverse Reactions**

"	≥"203 ' " " >"7 ' "	>"203 ' "	Htgswgpe{"wmpqy p"
J{ rgtugpukvkvkxk{"	Wtvkectk"	Jqv"hnwuj" "	kvj kpi."Tcu j."Hnwujkpi" "
Ectfkxcuewnct" fkuqtfgtu"	"	"	Rcnrkvcvkqpu."Dnqqf"rtguuwtg"fgetgcugf." Dnqqf"rtguuwtg"kpetgcugf"
Tgrktcvqt{"fkuqtfgtu"	"	Eqw i j" "	Uppg kpi."Jctugpguu."Rjct{piqnt{pigcn" fkieq o hqtv."Tj kpkvku."Cuvj o c"
Icuvtkpvguvkpcn" fkuqtfgtu"	Swgcu{IXq o kvkpi"	"	Vjktuv."Cdfq o kpcn"rckp"
Ru{ejqpgwtqvke" fkuqtfgtu"	"	I k f f k p g u u . " J g c f c e j g "	Pw o d p g u u . " V t g o q t u . " V t c p u k g p v " n q u u " q h " e q p u e k q w u p g u u " "
Jg o cvqni {" kpxguk i cvkqpu"	"	"	Y j k v g " d n q q f " e g n " k p e t g c u g f . " R n c v n g v u " k p e t g c u g f " "
Jgrcvqdknct{" fkuqtfgtu"	"	"	Jgrcvke"hwpevkqkq"cdpqt o cn."CUV"kpetgcugf." CNV"kpetgcugf"
Cf o kpkuvtkvqkq"ukvg" eqpfkvkqpu"	"	Xcuewnct"rckp"	Rckp"
Qvjgtu" "	Hggkpi"jqv"	"	Ugtw o " r q v c u k w o " k p e t g c u g f . " H g g n u " r q q t n { . " D W P " k p e t g c u g f . " E j g u v " r c k p . " U g t w o " k t q p " f g e t g c u g f . " D n q q f " e t g c v k p k p g " k p e t g c u g f . " H g g n k p i " e q n f . " J g c x { " u y g c v k p i . " V c u v g " c d p q t o c n k v { . " G { g " c d p q t o c n k v { . " O c n c k u g " "

**14. PRECAUTIONS CONCERNING USE**

**14.1 Precautions Concerning Administration of the Drug**

**14.1.1** Fq"pqv"cf o kpkuvgt"vjku"ftwi"kpqv"vjg"dtckp"qt" o gfwmnct{"ecxkv{0"jugg"303\_"

**14.1.2** Xcuewnct"rckp" o c{"qeewt"chvgt"kpvtcxgpqwu"cf o kpkuvtkvqkq"qh"vjku"ftwi"0" "

**14.1.3** Kp"ecug"gzvtxcucvkqkq"qh"eqvttcu" o gfk"qeewt."rcvkgpv" o c{"fgxgnqr"tgfpguu."uygnkpi."dnkvgt."qt"rckp."gve0"Gzvtg o g" ecwvkqkq"fwtkpi"cf o kpkuvtkvqkq"ku"pgeguuct{"vq"cxqkf"gzvtxcucvkqkq0" "

**14.2 Precautions Concerning Post-Administration of the Drug**

" Wug"gej" xkcnlu{tkpi g"ht" c"ukp ing"zco kpcvkqkq"cpf"fkuectf"gzeguu"uqnwvkqkq0" "

**16. PHARMACOKINETICS**

**16.1 Blood Level**

C"fqug"qh"203."204."206"<sup>Pqvg+</sup>."207"<sup>Pqvg+</sup>"qt"208"<sup>Pqvg+</sup>" o Nlmi "\*"2027."203."204."2047"qt"205" o o qnlmi+"qh"vjku"ftwi"y cu"

cf o kpkvgtgf "kpvtxgpgqun {"vq" jgcnvj {" o cng"xqnpvvggt."vjg"gnk o kpcvkqp" jcnh/nkhg"kp"dnqqf" ycu"302 ;/3088" jqwtu<sup>0"3+."4+" "</sup>  
 Pqvg+"Vjg" cr rtqxf" fqug"qh"vjk"ftwi"ku"204" o Nlmi "\*"203" o o qnlmi+"hqt" igpgtcn" wug"cpf"203" o Nlmi "\*"2027" o o qnlmi+"hqt"  
 mkfpg {"kocikpi0" "

**16.5 Excretion**

C" fqug"qh"203."204."206"<sup>Pqvg+."207"<sup>Pqvg+."qt"208"<sup>Pqvg+." o Nlmi "\*"2027."203."204."2047"qt"205" o o qnlmi+"qh"vjk"ftwi" ycu"  
 cf o kpkvgtgf "kpvtxgpgqun {"vq" jgcnvj {" o cng"xqnpvvggt.":60:/3280: ' "qh"vjg" fqug" ycu"gzetvgvf"kp"wtkpg" ykvjkp"46"jqwtu"  
 chvgt"cf o kpkvtxgpgqun<sup>0"3+."4+" "</sup>  
 Pqvg+"Vjg" cr rtqxf" fqug"qh"vjk"ftwi"ku"204" o Nlmi "\*"203" o o qnlmi+"hqt" igpgtcn" wug"cpf"203" o Nlmi "\*"2027" o o qnlmi+"hqt"  
 mkfpg {"kocikpi0"  
 "</sup></sup></sup>

**17. CLINICAL STUDIES**

**17.1 Clinical Studies for Efficacy and Safety**

**<MRI of brain and spinal cord>**

**17.1.1 Domestic phase II clinical study**

Vjg"ghhkece {"tcvg" ycu"930: ' "\*"7819:+"kp"9:"gxcnwdng"rcvkp"vuhqt"eqpvtcu"ghhkece {"cv"vjg" cr rtqxf" fqug0"Cfxgtug"  
 tgcevkqpu" ygtg"qdugtxf"kp"406 ' "\*"41:6+."dqvj"qh"vjg o " ygtg"swgcu {0<sup>5+" "</sup>

**17.1.2 Domestic phase III clinical study**

Vjg"ghhkece {"tcvg" ycu"9305 ' "\*" :91344+"kp"344" gxcnwdng"rcvkp"vuhqt"eqpvtcu"ghhkece {"cv"vjg" cr rtqxf" fqug0"Cfxgtug"  
 tgcevkqpu" ygtg"qdugtxf"kp"405 ' "\*"51352+" ykvj" qpg"rcvkp"vuhgcej"qh"hggnkpi" j qvlpcwugc."xq o kvkpi."cpf"pcwugc0<sup>6+" "</sup>

**17.1.3 Domestic phase II/III clinical study**

" " kp"enkpkcn"uwvf {"kp"rcvkp"vuhgcej"qh"vjk"ftwi"ku"204" o Nlmi "\*"203" o o qnlmi+"hqt" igpgtcn" wug"cpf"203" o Nlmi "\*"2027" o o qnlmi+"hqt"  
 5202 ' "\*"43192+"qh"rcvkp"vuhgcej"qh"vjk"ftwi"ku"204" o Nlmi "\*"203" o o qnlmi+"hqt" igpgtcn" wug"cpf"203" o Nlmi "\*"2027" o o qnlmi+"hqt"  
 eq o rctkuq" ykvj"vjg"kpvkcn" fqug0"Cfxgtug"tgcevkqpu" ygtg"qdugtxf"kp"40: ' "\*"4194+."cpf" ykvj" qpg"rcvkp"vuhgcej"qh"  
 eqpxwnukqpu"cpf"hggnkpi" j qvlswgcu {0<sup>7+" "</sup>Jugg":05\_ "

**<MRI of trunk and extremities>**

**17.1.4 Domestic phase II clinical study**

Kp" c" fqug/hkpfkpi"uwvf {"eqpfwevgf"kp"622"rcvkp"vuhgcej"vjtggi"tqwruc" cr rtqxf" fqug."jcnh"qh"vjg" cr rtqxf" fqug."qt"fqwdng"qh"  
 vjg" cr rtqxf" fqug+."eqpvtcu"gpjcpegf"ghhkece {" ycu"cuuugf"kp"5;4"rcvkp"vuhgcej"vjtggi"tqwruc" cr rtqxf" fqug."jcnh"qh"vjg" cr rtqxf" fqug."qt"fqwdng"qh"  
 uecnguc" o ctmgn {"gpjcpegf."gpjcpegf."unkijvn {"gpjcpegf."wpejcpigf."fgetgcugf."cpf"wpqxcnwdng."vjqug"tcvgf"cu"  
 õgpjcpegfõ"qt"dgwgt"ctg"ujqyp"kp"Vcdng"30"Vjgtg" ycu"pq" fqug/tgurqpug"tgncvkp"vuhgcej"vjtggi"tqwruc" cr rtqxf" fqug."jcnh"qh"vjg" cr rtqxf" fqug."qt"fqwdng"qh"  
 uq o g"zco kpcvkqp"tgikqpu0" "

**Table 1. Contrast enhanced efficacy**

Gzco kpcvkqp"tgikqpu"	Fqug*" o Nlmi+"	õGpjcpgefõ"qt"dgwgt"
Jgcf"cpf"pgem"	203"	:505 ' "*"37"1"3:+"
	204 <sup>Pqvg+."</sup>	;603 ' "*"38"1"39+"
	206"	:;0; ' "*"38"1"3:+"
Ejguv"	203"	8202 ' "*"34"1"42+"
	204 <sup>Pqvg+."</sup>	9:0; ' "*"37"1"3;+"
	206"	;609 ' "*"3: "1"3;+"
Jgctv"	203"	:202 ' "*"38"1"42+"
	204 <sup>Pqvg+."</sup>	:;07 ' "*"39"1"3;+"
	206"	7;03 ' "*"35"1"44+"
Nkxgt"	203"	6403 ' "*" : "1"3;+"
	204 <sup>Pqvg+."</sup>	:604 ' "*"38"1"3;+"
	206"	:;07 ' "*"39"1"3;+"
kpvtxgpgqun	203"	8809 ' "*"34"1"3:+"
	204 <sup>Pqvg+."</sup>	:907 ' "*"36"1"38+"
	206"	;50: ' "*"37"1"38+"

Dqpg"cpf"uqhv"vkuuwg"	203"	8303 ' "*33"1"3 :+"
	204 <sup>Pqvg+"</sup>	:505 ' "*37"1"3 :+"
	206"	9:0; ' "*37"1"3 ;+"
Mkfpqg{u"	" 2027"	790; ' "*33"1"3 ;+"
	203 <sup>Pqvg+"</sup>	:702 ' "*39"1"42+"
	204"	9:0; ' "*37"1"3 ;+"

Pqvg+"Crrtqxgf"fqug"

"

k o r t q x g o g p v " k p " f k c i p q u v k e " r g t h q t o c p e g " y c u " t c v g f " w u k p i " 7 " u e c n g u < " o c t m g f n { " k o r t q x g f . " k o r t q x g f . " u n k i j v n { " k o r t q x g f . " p q v " k o r t q x g f . " c p f " w p g x c n w c d n g 0 " V j g " f g v c k n u " q h " k o r t q x g f " f k c i p q u v k e " r g t h q t o c p e g " k p " 5 4 : " r c v k g p v u " t c v g f " c u " o k o r t q x g f o " q t " d g w v g t " c t g " u j q y p " k p " V c d n g " 4 0 "

**Table 2. Improvement in diagnostic performance**

Gzco k p c v k q p " t g i k q p "	Fqug" *oNlmi+"	C"	D"	E"	F"	G"	H"	Ecugu"
Jgcf"cpf"pgeu"	203"	2"	" 5"	34"	" :	" 4"	2"	38"
	204 <sup>Pqvg+"</sup>	2"	" 7"	33"	" 3"	" 4"	2"	35"
	206"	2"	" 7"	35"	" 9"	" 4"	2"	38"
Ejguv"	203"	2"	" 6"	33"	33"	" 4"	2"	36"
	204 <sup>Pqvg+"</sup>	2"	" 4"	" ;"	33"	" 6"	2"	36"
	206"	2"	" 5"	36"	34"	" 5"	2"	39"
Jgctv"	203"	2"	32"	37"	" 5"	" 4"	2"	38"
	204 <sup>Pqvg+"</sup>	2"	36"	3:"	" 5"	" 2"	3"	3 ;"
	206"	3"	32"	38"	" 5"	" 3"	3"	3 ;"
Nkxgt"	203"	3"	" 4"	" 3"	" :	34"	2"	35"
	204 <sup>Pqvg+"</sup>	4"	" 9"	" 9"	33"	36"	3"	39"
	206"	4"	32"	32"	32"	35"	2"	3 :"
kpvtrgnxke"	203"	3"	" 7"	" ;"	" 7"	" 8"	2"	35"
	204 <sup>Pqvg+"</sup>	2"	" 5"	" 6"	" 6"	" 7"	2"	35"
	206"	3"	" 7"	" 9"	" :	" 7"	2"	38"
Dqpg"cpf"uqhv"vkuuwg"	203"	2"	" 5"	" 9"	33"	" :	3"	34"
	204 <sup>Pqvg+"</sup>	2"	" 8"	35"	35"	" :	4"	39"
	206"	4"	" 8"	32"	35"	" ;"	3"	37"
Mkfpqg{u"	" 2027"	2"	" 6"	" 7"	" 9"	" 7"	2"	36"
	203 <sup>Pqvg+"</sup>	2"	" 7"	" ;"	36"	" 7"	2"	3 :"
	204"	4"	" ;"	" :	32"	" 4"	2"	3 :"

Owvkrng"ugnevkap"ycu"rgt okvvgf"ht"gxcnwcvkqp"qh"ko r t q x g o g p v " k p " f k c i p q u v k e " r g t h q t o c p e g 0 "

Pqvg+"Crrtqxgf"fqug"

C<"Fgvevkap"qh"pgy"ngukapu" " " " D<"Enctkhkecvkap"qh"vjg"rtgugpeg"qh"ngukapu"

E<"Enctkhkecvkap"qh"vjg"tcpig"qh"urtgcfirtqigtgukap" " " F<"Enctkhkecvkap"qh"kpvgtpcn"uvtwevwtg" "

G<"Fkhgtgpvcn"fkcpquku" " " " H<"Qvjgtu"

Cfxgtug"tgcevkapu"ygtg"qeewtgf"kp"305 ' "\*715;9+"qh"rcvkgpvu<"swgcu{lxq okvpi"cpf"wtvkectk"kp"qpg"rcvkgpv"gej"kp" cr r t q x g f " f q u g " i t q w r . " p c w u g c " c p f " s w g c u { " k p " q p g " c p f " v y q " r c v k g p v u " t g u r g e v k x g n { " k p " v j g " f q w d n g " f q u g " i t q w r 0 " 8 + "

"

**17.1.5 Domestic phase III comparative study**

k p " v j g " e q o r c t c v k x g " u w f { " y k v j " i c f q r g p v g c v g " f k o g i n w o k p g " h q e w u k p i " q p " j g r c v k e " t g i k q p . " q x g t c m " g x c n w c v k p " \* g h h k e c e { + " y c u " c u u g u g f " w u k p i " 7 " u e c n g u < " o c t m g f n { " g h h g e v k x g . " g h h g e v k x g . " u n k i j v n { " g h h g e v k x g . " k p g h h g e v k x g " c p f " w p g x c n w c d n g . " v j q u g " c u u g u g f " c u " o g h h g e v k x g o " q t " d g w v g t " c t g " u j q y p " k p " V c d n g " 5 0 " V j g " s w k x c n g p e g " q h " v j k u " f t w i " v q " i c f q r g p v g c v g " f k o g i n w o k p g " y c u " x g t k h g f 0 " P q " c f x g t u g " t g c e v k a p " y c u " t g r q t v g f " k p " v j g " i c f q v g t k f a n " i t q w r " \* 3 4 4 " r c v k g p v u + 0 " 9 + "

**Table 3. Overall evaluation (Efficacy)** \*Cuuguu o gpv"d{ "k o c i g" t g c f k p i " e q o o k w g g +"

Ftwi "	ōGhhgevkxgō"qt"dgwgt"	Gzcev"vguv"
Icfqvtkfqn"	; 808 ' *336"l"33 : +"	r = 2075 ;"
Icfqrgpvgyvcg"fk o g i n w o k p g"	; 604 ' *335"l"342 +"	

**17.1.6 Domestic phase III open-label study**

" Kp"qrgp/ncdgn"uvwf{"eqpfwevgf"kp"397"rcvkpovu."qxgtcnn"gxcnwcvkqp"\*ghhkece{"+eqpukfgtkpi"eqpvtcuv"gpjcpegf"ghhgev"cpf" k o r t q x g o g p v " k p " f k c i p q v k e " r g t h q t o c p e g " k p " 3 9 2 " g x c n w c d n g " r c v k p p v u " y c u " c u u g u u g f " w u k p i " 7 " u e c n g u < " o c t m g f n { " g h h g e v k x g . " g h h g e v k x g . " u n k i j v n { " g h h g e v k x g . " k p g h h g e v k x g . " c p f " w p g x c n w c d n g . " c p f " v j q u g " c u u g u u g f " c u " o g h h g e v k x g o " q t " d g w g t " c t g " u j q y p " k p " V c d n g " 6 0 " C f x g t u g " t g c e v k p u " q e e w t t f " k p " 5 0 7 ' " \* 8 1 3 9 3 + " q h " r c v k p p v u < " s w g c u { " k p " 4 " r c v k p p v u " c p f " h n w u j g f " h c e g l e q w i j . " h g g n k p i " j q v . " p c w u g c . " c p f " k p l g e v k p " u k v g " x c u e w n c t " r c k p " k p " q p g " r c v k p p v " g c e j 0 " : + "

**Table 4. Overall evaluation (Efficacy)**

Gzco k p c v k p p " t g i k p p "	ōGhhgevkxgō"qt"dgwgt"
Jgcf"cpf"pgem"	: 704 ' *45"l"49 +"
Ejguv"	; 503 ' *49"l"4 ; +"
Jgctv"	; 408 ' *47"l"49 +"
kpvtrgnxke"	: 709 ' *46"l"4 : +"
Dqpg"cpf"uqhv"vkuuwg"	9 : 0 : ' *48"l"55 +"
Mkfp g { u "	: : 07 ' *45"l"48 +"

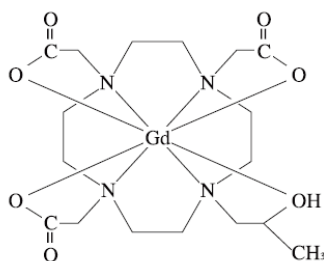
**18. PHARMACOLOGY**

**18.1 Mechanism of Contrast Enhancement**

Icfqkpkw o "kqpu"ctg"rtco o c i p g v k e " c p f " j c x g " v j g " c d k n k v { " v q " r t q o q v g " t g n c z c v k p p " q h " j { f t q i g p " p w e n g k " \* r t q v q p u + " k p " o c i p g v k e " t g u a p c p e g " r j g p q o g p q p " c p f " u j q t v g p " t g n c z c v k p p " v k o g l " V j k u " f t w i " k u " c " e j g n c v g " e q o r q w p f " q h " r t c o o c i p g v k e " o g v c n " i c f q n k p k w o " k q p u " v j c v " g p j c p e g u " e q p v t c u v " q h " v k u u w g u " c p f " n g u k p p u " d { " u j q t v g p k p i " v j g " n q p i k w f k p c n " t g n c z c v k p p " v k o g " \* V 3 + " k p " O T K " k o c i k p i 0 " "

**19. PHYSICO-CHEMICAL PROPERTIES**

Pqprtqrtkvct{"pc o g < Icfqvtkfqn"  
 Ejgokecn"pc o g < \*ō+/32/\*4/j {ftqz {rtqr {n+/3."6."9."32/vgytcc|ce{enq/fqfgecp/3."6."9/vtkcegvqvcifqkpkw o"} \_"  
 Oqngewnt"htq o wnc<E<sub>39</sub>J<sub>4</sub>; I f P<sub>6</sub>Q<sub>9</sub>"  
 Oqngewnt"y gki j v<"77:08:"  
 Uvtwewtcn"htq o wnc<



Rj {ukeqejg o kecn"fguetkrvkqp<"  
 Icfqvtkfqn"ku"c"y jkv g"et {uvcnkpg"rqy fgt."cpf"kv"ku"qfqtngu0"kv"ku"jki jn {"ycvgt/uqndng."cpf"unkijvn {"  
 uqndng"kp"gvjcpqn"; 7+"cpf"rtceveken {"kpuqndng"kp"fkvj {n"gvjgt0" "  
 C"uqndng"q h" Icfqvtkfqn"\*3"kp"322+"ujqyu"pq"qrvecn"tqvcvkp0" "

## 22. PACKAGING

>Rtq J cpeg"kpvtcxgpqwu"klgevkqp"7 o N@  
Dqzgu"qh"7"xkcnu"  
>Rtq J cpeg"kpvtcxgpqwu"klgevkqp"32 o N@  
Dqzgu"qh"7"xkcnu"  
>Rtq J cpeg"kpvtcxgpqwu"klgevkqp"37 o N@  
Dqzgu"qh"7"xkcnu"  
>Rtq J cpeg"kpvtcxgpqwu"klgevkqp"42 o N@  
Dqzgu"qh"7"xkcnu"  
>Rtq J cpeg"kpvtcxgpqwu"u{tkpig"35 o N@  
Dqzgu"qh"3"qt"7"u{tkpig"  
>Rtq J cpeg"kpvtcxgpqwu"u{tkpig"39 o N@  
Dqzgu"qh"3"qt"7"u{tkpig"

## 23. REFERENCES

- |  |               |
|--|---------------|
| 1) [qujkmcy c"J0"gv"cn0."Ogf"Eqpu"Pgy/Tgogf0"3 ; ; 3="4: *7+<":25/:34          | JRTQ/2283_    |
| 2) Ujkdcvc"J0"gv"cn0."Ogf"Eqpu"Pgy/Tgogf0"3 ; ; 5="52*32+<"3:85/3:94           | JRTQ/2295_    |
| 3) [qujkmcy c"J0"gv"cn0."Ogf"Eqpu"Pgy/Tgogf0"3 ; ; 3="4: *33+<<br>3 ; :9/3 ; ; | JRTQ/2284_    |
| 4) [qujkmcy c"J0"gv"cn0."Ogf"Eqpu"Pgy/Tgogf0"3 ; ; 4="4: *7+<"333;/3359        | JRTQ/2285_    |
| 5) Mqjtq"O0"gv"cn0."Ogf"Eqpu"Pgy/Tgogf0"3 ; ; 6="53* :+<"3583/3598             | JRTQ/228 ; _  |
| 6) Pckvq"J0"gv"cn0."Ogf"Eqpu"Pgy/Tgogf0"3 ; ; 7="54*6+<"937/959                | JRTQ/22 : 6 _ |
| 7) Jktqjcu jk"U0"gv"cn0."Ogf"Eqpu"Pgy/Tgogf0"3 ; ; 8="55*4+<"455/467           | JRTQ/2299_    |
| 8) Pckvq"J0"gv"cn0."Ogf"Eqpu"Pgy/Tgogf0"3 ; ; 8="55*4+<"439/454                | JRTQ/2298_    |

## 24. REFERENCE REQUEST AND CONTACT INFORMATION

Dtceeq"Lrcrp"Eq0."Nvf0  
1-35/43."Okpc okkmgdwmwtq."Vqujkoc/mw."Vqm{q.171-0022, Japan  
Toll-free number : 0120-318-170

## 26. MARKETING AUTHORIZATION HOLDER, etc.

### 26.1 Marketing Authorization Holder (Importer)

Dtceeq"Lrcrp"Eq0."Nvf0  
3/35/43."Okpc okkmgdwmwtq."Vqujkoc/mw."Vqm{q."Lrcrp

### 26.2 Licensed by:

Dtceeq"Uwkuug"U0C0